AHCCCS Fee-For-Service Program Pharmacy Prior Authorization Criteria

July 8, 2022

Table of Contents

Prior Authorization Guideline

GL-99555 Acetaminophen (Dose > 4 gm)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

. Criteria

Product Name: Acetaminophen (Dose > 4gm)	
Guideline Type	Administrative

Approval Criteria

1 - Requests for acetaminophen dosages greater than 4000mg per day should be denied. The total dose of acetaminophen (cumulative total daily dose of 4000mg) is not supported by the Food and Drug Administration (FDA).

. Revision History

Date	Notes
6/28/2021	7/1 Implementation

Prior Authorization Guideline

GL-105269 Actemra - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

. Criteria

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)

AND

History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

Patient is not receiving Actemra in combination with ANY of the following:

Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

History of failure, contraindication, or intolerance to BOTH of the following:

Humira (adalimumab)**
Enbrel (etanercept)**

AND

Prescribed by, or in consultation with, a rheumatologist

OR

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

Diagnosis of moderately to severely active RA

AND

Patient is not receiving Actemra in combination with ANY of the following:

Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

Prescribed by, or in consultation with, a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial. **Drug may require PA

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

- One of the following:

History of failure, contraindication, or intolerance to both of the following:

Humira (adalimumab)*
Enbrel (etanercept)*

OR

Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

- Patient is not receiving Actemra in combination with ANY of the following:

Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a rheumatologist

Notes	*May require PA

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic juvenile idiopathic arthritis

AND

- Patient is not receiving Actemra in combination with ANY of the following:

  Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
  Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
  Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

- Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis (PJIA), Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

- Patient is not receiving Actemra in combination with ANY of the following:

  Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
  Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
  Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ, Actemra IV	
Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of giant cell arteritis

AND

- One of the following:

History of failure, contraindication, or intolerance to ONE glucocorticoid (e.g., prednisone)

OR

Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

- Patient is not receiving Actemra in combination with ANY of the following:

Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Actemra Actpen, Actemra SQ, Actemra IV	
Diagnosis	Giant Cell Arteritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

- Patient is not receiving Actemra in combination with ANY of the following:

Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

- Prescribed by, or in consultation with, a rheumatologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of active systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:

ONE of the following:

Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

TWO of the following:

Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
Telangiectasia
Abnormal nailfold capillaries
Pulmonary arterial hypertension
Raynaud's phenomenon
SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

AND

- Patient is not receiving Actemra in combination with ANY of the following:

Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

- Prescribed by, or in consultation with, a pulmonologist

Product Name: Actemra Actpen, Actemra SQ	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

- Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Actemra therapy

AND

- Patient is not receiving Actemra in combination with ANY of the following:

Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

- Prescribed by, or in consultation with, a pulmonologist

2 . Revision History

Date	Notes
3/28/2022	Added Actemra IV formulation to GCA criteria. Updated all criteria re garding concomitant use to indicate no options are allowed. Added S ubmission of Records to all criteria boxes.

Prior Authorization Guideline

GL-102899 Acthar Gel, Cortrophin Gel

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

. Criteria

Product Name: Acthar Gel	
Diagnosis	Infantile spasm (i.e., West Syndrome)*
Approval Length	4 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of infantile spasms (i.e., West Syndrome)*	

AND

- Patient is less than 2 years old

AND

- Both of following:

Initial dose: 75 units per meters squared intramuscular (IM) twice daily for 2 weeks

AND

After 2 weeks, dose should be tapered according to the following schedule: 30 units per meters squared IM in the morning for 3 days; 15 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM in the morning for 3 days; 10 units per meters squared IM every other morning for 6 days (3 doses)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

Product Name: Acthar Gel, Cortrophin	
Diagnosis	Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

- Diagnosis of Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*

AND

- For Cortrophin requests ONLY: Trial and failure or intolerance to Acthar Gel (verified via paid pharmacy claims or submission of medical records/chart notes)

Notes	*Note: Acthar Gel is not medically necessary for treatment of acute ex acerbations of multiple sclerosis.

. Revision History

Date	Notes
2/3/2022	Added step through Acthar to get Cortrophin [for OMS Syndrome crit eria (not indicated for infantile spasms)]

Prior Authorization Guideline

GL-99673 Actimmune

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

. Criteria

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic granulomatous disease	

Product Name: Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, malignant osteopetrosis

Product Name: Actimmune	
Diagnosis	Severe, Malignant Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name: Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Actimmune will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Actimmune	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Actimmune therapy

. Revision History

Date	Notes
6/7/2021	7.1 Implementation

Prior Authorization Guideline

GL-99677 Adakveo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

. Criteria

Product Name: Adakveo	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of sickle cell disease, identified by any genotype	

AND

- ONE of the following:

BOTH of the following:

Age 16 to 20 years
Prescriber attests the service is medically necessary to correct or ameliorate a defect, a condition, or a physical or mental illness in an eligible patient

OR

Age greater than or equal to 21 years

AND

- Patient has experienced at least two vaso-occlusive crises within the past 12 months

. Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-104390 Adbry (tralokinumab-ldrm)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

. Indications

Drug Name: Adbry (tralokinumab-ldrm)
Atopic Dermatitis Indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. May be used with or without topical corticosteroids.

. Criteria

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	6 Months*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

- Diagnosis of moderate to severe atopic dermatitis

AND

- Submission of documentation (e.g., chart notes) demonstrating one of the following:

  Involvement of at least 10% body surface area (BSA)
  SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

- Patient is 18 years of age or older

AND

- Prescribed by or in consultation with one of the following:

  Dermatologist
  Allergist/Immunologist

AND

- Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following (verified via paid claims or submission of records):

  Medium or higher potency topical corticosteroid
  Pimecrolimus cream^
  Tacrolimus ointment
  Eucrisa (crisaborole) ointment^

Notes	*QL Override (For new starts only): Enter 2 PAs as follows: First PA: Approve 6 syringes per 28 days for one month; Second PA: Approve 4 syringes per 28 days (no overrides needed) for the remaining 11 mo nths. (Adbry is hard-coded with a quantity of 4 syringes per 28 days); ^Product may require step therapy

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation (e.g., chart notes) demonstrating positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

. Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05

	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium	Hydrocortisone butyrate	Cream, ointment, solution	0.1
potency	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
	Dexamethasone	Cream	0.1

Lowest potency	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

. Revision History

Date	Notes
3/4/2022	New Program

Prior Authorization Guideline

GL-99593 ADHD Products - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

. Criteria

Product Name: Brand Adderall, generic amphetamine/dextroamphetamine tablets, brand Adderall XR, brand Concerta ER, Daytrana, generic dexmethylphenidate tablets, brand Focalin XR, brand Methylin solution, generic methylphenidate tablets, brand Ritalin LA, generic methylphenidate ER (CD) capsules, Vyvanse capsules, generic atomoxetine, generic clonidine ER, generic guanfacine ER, generic dextroamphetamine tablets	
Diagnosis	ADHD Medications for Use in Children Under 6 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

- The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

- The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND

- The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND

- The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

Product Name: Non-Preferred Drugs: Brand Adhansia XR, Brand Adzenys XR-ODT, generic amphetamine ER, generic amphetamine , generic amphetamine/dextroamphetamine capsules, Brand Aptensio XR, Brand Azstarys, Brand Cotempla XR-ODT, Brand Desoxyn, Brand Dexedrine, generic dexmethylphenidate ER, generic dexmethylphenidate capsules, generic dexmethylphenidate ER, generic dextroamphetamine capsules, generic dextroamphetamine ER, Brand Dyanavel XR, Brand Evekeo ODT, Brand Focalin, Brand Intuniv, Brand Jornay PM, generic methamphetamine, generic methylphenidate capsule, generic methylphenidate ER tablets, generic methylphenidate ER (LA) , Brand Mydayis, Brand Procentra, Brand Qelbree, Brand Quillichew ER, Brand Quillivant XR, generic relexxii, Brand Ritalin, Brand Strattera, Brand Vyvanse Chewables, Brand Zenzedi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a history of failure, contraindication, or intolerance to a trial to FOUR of the following preferred products*:

- Brand Adderall

generic amphetamine/dextroamphetamine tablets Brand Adderall XR Brand Concerta ER Daytrana generic dexmethylphenidate tablets Brand Focalin XR Brand Methylin solution generic methylphenidate tablets Brand Ritalin LA generic methylphenidate ER (CD) capsules Vyvanse capsules generic atomoxetine generic clonidine ER generic guanfacine ER generic dextroamphetamine tablets	
Notes	*Alternatives may require prior authorization

. Revision History

Date	Notes
11/11/2021	Removed Sunosi and Wakix from guideline as these targets have dr ug-specific guidelines.

Prior Authorization Guideline

GL-107262 Aduhelm (aducanumab-avwa)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/17/2022

1 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - MEDICARE PART B*
Approval Length	6 month(s)
Guideline Type	Medicare Part B
Approval Criteria **1** - Requested medication is billed through Medicare Part B	

AND **2** - Submission of documentation confirming patient is enrolled in a CMS approved prospective comparative study

Notes	*Note: THIS SECTION SHOULD ONLY BE USED FOR DUAL ELIGIBLE MEMBERS (WILL HAVE AZMDUAL PLAN CODE) COVERED UNDER MEDICARE PART B THAT ARE REQUESTING SECONDARY COVERAGE.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - MEDICARE PART D*
Approval Length	None
Guideline Type	Prior Authorization requests from providers from Medicare Part D for Dual Eligible Members

Approval Criteria

1 - Requested medication is billed through Medicare Part D

AND

2 - Requests for coverage of Aduhelm (aducanumab) are not authorized and will not be approved under Part D

Notes	*Note: THIS SECTION SHOULD ONLY BE USED FOR DUAL ELIGIBLE MEMBERS (WILL HAVE AZMDUAL PLAN CODE). APPROVAL LENGTH: NONE - REQUESTS FOR ADUHELM ARE NOT COVERED UNDER MEDICARE PART D AND SHALL BE DENIED AS A BENEFIT EXCLUSION.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - FEE-FOR-SERVICE
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Mild cognitive impairment (MCI) due to Alzheimer's Disease (AD)
- Mild dementia due to Alzheimer's Disease (AD)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, examination histories) documenting the basis for diagnosis, including all of the following:

2.1 Documentation of a comprehensive history and neurological examination, inclusive of a description of the nature and duration of cognitive symptoms within the previous 3 months

AND

2.2 Medical records documenting baseline (within the previous three months) cognitive function based on ONE of the following objective assessments:

- Mini-Mental State Examination (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

AND

2.3 Medical records documenting confirmed evidence of clinically significant AD neuropathology based on ONE of the following:

- Cerebral Spinal Fluid (CSF) biomarkers
- Amyloid positron emission tomography (PET)

AND

3 - Patient has received recent (within the previous 3 months) baseline brain magnetic resonance imaging (MRI) prior to initiating treatment

AND

4 - Patient does not have significant cerebrovascular disease as established by brain MRI showing any of the following:

- Acute or sub-acute hemorrhage
- Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
- 4 or more brain microhemorrhages
- Cortical infarct
- More than 1 lacunar infarct
- Superficial siderosis
- History of diffuse white matter disease

AND

5 - Patient does not have any of the following non-AD neurodegenerative disorders:

- Probable dementia with Lewy bodies by consensus criteria
- Suspected frontotemporal degeneration
- Dementia in down syndrome

AND

6 - Patient does not have any of the following exclusionary neurological or psychiatric conditions:

- Uncontrolled seizure disorder
- Uncontrolled mood disorder, anxiety disorder, or psychosis
- Substance use disorder active in the past 2 years

AND

7 - Patient does not have any of the following cardiovascular conditions:

- Uncontrolled hypertension
- Coronary artery disease (including unstable angina and myocardial infarction)
- Heart failure
- Arrhythmia
- Clinically significant carotid atherosclerosis and/or peripheral arterial disease

AND

8 - Both of the following:

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less)
- Patient has no history of transient ischemic attack (TIA), stroke, or unexplained loss of consciousness within previous year prior to initiating treatment

AND

9 - Patient does not have any uncontrolled clinically significant chronic medical condition (e.g., liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HIV, HCV], poorly controlled diabetes mellitus)

AND

10 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

11 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatrics specialist

AND

12 - Prescriber attests that the patient and/or authorized representative (e.g., power of attorney, invoked health care proxy) has shared in decision-making and has been informed on the known and potential risks and lack of established clinical benefit associated with Aduhelm (aducanumab-avwa) treatment

AND

13 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. †Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity. ‡Requests should be evaluated case-by-case with clinical review and MD advisor.

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease - FEE-FOR-SERVICE
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed dosing is in accordance with the United States Food and Drug Administration approved labeling

AND

2 - Follow-up MRIs have been conducted at the following timeframes:

- Week 14 (after 4th infusion, prior to first 6 mg/kg dose)
- Week 22 (after 6th infusion, prior to first 10 mg/kg dose)
- Week 30 (after 8th infusion, prior to third 10 mg/kg dose)
- Week 42 (after 11th infusion, prior to sixth 10 mg/kg dose)

- Every 6 months thereafter

AND

3 - Patient's diagnosis continues to be mild cognitive impairment or mild dementia stage due to Alzheimer's disease as established by one of the following examination scales:

3.1 One of the following:

- Mini Mental State Exam (MMSE) score ≥ 24
- Montreal Cognitive Assessment (MoCA) score ≥ 15

OR

3.2 Both of the following:

- MMSE <24 or MoCA <15
- Rate of decline was slower than expected (<2 points/year)

AND

4 - ONE of the following (ARIA-H, microhemorrhages):

- Patient has had no new incident microhemorrhage
- Patient has had 1 to 4 new incident microhemorrhage(s) AND microhemorrhages are asymptomatic (no clinical symptoms)
- Patient has had 5 to 9 new incident microhemorrhages AND microhemorrhages are asymptomatic (no clinical symptoms) AND the microhemorrhages have been stabilized
- Patient has had 1 to 9 new incident microhemorrhages AND microhemorrhages resulted in mild, moderate or severe clinical symptoms AND the microhemorrhages have been stabilized

AND

5 - ONE of the following (ARIA-H, superficial siderosis)

- Patient has had no new incident areas of superficial siderosis
- Patient has had 1 new incident area of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms)

- Patient has had 2 new incident areas of superficial siderosis AND superficial siderosis is asymptomatic (no clinical symptoms) AND the superficial siderosis has been stabilized
- Patient has had 1 to 2 new incident areas of superficial siderosis AND superficial siderosis resulted in mild, moderate or severe clinical symptoms AND the superficial siderosis has been stabilized

AND

6 - ONE of the following (ARIA-E)

- Patient has had no new ARIA-E
- Patient has mild ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms)
- Patient has had moderate or severe ARIA-E on MRI AND ARIA-E is asymptomatic (no clinical symptoms) AND the ARIA-E is stable
- Patient has had mild, moderate or severe ARIA-E on MRI AND ARIA-E resulted in mild, moderate or severe clinical symptoms AND the ARIA-E is stable

AND

7 - One of the following:

7.1 Patient does not meet ANY of the following:

- Initiation of anticoagulation
- Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, SLE, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
- Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
- Development of other neurologic conditions (e.g., intracerebral bleeds, TBI, stroke)

OR

7.2 BOTH of the following:

- Patient does meet one of the above
- Prescriber documents clinical rationale for continued use of aducanumab‡

AND

8 - Prescribed by or in consultation with one of the following:

- Neurologist
- Geriatric specialist

AND

9 - Therapy should be discontinued permanently and the request should be denied if one or more of the following apply:

- If the patient has had ≥ 10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic)
- If the patient had a serious event [Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity]
- If the patient has had ≥ 3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied

Notes	*NOTE: If the patient has had ≥10 new incident microhemorrhages, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. *NOTE: If the patient had a serious event, therapy should be discontinued. † *NOTE: If the patient has had ≥3 new incident areas of superficial siderosis, regardless of clinical severity (including asymptomatic) therapy should be discontinued permanently and the request should be denied. †Serious events include concern for immediate risk of death (a life-threatening event); inpatient hospitalization or prolongation of existing hospitalization due to symptoms; new persistent or significant disability/incapacity. ‡Requests should be evaluated case-by-case with clinical review and MD advisor.

2 . Background

Clinical Practice Guidelines			
Appendix			
	ARIA - H (Microhemorrhages)		
	New Incident Microhemorrhages		
	Radiographic Severity		

		Mild (1 to 4)	Moderate (5 to 9)	Severe (≥10)
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		
	ARIA - H (Superficial Siderosis)			
		New Incident Areas of Superficial Siderosis (Central Read)		
		Radiographic Severity		
		Mild (1)	Moderate (2)	Severe (≥3)
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	Stop Permanently
	Mild	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved		Stop Permanently
	Moderate			
	Severe			
	Serious	Stop Permanently		
	ARIA - E			
		ARIA-E Severity on MRI (Central Read)		
		Radiographic Severity		
		Mild	Moderate	Severe
Clinical Symptom Severity	Asymptomatic	Continue treatment; MRI q4w until stable	Suspend treatment; MRI q4w until stable; Restart once stable	
	Mild			

	Moderate	Suspend treatment; MRI q4w until stable Restart once stable and clinical symptoms resolved
	Severe	
	Serious	Stop Permanently

3 . Revision History

Date	Notes
5/17/2022	Updated Medicare sections for clarification.

Prior Authorization Guideline

GL-99426 Aemcolo

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aemcolo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea

AND

2 - History of failure, contraindication, or intolerance to ONE of the following:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-99709 Afinitor

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Neuroendocrine tumors of pancreatic origin

- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin
- Neuroendocrine tumors of thymic origin

AND

2 - Disease is progressive

AND

3 - One of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell cancer

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

AND

3 - One of the following:

3.1 Patient with non-clear cell histology

OR

3.2 Both of the following:

3.2.1 Patient with predominantly clear cell histology

AND

3.2.2 History of failure, contraindication, or intolerance to at least one prior systemic therapy [e.g., Nexavar (sorafenib), Sutent (sunitinib), Opdivo (nivolumab), Cabometyx (cabozantinib)]

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal cell cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is not a candidate for curative surgical resection

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Subependymal Giant Cell Astrocytoma Associated with Tuberous Sclerosis Complex
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Disease is recurrent

OR

2.2 Disease is metastatic

AND

3 - One of the following:

3.1 Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

OR

3.2 BOTH of the following:

- Disease is hormone receptor negative (HR-)
- Disease has clinical characteristics that predict a HR+ tumor

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - One of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following:

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Used in combination with Aromasin (exemestane)

AND

6.1.2 One of the following:

6.1.2.1 Disease progressed while on or within 12 months of non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)] therapy

OR

6.1.2.2 Patient was treated with tamoxifen at any time

OR

6.2 Used in combination with ONE of the following:

- Fulvestrant
- Tamoxifen

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of classical Hodgkin lymphoma

AND

2 - ONE of the following:

- Disease is refractory
- Disease has relapsed

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PEComa (perivascular epitheliod cell tumor)

OR

2 - Diagnosis of recurrent angiomyolipoma

OR

3 - Diagnosis of lymphangioleiomyomatosis

OR

4 - All of the following:

4.1 Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

4.2 Disease has progressed after single agent therapy with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

AND

4.3 Used in combination with ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, lymphangioleiomyomatosis, or gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to at least one prior first-line chemotherapy regimen

OR

2.2 Patient has extrathoracic metastatic disease

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is recurrent or progressive

AND

3 - Surgery and/or radiation is not possible

AND

4 - Used in combination with bevacizumab (e.g., Avastin, Myasi)

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with letrozole

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Afinitor therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

AND

2 - Used as adjunctive therapy

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Afinitor therapy	

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Brand Afinitor, generic everolimus, Afinitor Disperz	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Afinitor therapy	

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99427 Afrezza

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Forced Expiratory Volume (FEV1) within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

AND

4 - Afrezza will not be approved in patients with ONE of the following:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months)
- With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

Product Name: Afrezza	
Diagnosis	Type 1 or Type 2 diabetes mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in Forced Expiratory Volume (FEV1)

AND

2 - Patient continues to be unable to self-inject short-acting insulin due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Patient continues to not smoke cigarettes

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-99428 Aldurazyme - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aldurazyme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Both the following:

1.2.1 Confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I)

AND

1.2.2 Have moderate to severe symptoms

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-99674 Alecensa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is one of the following:

- Metastatic
- Recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name: Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Alecensa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Alecensa therapy	

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99429 Alinia

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Giardia lamblia
Approval Length	3 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of giardiasis	

AND

2 - History of failure, contraindication, or intolerance to metronidazole

Product Name: Brand Alinia, generic nitazoxanide	
Diagnosis	Diarrhea caused by Cryptosporidium parvum
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cryptosporidiosis

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-105169 Alpha Interferons - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Intron A	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hairy cell leukemia

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of condylomata acuminata (genital or perianal)

OR

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of AIDS-related Kaposi's sarcoma

OR

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of leptomeningeal metastases

OR

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of meningiomas

OR

6 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of kidney cancer

OR

7 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting treatment of myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)

OR

8 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of follicular lymphoma

OR

9 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of adult T-cell leukemia, lymphoma

OR

10 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of mycosis fungoides, Sézary syndrome

OR

11 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of desmoid tumors/aggressive fibromatosis

OR

12 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of giant cell tumor of the bone

OR

13 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of malignant melanoma

Product Name: Alferon N	
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting treatment of refractory or recurring external condylomata acuminata (genital or venereal warts) due to the human papillomavirus (HPV) infection

2 . Revision History

Date	Notes
3/24/2022	Removed Sylatron from guideline, Added Submission of Medical Records

Prior Authorization Guideline

GL-99810 Alunbrig

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is one of the following:

- Metastatic
- Recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name: Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alunbrig therapy

Product Name: Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Alunbrig therapy	

2 . Revision History

Date	Notes
9/27/2021	Update the Guideline with the new GPIs provided per service now ts k003780948 eff 9.27.2021

Prior Authorization Guideline

GL-108621 Alzheimer's Agents - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Aricept, generic donepezil, Brand Namenda, generic memantine, Brand Razadyne, generic galantamine hydrobromide, Brand Razadyne ER, generic galantamine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of dementia of the Alzheimer’s type	

Product Name: Brand Exelon, generic rivastigmine

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

OR

2 - Diagnosis of dementia associated with Parkinson's disease

Product Name: Adlarity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dementia of the Alzheimer's type

AND

2 - One of the following:

2.1 History of failure, contraindication or intolerance to ALL of the following preferred drugs* (verified via paid pharmacy claims):

- generic donepezil
- generic galantamine IR/ER
- generic memantine
- generic oral rivastigmine

OR

2.2 Both of the following:

2.2.1 History of failure, contraindication or intolerance to generic rivastigmine patch* (verified via paid pharmacy claims)

AND **2.2.2** Patient is unable to swallow oral formulations or has documented swallowing difficulties	
Notes	*PA may be required

2 . Revision History

Date	Notes
6/23/2022	Updated product list. Added Adlarity as NP target.

Ampyra

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99666 Ampyra

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Ampyra, generic dalfampridine ER	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis	

AND

2 - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test)

Product Name: Brand Ampyra, generic dalfampridine ER	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician confirmation that the patient's walking improved with Ampyra therapy

2 . Revision History

Date	Notes
3/18/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99431 Anthelmintics - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Albenza, generic albendazole	
Diagnosis	See Note section*
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Enterobius vermicularis (pinworm)	

OR

2 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

OR

3 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

OR

4 - Diagnosis of Ascariasis (Roundworm)

OR

5 - Diagnosis of Mansonella perstans (Filariasis)

OR

6 - Diagnosis of Toxocariasis (Roundworm)

OR

7 - Diagnosis of Trichinellosis

OR

8 - Diagnosis of Trichuriasis (Whipworm)

OR

9 - Diagnosis of Capillariasis

Notes	* Enterobius vermicularis (pinworm), Hydatid Disease [Echinococcosis (Tapeworm)] Ancylostoma/Necatoriasis (Hookworm), Ascariasis (Roundworm), Mansonella perstans (Filariasis), Toxocariasis (Roundworm), Trichinellosis, Trichuriasis (Whipworm), Capillariasis

Product Name: Brand Albenza, generic albendazole	
Diagnosis	Neurocysticercosis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurocysticercosis

Product Name: Brand Stromectol, generic ivermectin	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of intestinal strongyloidiasis due to the nematode parasite Strongyloides stercoralis

OR

2 - Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-107448 Anticonvulsants - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Aptiom, Briviact, Brand Vimpat, generic lacosamide, Xcopri	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 One of the following:

1.1.3.3 Trial and failure, contraindication, or intolerance to generic lacosamide (APPLIES TO BRAND VIMPAT ONLY)

AND

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Fycompa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset or primary generalized tonic-clonic seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 One of the following:

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

OR

1.2 All of the following:

1.2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

1.2.2 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*
- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*
- Topiramate*
- Valproic acid*

AND

1.2.3 One of the following:

1.2.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.2.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.3 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Onfi, generic clobazam

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

1.2 Both of the following:

- Diagnosis of Dravet syndrome
- Patient is currently taking Diacomit

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Banzel, generic rufinamide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Gabitril, generic tiagabine

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.1.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.1.3 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Divalproex*
- Lamotrigine*
- Topiramate*
- Valproic acid*
- Felbamate*
- Banzel*

AND

1.1.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.2 ALL of the following:

1.2.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

1.2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.2.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.3 ALL of the following:

1.3.1 Diagnosis of Dravet syndrome

AND

1.3.2 Patient is currently taking Diacomit

AND

1.3.3 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.4 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril Oral Solution, generic vigabatrin oral solution, generic vigadrone oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of infantile spasms

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril Tablets, generic vigabatrin tablets	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of complex partial seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Dravet syndrome and currently taking clobazam

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome

AND

1.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies):

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial

AND

1.3.1.2 Lack of compliance as a reason for treatment failure has been ruled out

OR

1.3.2 BOTH of the following:

1.3.2.1 Documentation of failure due to intolerable side effects

AND

1.3.2.2 Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*

- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*
- Topiramate*
- Valproic Acid*

AND

2.3 ONE of the following:

2.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

2.3.2 BOTH of the following:

- Documentation of failure due to intolerable side effects
- Lack of compliance as a reason for treatment failure has been ruled out

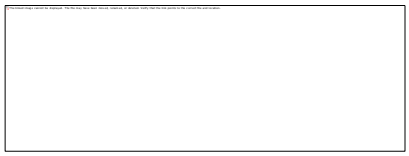
OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

2 . Revision History

Date	Notes
5/24/2022	Added generic lacosamide as target. Added criteria for Fintepla's ne w indication of Lennox-Gastaut Syndrome



Prior Authorization Guideline

GL-107448 Anticonvulsants - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Aptiom, Briviact, Brand Vimpat, generic lacosamide, Xcopri	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 One of the following:

1.1.3.3 Trial and failure, contraindication, or intolerance to generic lacosamide (APPLIES TO BRAND VIMPAT ONLY)

AND

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Fycompa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset or primary generalized tonic-clonic seizures

AND

1.1.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.1.3 One of the following:

1.1.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.1.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

OR

1.2 All of the following:

1.2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

1.2.2 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*
- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*
- Topiramate*
- Valproic acid*

AND

1.2.3 One of the following:

1.2.3.1 Both of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

1.2.3.2 Both of the following:

- Documentation of failure due to intolerable side effects.
- Reasonable efforts were made to minimize the side effect (e.g. change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

1.3 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Onfi, generic clobazam

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

1.2 Both of the following:

- Diagnosis of Dravet syndrome
- Patient is currently taking Diacomit

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Banzel, generic rufinamide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of seizures associated with Lennox-Gastaut syndrome

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Brand Gabitril, generic tiagabine

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of partial-onset seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

1.1.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.1.3 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Divalproex*
- Lamotrigine*
- Topiramate*
- Valproic acid*
- Felbamate*
- Banzel*

AND

1.1.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.2 ALL of the following:

1.2.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

1.2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment.)
- Not used as primary treatment

AND

1.2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

AND

1.2.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.3 ALL of the following:

1.3.1 Diagnosis of Dravet syndrome

AND

1.3.2 Patient is currently taking Diacomit

AND

1.3.3 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

1.4 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril Oral Solution, generic vigabatrin oral solution, generic vigadrone oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of infantile spasms

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Brand Sabril Tablets, generic vigabatrin tablets	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of complex partial seizures

AND

1.1.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

1.1.3 Not used as primary treatment

AND

1.1.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies):

- Carbamazepine*
- Divalproex*
- Gabapentin*
- Lamotrigine*
- Levetiracetam*
- Oxcarbazepine*
- Phenytoin*
- Pregabalin*
- Topiramate*
- Valproic acid*
- Zonisamide*

OR

1.2 For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

Product Name: Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Dravet syndrome and currently taking clobazam

OR

2 - For continuation of prior therapy for a seizure disorder

Product Name: Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of seizures associated with Dravet syndrome

AND

1.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies):

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial

AND

1.3.1.2 Lack of compliance as a reason for treatment failure has been ruled out

OR

1.3.2 BOTH of the following:

1.3.2.1 Documentation of failure due to intolerable side effects

AND

1.3.2.2 Reasonable efforts were made to minimize the side effect (e.g., change timing of dosing, divide dose out for more frequent but smaller doses, etc.)

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 History of greater than or equal to 8 week trial, contraindication or intolerance of at least TWO of the following (any release formulation qualifies):

- Banzel (rufinamide)*

- Clobazam*
- Divalproex*
- Felbamate*
- Lamotrigine*
- Topiramate*
- Valproic Acid*

AND

2.3 ONE of the following:

2.3.1 BOTH of the following:

- Documented history of persisting seizures after titration to the highest tolerated dose with each medication trial
- Lack of compliance as a reason for treatment failure has been ruled out

OR

2.3.2 BOTH of the following:

- Documentation of failure due to intolerable side effects
- Lack of compliance as a reason for treatment failure has been ruled out

OR

3 - For continuation of prior therapy for a seizure disorder

Notes	*Drug may require PA

2 . Revision History

Date	Notes
5/24/2022	Added generic lacosamide as target. Added criteria for Fintepla's ne w indication of Lennox-Gastaut Syndrome

Prior Authorization Guideline

GL-107257 Antidepressants - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/17/2022

1 . Criteria

Product Name: generic citalopram oral solution, generic fluoxetine oral solution, generic sertraline oral conc for solution	
Diagnosis	Requests for Patients greater than 12 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The member is unable to swallow the oral tablet/capsule.	

Product Name: Amitriptyline, amoxapine, bupropion tabs/SR tabs/XL tabs (150 and 300mg), citalopram tabs/oral soln, clomipramine, desipramine, doxepin caps/oral conc for solution, duloxetine capsules (20, 30, 60mg), escitalopram, fluoxetine caps/oral soln, fluvoxamine IR, generic mirtazapine tabs/ODT, imipramine tabs/caps, nortriptyline caps/oral soln, paroxetine tabs, protriptyline, sertraline tabs/oral soln, trazodone, trimipramine, venlafaxine tabs/ER capsules	
Diagnosis	PREFERRED DRUG Requests for patient 6 years of age or younger
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted) **AND** **2** - The physician attests that the requested medication is medically necessary. (Document rationale for use)	
Notes	Drug may require PA

Product Name: Aplenzin, Brand Anafranil, Caplyta, Brand Celexa, generic citalopram capsules, Brand Cymbalta, generic duloxetine 40mg caps, Drizalma , Brand Effexor XR, generic venlafaxine ER tabs, Emsam, Fetzima, fluvoxamine ER, Brand Lexapro, maprotiline, Marplan, Brand Nardil, generic phenelzine, nefazodone, Brand Norpramin, Brand Pamelor caps/oral soln, Brand Parnate, generic tranylcypromine, Brand Paxil, generic paroxetine capsules, Paxil susp, Brand Paxil CR, generic paroxetine ER, Pexeva, Brand Pristiq, generic desvenlafaxine ER, Brand Prozac, generic fluoxetine tablets, Brand Remeron SLTB, Brand Remeron, Trintellix, Viibryd, Brand Wellbutrin SR, Brand Wellbutrin XL/Forfivo, generic bupropion ER (XL) 450mg tabs, Brand Zoloft, generic sertraline capsules	
Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)	

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

AND

3 - Patient has a history of failure, contraindication or intolerance to at least 3 preferred alternatives*

- Bupropion (Generic Wellbutrin)
- Bupropion SR (Generic Wellbutrin SR)
- Bupropion XL (Generic Wellbutrin XL)
- Citalopram (Generic Celexa)
- Escitalopram Tablets (Generic Lexapro)
- Esketamine (Spravato)
- Fluoxetine Capsules (Generic Prozac)
- Fluoxetine Solution (Generic Prozac)
- Fluvoxamine Tablets (Generic Luvox)
- Mirtazapine (Generic Remeron)
- Paroxetine (Generic Paxil)
- Sertraline (Generic Zoloft)
- Trazodone (Generic Desyrel)
- Venlafaxine (Generic Effexor)
- Venlafaxine ER Capsules (Generic Effexor ER)

Notes	*Drug may require PA

2 . Revision History

Date	Notes
5/17/2022	Moved Caplyta to NP criteria section. Updated NP verbiage.

Prior Authorization Guideline

GL-99432 Antiemetics - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Nausea and vomiting associated with cancer chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prevention or treatment of nausea and vomiting associated with cancer chemotherapy	

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet

Diagnosis	Nausea and vomiting associated with radiotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention or treatment of nausea and vomiting associated with radiotherapy (total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen)

Product Name: Anzemet, granisetron tablet, ondansetron 24mg tablet	
Diagnosis	Postoperative nausea and/or vomiting
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prevention of postoperative nausea and/or vomiting (administration prior to induction of anesthesia)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy C&S Arizona to Arizona Standard

Prior Authorization Guideline

GL-99587 Antiglaucoma Agents - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zioptan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of elevated intraocular pressure due to ocular hypertension or open angle glaucoma	

2 . Revision History

Date	Notes
10/25/2021	Removed Azopt, Brand/generic Travatan Z as targets

Prior Authorization Guideline

GL-99551 Antipsoriatic Agents

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Dovonex cream, generic calcipotriene cream, Brand Calcitrene ointment, generic calcipotriene ointment, Brand Vectical, generic calcitriol ointment	
Diagnosis	Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of psoriasis

AND

2 - History of failure, contraindication, or intolerance to TWO medium to Very high potency corticosteroid topical treatments (see Table 1 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1. Relative Potency of Selected Topical Corticosteroid Products

Drug	Dosage Form	Strength
Super High Potency		
Augmented betamethasone dipropionate (Diprolene)	Gel, Ointment	0.05%
Clobetasol propionate (Temovate, Temovate E)	Cream, Solution	0.05%
Halobetasol propionate (Ultravate)	Cream	0.05%
High Potency		
Augmented betamethasone dipropionate (Diprolene, Diprolene AF)	Cream, Lotion	0.05%
Betamethasone dipropionate	Lotion, Ointment	0.05%
Fluocinonide (Lidex, Lidex E)	Cream, Solution	0.05%
Triamcinolone acetonide (Kenalog)	Cream, Ointment	0.5%
Medium Potency		

Betamethasone valerate (Beta-Val)	Cream	0.1%
Fluocinolone acetonide (Synalar)	Cream, Ointment	0.025%
Fluticasone propionate (Cutivate)	Cream, Lotion	0.05%
	Ointment	0.005%
Hydrocortisone butyrate (Locoid)	Ointment, Solution	0.1%
Mometasone furoate (Elocon)	Cream, Ointment, Solution	0.1%
Prednicarbate (Dermatop)	Cream	0.1%
Triamcinolone acetonide (Kenalog)	Cream, Lotion, Ointment	0.1%
	Ointment	0.025%

Prior Authorization Guideline

GL-109167 Antipsychotics - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/8/2022

1 . Criteria

Product Name: haloperidol concentrate, haloperidol tablets, loxapine, perphenazine, thioridazine, thiothixene, generic pimozide, fluphenazine (tablets, concentrate and elixir), trifluoperazine, chlorpromazine (tabs and inj), lithium carbonate (caps, tabs and oral solution), generic lithium carbonate ER, generic aripiprazole tabs, generic ziprasidone, Latuda, generic risperidone (tabs and oral solution), risperidone ODT tabs, generic quetiapine, generic olanzapine (tabs and ODT tabs)	
Diagnosis	Preferred Antipsychotics: Children Under 6 Years Old
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient has been diagnosed per current DSM (Diagnostic and Statistical Manual of Mental Disorders) criteria with one of the following disorders:

- Bipolar Spectrum Disorder
- Schizophrenic Spectrum Disorder
- Tourette's or other tic disorder
- Autism Spectrum Disorder

AND

2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

AND

3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

AND

4 - The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

AND

5 - The patient does not have a known hypersensitivity to the requested agent

Product Name: Invega Sustenna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral paliperidone or oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Risperdal Consta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Abilify Maintena	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Invega Trinza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - Patient has been treated with Invega Sustenna for at least 4 months

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Aristada, Aristada Initio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral aripiprazole

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Perseris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is non-adherent with oral atypical antipsychotic dosage forms
- Patient has established tolerability with oral risperidone

OR

2.2 Patient is unable to take oral solid alternatives

AND

3 - If the patient is less than 18 years of age, the prescriber attests they are aware of FDA (Food and Drug Administration) labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

Product Name: Brand Abilify tabs, Brand Clozaril tabs, Brand Geodon, Brand Haldol decanoate inj, Brand Lithobid, Brand Orap, Brand Risperdal (tabs and oral soln), Brand Seroquel, Brand Zyprexa, Brand Zyprexa Zydis, perphenazine-amitriptyline, molindone, aripiprazole ODT, aripiprazole oral solution, Caplyta, Brand Invega, generic paliperidone, Fanapt, Brand Seroquel XR, generic quetiapine ER, Rexulti, Saphris, Secuado, Brand Symbyax, generic fluoxetine-olanzapine, Versacloz, Vraylar, Zyprexa Relprevv

Diagnosis	Non-Preferred Drugs
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient has a history of failure, contraindication or intolerance to at least THREE preferred alternatives

- Aripiprazole (Abilify Maintena)
- Aripiprazole (Aristada Initio)
- Aripiprazole (Aristada)
- Aripiprazole (Generic Abilify)
- Clozapine (Generic Clozaril)

- Clozapine ODT (Generic Fazaclo ODT)
- Lurasidone (Latuda)
- Olanzapine (Generic Zyprexa)
- Olanzapine ODT (Generic Zyprexa Zydis)
- paliperidone (Invega Sustenna)
- paliperidone (Invega Trinza)
- Quetiapine (Generic Seroquel)
- Risperidone (Generic Risperdal)
- Risperidone (Risperdal Consta)
- Risperidone ODT (Generic Risperdal ODT)
- Ziprasidone (Generic Geodon)

OR

1.1.1.2 There are no preferred formulary alternatives for the requested drug

AND

1.1.2 If the request is for a multi-source brand medication (i.e., MSC O), ONE of the following:

1.1.2.1 BOTH of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications
- If there are generic product(s), the member has tried at least three (if available)

OR

1.1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure)
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.1.3 ONE of the following:

1.1.3.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.4 ONE of the following:

1.1.4.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

1.1.4.2 The drug falls within dosing guidelines found in ONE of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons

- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.5 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program*

OR

1.2 The requested medication is a behavioral health medication and ONE of the following:

1.2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: Abilify Mycite	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has ONE of the following:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder
- Autism
- Major depressive disorder
- Tourette's

AND

1.1.2 Submission of medical records or claims history documenting the patient is currently prescribed aripiprazole and tolerates the medication

AND

1.1.3 Submission of medical records or claims history documenting the patient's adherence to aripiprazole is less than 80 percent within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100)

AND

1.1.4 ALL of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:

- Utilization of a pill box
- Utilization of a smart phone reminder (ex. alarm, application, or text reminder)
- Involving family members or friends to assist
- Coordinating timing of dose to coincide with dosing of another daily medication

AND

1.1.5 Submission of medical records or claims history documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole

AND

1.1.6 Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence

AND

1.1.7 Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer

AND

1.1.8 The patient has a history of failure, contraindication, or intolerance or reason or special circumstance they cannot use TWO of the following: (Drug may require PA)

- Abilify Maintena
- Invega Sustenna
- Risperdal Consta
- Aristada
- Perseris

OR

1.2 ONE of the following:

1.2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Product Name: Abilify Mycite

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient is clinically stable on Abilify MyCite

AND

2 - Submission of medical records or claims history documenting that the use of Abilify MyCite has increased adherence to 80 percent or more

AND

3 - Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent

Product Name: Lybalvi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Paid claims or submission of medical records (e.g., chart notes) (document drug, duration, dose and date of use) confirming BOTH of the following:

1.1.1.1 Patient has a history of failure, contraindication or intolerance to at least FOUR preferred alternatives:

- Aripiprazole (Abilify Maintena)
- Aripiprazole (Aristada Initio)
- Aripiprazole (Aristada)
- Aripiprazole (Generic Abilify)
- Clozapine (Generic Clozaril)

- Clozapine ODT (Generic Fazaclo ODT)
- Lurasidone (Latuda)
- Paliperidone (Invega Sustenna)
- Paliperidone (Invega Trinza)
- Quetiapine (Generic Seroquel)
- Risperidone (Generic Risperdal)
- Risperidone (Risperdal Consta)
- Risperidone ODT (Generic Risperdal ODT)
- Ziprasidone (Generic Geodon)

AND

1.1.1.2 Failure to respond to generic olanzapine (Generic Zyprexa) given at maximum dosage

AND

1.1.2 ONE of the following:

1.1.2.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.1.2.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.3 ONE of the following:

1.1.3.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

1.1.3.2 The drug falls within dosing guidelines found in ONE of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program*

OR

1.2 The requested medication is a behavioral health medication and ONE of the following:

1.2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: Caplyta	
Diagnosis	Caplyta Requests Exceeding Quantity Limit**
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from one of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The requested dose falls within dosing guidelines found in one of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program*

AND

5 - Physician has provided rationale for needing to exceed the quantity limit of one capsule

(42 milligrams [mg]) per day (NOTE: The treatment effect of Caplyta 84mg daily versus placebo was NOT statistically significant in clinical trials.)	
Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED. **Ca plyta requests should be reviewed using the Non-Preferred criteria. Th is section is for Caplyta quantity limit requests only.

Product Name: generic haloperidol decanoate inj, fluphenazine decanoate, generic clozapine (tabs and ODT tabs)	
Diagnosis	Patients <18 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 The requested medication must be used for an FDA (Food and Drug Administration) approved indication

OR

1.1.1.2 The use of the drug is supported by information in ONE of the following appropriate compendia of literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex

- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.1.2 The patient meets the FDA minimum age limit or the prescriber attests they are aware of FDA labeling regarding the use of the antipsychotic medication and feels the treatment with the requested medication is medically necessary (Document rationale for use)

OR

1.2 The patient is currently on the requested medication

2 . Revision History

Date	Notes
7/7/2022	Added drug specific criteria for Lybalvi. Updated general NP criteria r egarding MSB to align with NP admin guideline criteria.

Prior Authorization Guideline

GL-105536 Anxiolytics- AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: buspirone, Brand Xanax tabs, generic alprazolam tabs, alprazolam ODT, alprazolam conc, Brand Xanax XR, generic alprazolam ER, chlordiazepoxide, Brand Tranxene T, generic clorazepate dipotassium, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam oral soln, Brand Ativan, Loreev XR, generic lorazepam, lorazepam conc, generic oxazepam, Brand Klonopin tabs, generic clonazepam tabs, clonazepam ODT	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted).

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

Product Name: Loreev XR	
Diagnosis	Requests for Patients 6 years of age and older
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, or contraindication to generic lorazepam

AND

2 - The physician attests that the requested medication is medically necessary (Document rationale for use)

Product Name: buspirone, Brand Xanax tabs, generic alprazolam tabs, alprazolam ODT, alprazolam conc, Brand Xanax XR, generic alprazolam ER, chlordiazepoxide, Brand Tranxene T, generic clorazepate dipotassium, Brand Valium tabs, generic diazepam tabs, diazepam conc, diazepam oral soln, Brand Ativan, Loreev XR, generic lorazepam, lorazepam conc, generic oxazepam, Brand Klonopin tabs, generic clonazepam tabs, clonazepam ODT	
Diagnosis	Reject 88: Drug Utilization Review: Greater than 1 Anxiolytic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The medication is being used to adjust the dose of the drug

OR

2 - The medication will be used in place of the previously prescribed drug, and not in addition to it

OR

3 - The medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

4 - The physician attests they are aware of the multiple anxiolytics prescribed to the patient and feels treatment with both medications is medically necessary (Document rationale for use)

2 . Revision History

Date	Notes
3/31/2022	Added criteria for Loreev XR

Prior Authorization Guideline

GL-99571 Apidra and Apidra Solostar

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Apidra and Apidra Solostar	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Apidra, and Apidra Solostar should be denied. The plan's preferred products are.

- Generic Novolog
- Generic Humalog
- Novolog
- Humalog

2 . Revision History

Date	Notes
7/13/2021	New policy

Prior Authorization Guideline

GL-107440 Apomorphine products (Apokyn, Kynmobi)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of Parkinson’s disease

AND

1.2 Medication will be used as intermittent treatment for OFF episodes

AND

1.3 Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

1.4 Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

1.5 History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

AND

2 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

Product Name: Brand Apokyn, generic apomorphine injection, Kynmobi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
5/24/2022	Added generic apomorphine injection and Kynmobi as targets

Prior Authorization Guideline

GL-99514 Aquadeks

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Aquadeks	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis	

2 . Revision History

Date	Notes
4/10/2021	7/1 Implementation

Prior Authorization Guideline

GL-100647 Aralast NP - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Aralast NP	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has clinically evident emphysema	

AND

2 - Patient has a diagnosis of severe congenital deficiency of Alpha1- proteinase inhibitor (alpha1 antitrypsin deficiency)

2 . Revision History

Date	Notes
12/16/2021	no changes to criteria, formulary name update

Prior Authorization Guideline

GL-105172 Arcalyst

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) [including Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), etc]

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Arcalyst therapy

2 . Revision History

Date	Notes
3/24/2022	Updated diagnosis verbiage for clarification. Added Submission of M edical Records.

Prior Authorization Guideline

GL-99710 Arikayce

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease	

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting respiratory cultures positive for MAC within the previous 6 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Macrolide antibiotic* (e.g., azithromycin, clarithromycin)
- Ethambutol*
- Rifamycin antibiotic* (e.g., rifampin, rifabutin)

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	*Drug may require PA)

Product Name: Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 ALL of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with an minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

- Macrolide antibiotic* (e.g., azithromycin, clarithromycin)
- Ethambutol*
- Rifamycin antibiotic* (e.g., rifampin, rifabutin)

AND

3 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Notes	*Drug may require PA

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Austedo

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99806 Austedo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Austedo	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chorea associated with Huntington's Disease	

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Age ≥ 18 years

AND

4 - Targeted mutation analysis demonstrates a cytosine-adenine-guanine (CAG) trinucleotide expansion of ≥ 36 repeats in the huntingtin (HTT) gene

AND

5 - Patient has a Unified Huntington Disease Rating Scale (UHDRS) score ranging from 1 to 4 on any one of UHDRS chorea items 1 through 7

AND

6 - Failure of tetrabenazine as indicated by utilization per patient's pharmacy claims or clinically significant adverse effects are experienced

AND

7 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

8 - Dose does not exceed 48 mg per day

Product Name: Austedo

Diagnosis	Moderate to Severe Tardive dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD)secondary to treatment with a centrally acting dopamine receptor blocking agent (DRBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Age ≥ 18 years

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9.

AND

5 - Failure of tetrabenazine as indicated by utilization per patient's pharmacy claims or clinically significant adverse effects are experienced

AND

6 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

7 - Dose does not exceed 48 mg per day

Product Name: Austedo	
Diagnosis	Chorea Associated with Huntington Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the UHDRS chorea items 1 through 7

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

Product Name: Austedo	
Diagnosis	Moderate to Severe Tardive dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline score of any one of the AIMS items 1 through 9

AND

2 - Austedo is not prescribed concurrently with tetrabenazine or Ingrezza

AND

3 - Dose does not exceed 48 mg per day

2 . Revision History

Date	Notes
8/25/2021	Arizona Medicaid Implementation

Prior Authorization Guideline

GL-99797 Ayvakit

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - ONE of the following:

2.1 Treatment is used for ONE of the following:

- Unresectable, recurrent, or metastatic disease after failure on approved therapies [e.g., imatinib (Gleevec) and Sutent (sunitinib)]
- Continuation of therapy for limited progression

OR

2.2 BOTH of the following:

2.2.1 Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation (including PDGFRA D842V mutations)

AND

2.2.2 ONE of the following:

2.2.2.1 Mutations are insensitive to imatinib (Gleevec) and used for treatment of resectable disease with significant morbidity

OR

2.2.2.2 Mutations are sensitive to imatinib (Gleevec) and used for treatment of one of the following:

- Unresectable, recurrent, metastatic disease
- Persistent residual disease

Product Name: Ayvakit	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of FIP1L1-PDGFRA (platelet-derived growth factor receptor alpha) rearrangement

AND

3 - PDGFRA D842V mutation is found to be resistant to imatinib (Gleevec)

Product Name: Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ayvakit therapy

Product Name: Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ayvakit will be approved for uses supported by The National Comprehensive Cancer

Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ayvakit therapy

Prior Authorization Guideline

GL-99585 Azole Antifungals

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Systemic Fungal Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following

1.1 Diagnosis of ONE of the following:

- Blastomycosis

- Histoplasmosis
- Aspergillosis

OR

1.2 Both of the following:

1.2.1 Diagnosis of coccidioidomycosis

AND

1.2.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 6-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history

Product Name: Brand Sporanox capsules, generic itraconazole capsules

Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Three months have elapsed since completion of initial therapy for fingernail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of toenail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

AND

2 - Patient has a history of at least a 12-week trial resulting in therapeutic failure, contraindication, intolerance, or resistance to Terbinafine as evidenced by submission of medical records or claims history.

Product Name: Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Nine months have elapsed since completion of initial therapy for toenail onychomycosis

AND

1.2 Documentation of positive clinical response to therapy

Product Name: Brand Sporanox Oral Solution, generic itraconazole oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Oropharyngeal candidiasis
- Esophageal candidiasis

Product Name: Brand Vfend tablets, generic voriconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.3 Both of the following:

1.3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

1.3.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.4 Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.6 Diagnosis of Exserohilum species infection

Product Name: Brand Vfend Powder for Oral Suspension, generic voriconazole powder for oral suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.1.2 ALL of the following:

- Diagnosis of Candidemia
- Patient is non-neutropenic
- Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.1.3 Both of the following:

1.1.3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall

- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

1.1.3.2 Patient has a history of failure, contraindication, intolerance, or resistance to fluconazole (generic Diflucan) as evidenced by submission of medical records or claims history

OR

1.1.4 Diagnososis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.1.6 Diagnosis of Exserohilum species infection

AND

1.2 Physician has provided rationale for the patient needing to use voriconazole oral suspension instead of voriconazole tablets.

Product Name: Brand Noxafil tablets, generic posaconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension	
Diagnosis	Prophylaxis of Aspergillus or Candida Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

1.2 One of the following conditions:

1.2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy [eg, acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

1.2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name: Noxafil Suspension	
Diagnosis	Oropharyngeal Candidiasis (OPC)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of oropharyngeal candidiasis (OPC)

AND

1.2 The patient has a history of failure, contraindication, intolerance, or resistance to TWO of the following as evidenced by submission of medical records or claims history:

- Fluconazole* (generic Diflucan)
- Itraconazole* (generic Sporanox)
- Clotrimazole Lozenges*

Notes	*Drug may require PA

Product Name: Cresemba	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of invasive aspergillosis

AND

1.1.2 Patient has a history of failure, contraindication, intolerance, or resistance to voriconazole* (generic Vfend) as evidenced by submission of medical records or claims history

OR

1.2 Diagnosis of invasive mucormycosis

Notes	*Drug may require PA

Product Name: Tolsura	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of ONE of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

1.2 Patient has a history of failure, contraindication, intolerance, or resistance to

itraconazole* capsules (generic Sporanox) as evidenced by submission of medical records or claims history	
Notes	*Drug may require PA

Product Name: Brand Sporanox capsules, generic itraconazole capsules, Brand Sporanox oral solution, generic itraconazole oral solution, Brand Vfend tablets, generic voriconazole tablets, Brand Vfend powder for oral suspension, generic voriconazole powder for oral suspension, Brand Noxafil tablets, generic posaconazole tablets, Noxafil oral suspension, Cresemba, Tolsura	
Diagnosis	All Other Diagnoses
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

2 - The medication is being prescribed by or in consultation with an infectious disease specialist.

Notes	*Authorization duration based on provider recommended treatment du rations, not to exceed 12 months

2 . Revision History

Date	Notes
9/30/2021	UM criteria update per SN TSK003786763 eff 10.15.2021

Prior Authorization Guideline

GL-99675 Balversa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Balversa	
Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urothelial carcinoma	

AND

2 - ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations

AND

4 - Patient has progressed during or following at least one line of prior chemotherapy or immunotherapy, or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

Product Name: Balversa	
Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Balversa therapy

Product Name: Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Balversa therapy

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99516 Baxdela

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Baxdela	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	10 Days*
Guideline Type	Prior Authorization
Approval Criteria **1** - For continuation of therapy upon hospital discharge	

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin**
- A macrolide**
- Doxycycline**
- A fluoroquinolone**
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Notes	*Note: Authorization will be issued for up to 10 days. **Drug may requi re PA

Product Name: Baxdela	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 One of the following diagnoses:

3.1.1 Both of the following

3.1.1.1 Acute bacterial skin and skin structure infections

AND

3.1.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.1.2 Both of the following:

3.1.2.1 Empirical treatment of patients with acute bacterial skin and skin structure infections

AND

3.1.2.2 Presence of MRSA infection is likely

AND

3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- A tetracycline**
- Clindamycin**

OR

4 - All of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin**
- A cephalosporin**
- A tetracycline**
- Sulfamethoxazole-trimethoprim (SMZ-TMP)**
- Clindamycin**

Notes	*Note: Authorization will be issued for up to 14 days. **Drug may require PA

Product Name: Baxdela	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria **1** - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication	
Notes	*Note: Authorization duration based on provider recommended treatment durations, up to 6 months.

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99547 Belbuca_Butrans- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is being treated for cancer, hospice, or end of life related pain	

AND

2 - If the request is for Belbuca or generic Butrans BOTH of the following:

2.1 Prescriber attests to the following: The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information

AND

2.2 The patient has a history of failure, contraindication or intolerance to BRAND Butrans.

Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for brand buprenorphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches	
Diagnosis	Cancer/Hospice/End of Life related pain
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for cancer, hospice, or end of life related pain (Document diagnosis and date of diagnosis)

AND

2 - If the request is for Belbuca or generic Butrans, the prescriber attests to the following: The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

1.1 The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

AND

1.2 Treatment goals are defined, including estimated duration of treatment

AND

1.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

1.4 Patient has been screened for substance abuse/opioid dependence

AND

1.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

1.6 Pain is moderate to severe and expected to persist for an extended period of time

AND

1.7 Pain is chronic

AND

1.8 Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)

AND

1.9 Pain management is required around the clock with a long-acting opioid

AND

2 - The patient has a history of failure, contraindication, or intolerance to a trial of tramadol IR (immediate release), unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (Drug may require PA)

AND

3 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following must be met:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial)

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial)

AND

4 - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication or intolerance to BRAND Butrans

Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorizati on criteria requirements for treatment with an opioid, a denial should b e issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is curr ently taking the requested long-acting opioid for at least 30 days and h as met the medical necessity authorization criteria requirements for tr eatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination u p to the requested quantity for transition to an alternative treatment. A dditionally, a 6 month authorization should be entered for brand bupre norphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Diagnosis	Non-cancer pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates meaningful improvement in pain and function (document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (document rationale)

AND

3 - Prescriber attests to ALL of the following:

3.1 The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

AND

3.2 Treatment goals are defined, including estimated duration of treatment

AND

3.3 Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

AND

3.4 Patient has been screened for substance abuse/opioid dependence

AND

3.5 If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND **3.6** Pain is moderate to severe and expected to persist for an extended period of time **AND** **3.7** Pain is chronic **AND** **3.8** Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time) **AND** **3.9** Pain management is required around the clock with a long-acting opioid **AND** **4** - If the request is for Belbuca or generic Butrans, the patient has a history of failure, contraindication, or intolerance to BRAND Butrans	
Notes	* If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorizati on criteria requirements for treatment with an opioid, a denial should b e issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the member is curr ently taking the requested long-acting opioid for at least 30 days and h as met the medical necessity authorization criteria requirements for tr eatment with an opioid, but has not tried brand buprenorphine patches a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination u p to the requested quantity for transition to an alternative treatment. A dditionally, a 6 month authorization should be entered for brand bupre norphine patches.

Product Name: Brand Belbuca, Brand Butrans, generic buprenorphine patches *	
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists (see Table 1 in Background section)	
Notes	*Approval durations: 12 months for cancer pain/hospice/end of life related pain; 6 months for non-cancer pain/non-hospice/non-end of life related pain

2 . Revision History

Date	Notes
6/10/2021	Updated guideline

Prior Authorization Guideline

GL-99711 Benlysta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]

AND

3 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

4 - Patient does NOT have severe active central nervous system lupus

AND

5 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta SQ	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus

erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

Product Name: Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus, Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is not receiving Benlysta in combination with a biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]

2 . Revision History

Date	Notes
5/12/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99434 Benznidazole

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Benznidazole	
Diagnosis	Chagas disease (American trypanosomiasis)
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Ariz ona Medicaid

Prior Authorization Guideline

GL-99661 Berinert

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Berinert	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - Prescribed for the treatment of acute HAE attacks

AND

3 - Not used in combination with other approved treatments for acute HAE attacks (e.g. Firazyr, Ruconest)

AND

4 - ONE of the following:

4.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to Ruconest (C1 esterase inhibitor [recombinant])

OR

4.2 Patient is currently on Berinert therapy

AND

5 - Prescribed by ONE of the following:

5.1 Immunologist

OR

5.2 Allergist

Product Name: Berinert	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

AND

2 - Prescribed for the acute treatment of HAE (hereditary angioedema) attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g. Firazyr, Ruconest)

AND

4 - Prescribed by ONE of the following:

4.1 Immunologist

OR

4.2 Allergist

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona Medicaid SP to Medicaid Arizona SP for eff 7 /1

Prior Authorization Guideline

GL-99566 Blood Glucose Monitors

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Non-preferred Blood Glucose Monitors*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is visually impaired	
Notes	*Please reference background table for list of Non-preferred Blood Glucose Monitors **Approve Glucose Monitor at NDC Level

2 . Background

Benefit/Coverage/Program Information

Non-preferred Blood Glucose Monitors*

CONTOUR KIT NEXT LNK	EASY TOUCH KIT MONITOR	EASYMAX V KIT SYSTEM
CONTOUR NXT KIT LINK 2.4	KROGER BGM KIT SYSTEM	EASYMAX NG KIT SYSTEM
CONTOUR KIT NEXT EZ	ELEMENT AUTO KIT SYSTEM	MEIJER BGM KIT ESSENTIA
CONTOUR KIT NEXT	SMARTEST KIT EJECT	MEIJER GLUCO KIT MONITOR
CONTOUR KIT MONITOR	SMARTEST KIT PROTEGE	MEIJER BGM KIT PREMIUM
RELION MICRO KIT	SMARTEST KIT PRONTO	FORA V30A KIT
RELION KIT MONITOR	SMARTEST KIT PERSONA	FORA TN'G KIT VOICE
BD LOGIC KIT MONITOR	GLUCOCOM KIT MONITOR	REFUAH PLUS KIT SYSTEM
BD LATITUDE KIT	RIGHTEST SYS KIT GM300	KROGER BGM KIT
BD LATITUDE KIT SYSTEM	RIGHTEST SYS KIT GM100	KROGER BGM KIT PREMIUM
QUICKTEK KIT	RIGHTEST SYS KIT GM550	CONTOUR KIT LINK 2.4
ADVANCE KIT INTUITIO	IGLUCOSE KIT	EASYMAX V KIT SYSTEM
GLUCOCARD KIT SHNE CON	NOVA MAX KIT SYSTEM	EASYMAX NG KIT SYSTEM

GLUCOCARD KIT SHNE EXP	WAVESENSE KIT KEYNOTE	MYGLUCOHEALT KIT SYSTEM
GLUCOCARD KIT EXPRESSI	AGAMA JAZZ KIT WRLSS 2	MICRODOT KIT SYSTEM
POCKETCHEM KIT EZ	AGAMATRIX KIT PRESTO	ONE TOUCH KIT VERIO FL
GLUCOCARD 01 KIT SYSTEM	WAVESENSE KIT AMP	RELION TRUE KIT MET AIR
GLUCOCARD 01 KIT MINI	SOLUS V2 KIT SYSTEM	VERASENS KIT
GLUCOCARD KIT X-METER	COOL MONITOR KIT	INFINITY KIT VOICE
GLUCOCARD KIT VITAL	TRUERESULT KIT MONITOR	OPTIUM KIT BL GLUC
RELION PREMI KIT COMP SYS	TRUERESULT KIT SYSTEM	PRECISION KIT XTRA
SMART SENSE KIT GLUC SYS	MEIJER BGM KIT ESSENTIA	PRECISION KIT LINK
CVS GLUCOSE KIT METER	MEIJER GLUCO KIT MONITOR	BIOTEL CARE KIT SYSTEM
INFINITY KIT SYSTEM	MEIJER BGM KIT PREMIUM	BIOTEL CARE KIT
EASYPRO KIT MONITOR	FORA V30A KIT	FREESTYLE KIT SIDEKICK
EASYPRO PLUS KIT	FORA TN'G KIT VOICE	FREESTYLE KIT FREEDOM
PRODIGY PCKT KIT METER	REFUAH PLUS KIT SYSTEM	KROGER BGM KIT PREMIUM
PRODIGY AUTO KIT MONITOR	KROGER BGM KIT	CONTOUR KIT LINK 2.4

PRODIGY VOIC KIT METER		
PRODIGY KIT NO CODIN		

3 . Revision History

Date	Notes
7/12/2021	New Program

Prior Authorization Guideline

GL-99436 Bonjesta and Diclegis

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Bonjesta, Brand Diclegis, generic doxylamine/pyridoxine	
Diagnosis	Nausea and vomiting associated with pregnancy
Approval Length	9 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of nausea and vomiting associated with pregnancy	

AND

2 - Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

AND

3 - Documented trial and failure or contraindication to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly)

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Ariz ona Medicaid

Prior Authorization Guideline

GL-99736 Bosulif

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Bosulif	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient must have a diagnosis of chronic myeloid leukemia	

AND

2 - One of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Bosulif therapy

Product Name: Bosulif	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

Product Name: Bosulif	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of ABL1 (gene) rearrangement

Product Name: Bosulif	
Diagnosis	Chronic Myeloid Leukemia, Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Bosulif therapy

Product Name: Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Bosulif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bosulif therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99737 Braftovi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Braftovi	
Diagnosis	Unresectable melanoma or Metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient must have ONE of the following diagnoses:

- Unresectable melanoma

- Metastatic melanoma

AND

2 - Patient is positive for BRAF V600 mutation

AND

3 - Braftovi will be used in combination with Mektovi (binimetinib)

AND

4 - ONE of the following:

4.1 Patient has a contraindication or history of intolerance to ONE of the following regimens: (Drug may require PA)

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens: (Drug may require PA)

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.3 For continuation of prior Braftovi therapy

Notes	(Drug may require PA)

Product Name: Braftovi	
Diagnosis	Unresectable melanoma or Metastatic melanoma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Braftovi is used in combination with Mektovi (binimetinib)

Product Name: Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of colon cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - Patient has received prior therapy

AND

5 - Braftovi will be used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

Product Name: Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of rectal cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - Patient has received prior therapy

AND

5 - Braftovi will be used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

Product Name: Braftovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Braftovi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Braftovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Braftovi therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99590 Brand Over Generic Not Covered

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic products on a brand* over generic program	
Guideline Type	Administrative
Approval Criteria **1** - Requests for a generic product on a brand over generic program (presence of Brand over generic-Not Covered clinical program in formulary lookup) shall be denied. The plan's preferred product is the brand medication.	
Notes	* Brand product may require prior authorization.

2 . Revision History

Date	Notes
10/29/2021	Changed effective date to 12/1/21

Prior Authorization Guideline

GL-99572 Brand Vascepa, Generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Vascepa, Generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for brand Vascepa, generic Icosapent Ethyl, Brand Lovaza, generic omega-3-acid ethyl esters should be denied. The plan's preferred products are generic over-the-counter omega 3 fatty acids.	

2 . Revision History

Date	Notes
7/14/2021	New Policy

Prior Authorization Guideline

GL-99541 Breast Cancer - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Arimidex, generic anastrozole	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with hormone receptor-positive early breast cancer

OR

1.2 First-line treatment of postmenopausal patients with hormone receptor-positive or hormone receptor status unknown locally advanced or metastatic breast cancer

OR

1.3 Postmenopausal patients with disease progression following tamoxifen therapy

Product Name: Brand Aromasin, generic exemestane	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Adjuvant treatment of postmenopausal patients with estrogen receptor-positive early breast cancer who have received 2 to 3 years of tamoxifen and are switched to exemestane for completion of a total of 5 consecutive years of adjuvant hormonal therapy

OR

1.2 Treatment of advanced breast cancer in postmenopausal patients whose disease has progressed following tamoxifen therapy

Product Name: Brand Fareston, generic toremifene	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of metastatic breast cancer in postmenopausal patients with estrogen receptor positive tumors or with tumors of unknown estrogen receptor status

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Brand Arimidex, generic anastrozole, Brand Aromasin, generic exemestane, Brand Fareston, generic toremifene	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99564 Breo Ellipta

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Breo Ellipta	
Diagnosis	Asthma, COPD
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of asthma

AND

1.2 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

OR

2 - All of the following:

2.1 Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2.2 One of the following:

2.2.1 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza)

OR

2.2.2 History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/long-acting beta-agonist combination agent (e.g. Anoro Ellipta, Stiolto Respimat)

AND

2.3 The patient has a history of failure, contraindication, or intolerance to treatment with ALL of the following preferred products:

- Advair Diskus (brand) or Advair HFA
- Dulera
- Symbicort

Prior Authorization Guideline

GL-99561 Brilinta and Effient

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Brilinta, Brand Effient, Generic prasurgrel	
Diagnosis	Acute coronary syndrome (ACS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST	

elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

AND

2 - If request is for Effient (prasugrel), patient must be managed with percutaneous coronary intervention (PCI)

Prior Authorization Guideline

GL-99676 Brukinsa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brukinsa	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of mantle cell lymphoma (MCL)	

AND

2 - Patient has received at least one prior therapy for MCL

Product Name: Brukinsa	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Product Name: Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Brukinsa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Brukinsa therapy

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99600 Buphenyl

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Buphenyl oral powder, generic sodium phenylbutyrate oral powder	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs)	

Product Name: Brand Buphenyl tablets, generic sodium phenylbutyrate tablets

Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urea cycle disorders (UCDs)

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use Buphenyl (sodium phenylbutyrate) powder for oral solution

Product Name: Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99576 Buprenorphine Sublingual Tablet

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Buprenorphine Sublingual Tablet	
Approval Length	6 Months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of opioid abuse/dependence.

AND

2 - Prescriber attests they meet the DATA 2000 (Drug Addiction Treatment Act of 2000) requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X).

AND

3 - One of the following:

3.1 Patient is pregnant or breastfeeding;*

OR

3.2 Both of the following:

3.2.1 Patient had an intolerance or side effect to buprenorphine-naloxone sublingual tablet or film;

AND

3.2.2 Side effects or intolerances to buprenorphine-naloxone sublingual tablet or films were not resolved with a trial of anti-emetics (e.g. ondansetron) or non-opioid analgesics.

OR

3.3 Patient has a contraindication to naloxone.

OR

3.4 Both of the following:

3.4.1 Patient has a severe allergy to naloxone [e.g., Stevens-Johnson syndrome, DRESS (Drug Rash with Eosinophilia and Systemic Symptoms)];

AND

3.4.2 Provider has submitted a copy of the MedWatch Form 3500 to the Food and Drug Administration documenting the adverse reaction

AND

4 - Patient is not currently on ANY of the following:

- Benzodiazepines (e.g. Alprazolam, Diazepam, Lorazepam)
- Hypnotics (e.g. Temazepam, Rozerem, Zolpidem)
- Opioids (e.g. Oxycodone, Tramadol, Hydrocodone)

AND

5 - Prescriber attests that the Arizona State Board of Pharmacy Controlled Substance Prescription Drug Monitoring Program database has been reviewed and that patient has been warned about the dangers of ingesting concurrent sedating medications

Notes	*Approve for 1 year if pregnant or breastfeeding

Prior Authorization Guideline

GL-99601 Cablivi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)	

AND

2 - Cablivi was initiated in the inpatient setting in combination with plasma exchange therapy

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Product Name: Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99738 Cabometyx

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced renal cell carcinoma	

Product Name: Cabometyx	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

2.1 History of failure or intolerance to Nexavar (sorafenib) (Drug may require PA)

OR

2.2 Patient has metastatic disease

OR

2.3 Patient has extensive liver tumor burden

OR

2.4 Patient is inoperable by performance status or comorbidity, or has local disease or local disease with minimal extrahepatic disease only

OR

2.5 BOTH of the following:

- Patient is not a transplant candidate
- Disease is unresectable

Notes	(Drug may require PA)

Product Name: Cabometyx	
Diagnosis	Renal Cell Carcinoma, Non-small cell lung cancer (NSCLC), Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Product Name: Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Cabometyx will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cabometyx therapy

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99531 Calcium/Vitamin D

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin D deficiency	
Notes	Calcium carbonate and calcium lactate are covered without the need f or prior authorization.

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Prior Authorization Guideline

GL-99739 Calquence

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Calquence	
Diagnosis	Mantle cell lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of mantle cell lymphoma (MCL)	

AND **2** - Patient has received at least one prior therapy for MCL [e.g., Rituxan (rituximab)] (Drug may require PA)
Notes | Drug may require PA*

Product Name: Calquence	
Diagnosis	Mantle cell lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Calquence therapy	

Product Name: Calquence	
Diagnosis	Chronic lymphocytic leukemia/small lymphocytic lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma	

Product Name: Calquence	
Diagnosis	Chronic lymphocytic leukemia/small lymphocytic lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Calquence therapy

Product Name: Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Calquence therapy

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99678 Caprelsa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of medullary thyroid cancer (MTC)	

AND

2 - ONE of the following:

- Unresectable locally advanced disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

Product Name: Caprelsa	
Diagnosis	Medullary thyroid cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

2 - One of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

3 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

Product Name: Caprelsa	
Diagnosis	Follicular carcinoma, Hürthle cell carcinoma, Papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Non-Small Cell Lung Cancer (NSCLC)

AND

2 - Disease is positive for RET gene rearrangement

Product Name: Caprelsa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Caprelsa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-104872 Carbaglu (carglumic acid)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	3 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency	

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)

AND

3 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g. intravenous glucose, insulin, protein restriction, dialysis)

AND

3 - Patient's plasma ammonia level is greater than or equal to 50 micromol/L

AND

4 - Medication will be used for a maximum duration of 7 days

AND

5 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - NAGS deficiency has been confirmed by genetic/mutational analysis

AND

3 - Medication will be used as maintenance therapy

AND

4 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

Product Name: Brand Carbaglu, Generic carglumic acid

Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy (e.g., plasma ammonia level within the normal range)

2 . Revision History

Date	Notes
3/31/2022	New program for Carbaglu, mirrors ORx LOB. Added submission of MR to each section.

Prior Authorization Guideline

GL-107416 Carvykti (ciltacabtagene autoleucel)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/25/2022

1 . Criteria

Product Name: Carvykti	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of multiple myeloma

AND

1.2 Disease is one of the following:

- Relapsed
- Refractory

AND

1.3 Patient has received at least four prior lines of therapy

AND

1.4 Disease is refractory to all of the following:

- A proteasome inhibitor (e.g., bortezomib, carfilzomib)
- An immunomodulatory agent (e.g., lenalidomide, thalidomide)
- An anti-CD38 monoclonal antibody (e.g., daratumumab)

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist

Product Name: Carvykti	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Carvykti will be approved for uses supported by The National Comprehensive Cancer

Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

2 . Revision History

Date	Notes
5/23/2022	New Program

Cayston

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99603 Cayston

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cayston	
Diagnosis	Cystic Fibrosis (CF)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99517 CGRP - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ajovy, Emgality 120mg	
Diagnosis	Episodic Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic migraines with BOTH of the following:

- Less than 15 headache days per month

- Patient has 4 to 14 migraine days per month

AND

2 - Trial and failure (after a trial of at least two months), contraindication, or intolerance to TWO of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)*
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol*
- Divalproex sodium [Depakote/Depakote ER (extended-release)]*
- Topiramate (Topamax)*
- Venlafaxine [Effexor/Effexor XR (extended-release)*]

AND

3 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor [e.g. Aimovig, Vyepti (eptinezumab-jjmr)]

Notes	*Drug may require PA

Product Name: Aimovig	
Diagnosis	Episodic Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic migraines with BOTH of the following:

- Less than 15 headache days per month
- Patient has 4 to 14 migraine days per month

AND

2 - Trial and failure (after a trial of at least two months), contraindication, or intolerance to TWO of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)*
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol*
- Divalproex sodium [Depakote/Depakote ER (extended-release)]*
- Topiramate (Topamax)*
- Venlafaxine [Effexor/Effexor XR (extended-release)]*

AND

3 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g. Ajovy, Emgality, Vyepti)

AND

4 - The patient has a history of failure, contraindication, or intolerance to BOTH of the following (document date tried):

- Ajovy*
- Emgality 120 milligrams*

Notes	*Drug may require PA

Product Name: Aimovig, Ajovy, Emgality 120mg	
Diagnosis	Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g. Vyepti)

Product Name: Ajovy or Emgality 120mg	
Diagnosis	Chronic Migraine
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic migraines with BOTH of the following:

- Greater than or equal to 15 headache days per month
- Greater than or equal to 8 migraine days per month

AND

2 - Trial and failure (after a trial of at least two months), contraindication, or intolerance to TWO of the following prophylactic therapies from the list below:

- Amitriptyline (Elavil)*
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol *
- Divalproex sodium [Depakote/Depakote ER (extended-release)*]
- Topiramate (Topamax)*
- Venlafaxine [Effexor/Effexor XR (extended-release)*]

AND

3 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor

Notes	*Drug may require PA

Product Name: Aimovig	
Diagnosis	Chronic Migraine

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic migraines with BOTH of the following:

- Greater than or equal to 15 headache days per month
- Greater than or equal to 8 migraine days per month

AND

2 - Trial and failure (after a trial of at least two months), contraindication, or intolerance to TWO of the following prophylactic therapies from the list below (document name and date tried): prophylactic therapies from the list below:

- Amitriptyline (Elavil)*
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol*
- Divalproex sodium [Depakote/Depakote ER (extended-release)]*
- OnabotulinumtoxinA (Botox)*
- Topiramate (Topamax)*
- Venlafaxine [Effexor/Effexor XR (extended-release)]*

AND

3 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g., Ajovy Emgality, Vyepti)

AND

4 - The patient has a history of failure, contraindication, or intolerance to BOTH of the following (document date tried):

- Ajovy*
- Emgality 120 milligrams*

Notes	*Drug may require PA

Product Name: Aimovig, Ajovy, or Emgality 120mg	
Diagnosis	Chronic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g., Vyepti)

Product Name: Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

AND

3 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g., Aimovig, Ajovy, Vyepti)

Product Name: Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will NOT be used in combination with another biologic CGRP (calcitonin gene-related peptide) antagonist or inhibitor (e.g., Aimovig, Ajovy, Vyepti)

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Cholbam

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99700 Cholbam

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cholbam	
Diagnosis	Bile Acid Synthesis Disorder
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of a bile acid synthesis disorder	

AND

2 - It is due to single enzyme defects

Product Name: Cholbam	
Diagnosis	Peroxisomal Disorders Including Zellweger Spectrum Disorders
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of peroxisomal disorders including Zellweger spectrum disorders

AND

2 - Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

AND

3 - It is being used as adjunctive treatment

Product Name: Cholbam	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy

2 . Revision History

Date	Notes
4/10/2021	7/1 Implementation

Prior Authorization Guideline

GL-105174 Cialis for BPH - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Cialis 5mg, generic tadalafil 5mg	
Diagnosis	Benign Prostatic Hyperplasia (BPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 The patient has a diagnosis of benign prostatic hyperplasia (BPH)

AND

1.2 History of failure, intolerance, or contraindication to BOTH of the following:

- Alpha Blockers (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

AND

1.3 Dose does not exceed 5 milligrams once daily

AND

2 - Provider attests that patient is not using any form of organic nitrate (for example, nitroglycerin, isosorbide dinitrate, isosorbide mononitrate or amyl nitrate) or Adempas

2 . Revision History

Date	Notes
3/24/2022	Added physician attestation re: patient not using nitrates

Prior Authorization Guideline

GL-104977 Cibinqo (abrocitinib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Cibinqo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of moderate to severe atopic dermatitis	

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

4 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream*
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment*

AND

5 - One of the following:

5.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

5.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)

- Dupixent (dupilumab)

AND

6 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

Notes	*Product may require step therapy

Product Name: Cibinqo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with biologic immunomodulators (e.g., Dupixent, Adbry) or other immunosuppressants (e.g., azathioprine, cyclosporine)

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)

Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
	Hydrocortisone butyrate	Cream, ointment, solution	0.1

Hydrocortisone probutate	Cream	0.1

Lower-medium potency	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

4 . Revision History

Date	Notes
3/22/2022	New Program mirrors ORx with Submission of Records added to initi al and reauth

Prior Authorization Guideline

GL-99712 Cimzia- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cimzia	
Diagnosis	Crohn’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderately to severely active Crohn's disease

AND

1.1.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to Humira (adalimumab)

AND

1.1.5 Prescribed by or in consultation with a gastroenterologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of Crohn's disease

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.1.2 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of moderately to severely active RA

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs; e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cimzia

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure of a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying antirheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilsat)

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cimzia therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

• Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)] **AND** **1.2.4** Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND

2 - Patient is NOT receiving Cimzia in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes

5/19/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99662 Cinryze

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cinryze	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and one of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - Prescribed for the prophylaxis of HAE attacks

AND

3 - Not used in combination with other approved C1 esterase inhibitors indicated for prophylaxis against HAE attacks (e.g., Haegarda)

AND

4 - Prescriber attests that the patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze

AND

5 - ONE of the following:

5.1 Submission of medical records documenting a history of failure, contraindication, or intolerance to Haegarda (C1 esterase inhibitor, human)

OR

5.2 Patient is currently on Cinryze therapy

AND

6 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name: Cinryze	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response, defined as a clinically significant reduction in the rate and/or number of HAE attacks, while on Cinryze therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Cinryze therapy

AND

3 - Prescribed for the prophylaxis of HAE attacks

AND

4 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Haegarda, Takhzyro)

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona Medicaid SP to Medicaid Arizona SP for eff 7 /1

Prior Authorization Guideline

GL-99518 CMV and Herpes Virus Agents- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Valcyte tabs/oral soln, generic valganciclovir tabs/oral soln, Brand Cytovene inj, generic ganciclovir inj, Foscavir inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Cytomegalovirus (CMV) disease prophylaxis

OR

1.2 Cytomegalovirus (CMV) retinitis

OR

1.3 Cytomegalovirus (CMV) retinitis prophylaxis

OR

1.4 BOTH of the following:

1.4.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.4.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: cidofovir inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Cytomegalovirus (CMV) retinitis

OR

1.2 Cytomegalovirus (CMV) retinitis prophylaxis

OR

1.3 BOTH of the following:

1.3.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.3.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: famciclovir tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Herpes genitalis

OR

1.2 Herpes genitalis prophylaxis

OR

1.3 Herpes labialis

OR

1.4 Herpes simplex virus infection

OR

1.5 Herpes zoster (shingles) infection

OR

1.6 BOTH of the following:

1.6.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.6.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

Product Name: Brand Valtrex tabs, generic valacyclovir tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used for ONE of the following:

1.1 Herpes genitalis

OR

1.2 Herpes genitalis prophylaxis

OR

1.3 Herpes labialis

OR

1.4 Herpes simplex virus infection

OR

1.5 Herpes zoster (shingles) infection

OR

1.6 Varicella (chicken pox) infection

OR

1.7 BOTH of the following

1.7.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.7.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99802 Colony Stimulating Factors - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Neupogen, Nivestym	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Leukine, Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neupogen, Nivestym	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed either induction or consolidation chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Zarxio, Leukine	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed either induction or consolidation chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Fulphila, Udenyca, Neupogen, Nivestym, Nyvepria	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy –Dose Dense Chemotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Leukine, Zarxio	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy –Dose Dense Chemotherapy
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neulasta, Neulasta Onpro, Ziextenzo	
Diagnosis	Neutropenia Associated with Cancer Chemotherapy –Dose Dense Chemotherapy

Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of febrile neutropenia (FN) is unknown

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Fulphila, Udenyca, and Nyvepria

Product Name: Fulphila, Udenyca, Neupogen, Nivestym, Nyvepria	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Granix,Zarxio	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neulasta, Neulasta Onpro, Ziextenzo	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20 percent incidence of febrile neutropenia (FN)

OR

1.2 BOTH of the following:

- Patient is receiving chemotherapy regimen(s) associated with 10-20 percent incidence of FN
- Patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Fulphila,Udenyca, and Nyvepria

Product Name: Fulphila, Udenyca, Neupogen, Nivestym, Nyvepria	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Granix,Zarxio	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Neupogen, Fulphila, Udenyca, Nivestym, Nyvepria *

Product Name: Neulasta, Neulasta Onpro, Ziextenzo	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Patient has a history of febrile neutropenia (FN) during a previous course of chemotherapy

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Fulphila,Udenyca, and Nyvepria

Product Name: Fulphila, Udenyca, Neupogen, Nyvepria, Nivestym	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Leukine, Zarxio	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Fulphila, Udenyca, Neupogen, Nivestym, Nyvepria*

Product Name: Neulasta, Neulasta Onpro, Ziextenzo	
Diagnosis	Treatment of Febrile Neutropenia (FN) (off-label)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive anti-cancer drugs associated with neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Diagnosis of febrile neutropenia (FN) and patient is considered high risk for infection-associated complications

AND

3 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Fulphila and Udenyca and Nyvepria

Product Name: Neupogen, Nivestym	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells per mm3)

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neupogen, Nivestym	
Diagnosis	HIV-Related Neutropenia (off-label)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV) infection

AND

2 - Patient has an absolute neutrophil count (ANC) less than or equal to 1,000 cells per mm3

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist
- Infectious disease specialist

Product Name: Leukine, Zarxio	
Diagnosis	HIV-Related Neutropenia (off-label)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV) infection

AND

2 - Patient has an absolute neutrophil count (ANC) less than or equal to 1,000 cells per mm3

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist
- Infectious disease specialist

AND

4 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neupogen, Nivestym	
Diagnosis	Hepatitis C Treatment Related Neutropenia (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Diagnosis of hepatitis C virus
- Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)
- Documentation of neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3) after dose reduction of Peg-Intron or Pegasys

OR

1.2 BOTH of the following:

1.2.1 Documentation of interferon-induced neutropenia (ANC less than or equal to 500 cells per mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 ONE of the following:

- Diagnosis of human immunodeficiency virus (HIV) co-infection
- Status post liver transplant
- Diagnosis of established cirrhosis

AND

2 - Prescribed by, or in consultation with, a hematologist, oncologist, gastroenterologist, hepatologist, or infectious disease specialist

Product Name: Zarxio	
Diagnosis	Hepatitis C Treatment Related Neutropenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

- Diagnosis of hepatitis C virus
- Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)
- Documentation of neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells per mm3) after dose reduction of Peg-Intron or Pegasys

OR

1.2 BOTH of the following:

1.2.1 Documentation of interferon-induced neutropenia (ANC less than or equal to 500 cells per mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 ONE of the following:

- Diagnosis of human immunodeficiency virus (HIV) co-infection
- Status post liver transplant
- Diagnosis of established cirrhosis

AND

2 - Prescribed by, or in consultation with, a hematologist, oncologist, gastroenterologist, hepatologist, or infectious disease specialist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neupogen, Fulphila, Udenyca, Nivestym, Nyverpria	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

Product Name: Leukine, Zarxio	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Neupogen and Nivestym

Product Name: Neulasta, Neulasta Onpro, Ziextenzo	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by, or in consultation with, a hematologist or oncologist

AND

3 - Patient has a history of failure, contraindication, or intolerance to Fulphila, Udenyca, and Nyvepria

Prior Authorization Guideline

GL-99510 Combination Basal Insulin/GLP-1 Receptor Agonist

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Soliqua	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Inadequately controlled on BOTH of the following

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]

- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - Inadequately controlled on BOTH of the following

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

AND

3 - History of failure, intolerance, or contraindication to Soliqua

Product Name: Xultophy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xultophy therapy

2 . Revision History

Date	Notes
5/24/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99552 Combination DPP4-SGLT2- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Glyxambi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - History of failure, intolerance, or contraindication to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days

AND

3 - History and failure, intolerance, or contraindication to

- Janumet*
- Janumet XR*
- Januvia*
- Jentadueto*
- Kombiglyze XR*
- Onglyza*
- Tradjenta*
- Trijardy XR

Product Name: Qtern, Steglujan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - History of failure, intolerance, or contraindication to BOTH of the following:

- Metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days
- Glyxambi (empagliflozin/linagliptin)

AND

3 - History and failure, intolerance, or contraindication to

- Glyxambi*
- Janumet*

- Janumet XR*
- Januvia*
- Jentadueto*
- Kombiglyze XR*
- Onglyza*
- Tradjenta*
- Trijardy XR

2 . Revision History

Date	Notes
6/22/2021	update program

Prior Authorization Guideline

GL-99795 Cometriq

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of medullary carcinoma

OR

1.2 ALL of the following:

1.2.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.2.2 Clinical trials or other systemic therapies are not available or appropriate

AND

1.2.3 Disease is at least ONE of the following:

- Progressive
- Symptomatic iodine-refractory
- Unresectable locoregional recurrent or persistent disease
- Distant metastatic disease

Product Name: Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name: Cometriq

Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name: Cometriq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Cometriq will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Cometriq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cometriq therapy	

2 . Revision History

Date	Notes
6/14/2021	Updated GPI's

Prior Authorization Guideline

GL-99565 Compounds and Bulk Powders

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Requests for Compounds or Bulk Powders	
Approval Length	2 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 The compound is an antibiotic.

OR

1.2 Each active ingredient in the compounded drug is a covered medication

AND

2 - ONE of the following:

2.1 Each active ingredient in the compounded drug is to be administered for an FDA (Food and Drug Administration)-approved indication

OR

2.2 The use of each active ingredient in the compounded drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons.

AND

5 - ONE of the following:

5.1 A unique vehicle is required for topically administered compounds

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g. creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

OR

6.2 If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

AND

6.2.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.3 Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

OR

6.4 Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

2 . Background

Benefit/Coverage/Program Information

Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

(1) Ketamine

(2) Gabapentin

(3) Flurbiprofen (topical ophthalmic use not included)

(4) Ketoprofen

(5) Morphine

(6) Nabumetone

(7) Oxycodone

(8) Cyclobenzaprine

(9) Baclofen

(10) Tramadol

(11) Hydrocodone

(12) Meloxicam

(13) Amitriptyline

(14) Pentoxifylline

(15) Orphenadrine

(16) Piroxicam

(17) Levocetirizine

(18) Amantadine

(19) Oxytocin

(20) Sumatriptan

(21) Chorionic gonadotropin (human)

(22) Clomipramine

(23) Dexamethasone

(24) Hydromorphone

(25) Methadone

(26) Papaverine

(27) Mefenamic acid

(28) Promethazine

(29) Succimer DMSA

(30) Tizanidine

(31) Apomorphine

(32) Carbamazepine

(33) Ketorolac

(34) Dimercaptopropane-sulfonate

(35) Dimercaptosuccinic acid

(36) Duloxetine

(37) Fluoxetine

(38) Bromfenac (topical ophthalmic use not included)

(39) Nepafenac (topical ophthalmic use not included)

Table 2: Example compounds that contain ingredients for cosmetic purposes:

(1) Hydroquinone

(2) Acetyl hexapeptide-8

(3) Tocopheryl Acid Succinate

(4) PracaSil TM-Plus

(5) Chrysaderm Day Cream

(6) Chrysaderm Night Cream

(7) PCCA Spira-Wash

(8) Lipopen Ultra

(9) Versapro

(10) Fluticasone

(11) Mometasone

(12) Halobetasol

(13) Betamethasone

(14) Clobetasol

(15) Triamcinolone

(16) Minoxidil

(17) Tretinoin

(18) Dexamethasone

(19) Spironolactone

(20) Cycloserine

(21) Tamoxifen

(22) Sermorelin

(23) Mederma Cream

(24) PCCA Cosmetic HRT Base

(25) Sanare Scar Therapy Cream

(26) Scarcin Cream

(27) Apothederm

(28) Stera Cream

(29) Copasil

(30) Collagenase

(31) Arbutin Alpha

(32) Nourisil

(33) Freedom Cepapro

(34) Freedom Silomac Andydrous

(35) Retinaldehyde

(36) Apothederm

Table 3: Example ingredients on the FDA's Do Not Compound List:

(1) 3,3′,4′,5-tetrachlorosalicylanilide

(2) Adenosine phosphate

(3) Adrenal cortex

(4) Alatrofloxacin mesylate

(5) Aminopyrine

(6) Astemizole

(7) Azaribine

(8) Benoxaprofen

(9) Bithionol

(10) Camphorated oil

(11) Carbetapentane citrate

(12) Casein, iodinated

(13) Cerivastatin sodium

(14) Chlormadinone acetate

(15) Chloroform

(16) Cisapride

(17) Defenfluramine hydrochloride

(18) Diamthazole dihydrochloride

(19) Dibromsalan

(20) Dihydrostreptomycin sulfate

(21) Dipyrone

(22) Encainide hydrochloride

(23) Etretinate

(24) Fenfluramine hydrochloride

(25) Flosequinan

(26) Glycerol, iodinated

(27) Grepafloxacin

(28) Mepazine

(29) Metabromsalan

(30) Methapyrilene

(31) Methopholine

(32) Methoxyflurane

(33) Mibefradil dihydrochloride

(34) Nomifensine maleate

(35) Novobiocin sodium

(36) Oxyphenisatin acetate

(37) Oxyphenisatin

(38) Pemoline

(39) Pergolide mesylate

(40) Phenacetin

(41) Phenformin hydrochloride

(42) Phenylpropanolamine

(43) Pipamazine

(44) Potassium arsenite

(45) Propoxyphene

(46) Rapacuronium bromide

(47) Rofecoxib

(48) Sibutramine hydrochloride

(49) Sparteine sulfate

(50) Sulfadimethoxine

(51) Sweet spirits of nitre

(52) Tegaserod maleate

(53) Temafloxacin hydrochloride

(54) Terfenadine

(55) Ticrynafen

(56) Tribromsalan

(57) Trichloroethane

(58) Troglitazone

(59) Trovafloxacin mesylate:

(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

3 . Revision History

Date	Notes
7/7/2021	Update guideline

Prior Authorization Guideline

GL-107421 Constipation Agents - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/25/2022

1 . Criteria

Product Name: Amitiza, Brand lubiprostone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ONE of the following diagnoses:

- Opioid-induced constipation in an adult with chronic, non-cancer pain

- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
- Chronic idiopathic constipation

OR

1.2 Both of the following:

- Diagnosis of irritable bowel syndrome with constipation
- Patient was female at birth

AND

2 - BOTH of the following:

2.1 Trial and failure, contraindication, or intolerance to an osmotic laxative e.g., (lactulose, polyethylene glycol, sorbitol)

AND

2.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication or intolerance to ONE of the following:

- Amitiza
- Linzess
- Trulance

Product Name: Linzess	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

2 - Patient is greater than or equal to 18 years of age

AND

3 - Both of the following:

3.1 Trial and failure, contraindication, or intolerance to an osmotic laxative e.g., (lactulose, polyethylene glycol, sorbitol)

AND

3.2 Trial and failure, contraindication, or intolerance to ONE of the following:

- Bulk Forming Laxatives (e.g., psyllium, fiber)
- Stimulant Laxatives (e.g., bisacodyl, senna)

Product Name: Trulance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Chronic idiopathic constipation
- Irritable bowel syndrome with constipation

AND

2 - Patient is greater than or equal to 18 years of age

Product Name: Motegrity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic constipation

AND

2 - Both of the following

2.1 History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

2.2 History of failure, contraindication, or intolerance to BOTH of the following:

- Linzess
- Amitiza

Product Name: Movantik	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Product Name: Symproic	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Opioid-induced constipation in patients being treated for chronic, non-cancer pain
- Opioid-induced constipation in patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - History of failure, contraindication or intolerance to Movantik

Product Name: Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - Patient was female at birth

AND

3 - History of failure, contraindication or intolerance to BOTH of the following:

- Lactulose
- Polyethylene glycol (Miralax)

AND

4 - History of failure, contraindication or intolerance to ONE of the following:

- Amitiza
- Linzess
- Trulance

Product Name: Brand Amitiza, generic lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Symproic, Trulance, Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
5/23/2022	Added Ibsrela as target

Prior Authorization Guideline

GL-99740 Copiktra

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	

AND

2 - Disease is relapsed or refractory

AND

3 - History of failure, contraindication, or intolerance to at least TWO prior therapies for CLL/SLL [Examples include, but are not limited to, regimens consisting of: Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.]

Product Name: Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name: Copiktra	
Diagnosis	B-cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular lymphoma
- Gastric MALT (mucosa-associated lymphoid tissue) lymphoma

- Nodal marginal zone lymphoma
- Nongastric MALT lymphoma
- Splenic marginal zone lymphoma

AND

2 - Disease is relapsed or refractory

AND

3 - History of failure, contraindication, or intolerance to at least TWO prior systemic therapies [Examples include, but are not limited to, regimens consisting of: Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Rituxan (rituximab), Revlimid (lenalidomide), etc.]

Product Name: Copiktra	
Diagnosis	B-cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name: Copiktra	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Copiktra will be approved for uses supported by The National Comprehensive Cancer

Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Copiktra	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Copiktra therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99604 Copper Chelating Agents

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe active rheumatoid arthritis	

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Depen Titratabs therapy

Product Name: Brand Depen Titratab, generic penicillamine tablets	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)
- Diagnosis of Cystinuria

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Wilson's disease (i.e., hepatolenticular degeneration)
- Cystinuria

- Severe active rheumatoid arthritis

AND

2 - History of failure or intolerance to Depen (penicillamine)

Product Name: Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson’s disease (i.e., hepatolenticular degeneration), Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cuprimine (penicillamine) therapy

Product Name: Brand Syprine, generic trientine, generic Clovique	
Diagnosis	Wilson’s disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson’s disease (i.e., hepatolenticular degeneration)

AND

2 - History of failure, contraindication, or intolerance to Depen (penicillamine) or Cuprimine (penicillamine)

Product Name: Brand Syprine, generic trientine, generic Clovique

Diagnosis	Wilson’s disease (i.e., hepatolenticular degeneration)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Syprine (trientine) therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Corlanor

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99441 Corlanor

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Worsening heart failure in a diagnosis of stable, symptomatic chronic (e.g. New York Heart Association (NYHA) class II, III or IV) heart failure

AND

2 - Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

AND

3 - The patient is in sinus rhythm

AND

4 - Patient has a resting heart rate greater than or equal to 70 beats per minute

AND

5 - ONE of the following:

5.1 Patient is on maximum tolerated doses of beta blockers (e.g., carvedilol, metoprolol succinate, bisoprolol)

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

AND

2 - Patient is in sinus rhythm

AND

3 - Patient has an elevated heart rate

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure, Heart Failure due to Dilated Cardiomyopathy (DCM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Corlanor therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copy guidelines starting with B and C from C&S Arizona to Arizona Medicaid

Prior Authorization Guideline

GL-99664 Cosentyx - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 Both of the following:

1.1.3.1 History of failure to TWO of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

AND

1.1.4 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active ankylosing spondylitis

AND

1.1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis

AND

1.2.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)

AND

1.1.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist

- Dermatologist

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Cosentyx	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.1.4 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Cosentyx therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Cosentyx	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Patient is not receiving Cosentyx in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Taltz (ixekizumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99741 Cotellic

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of melanoma	

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Central Nervous System (CNS) Cancer

AND

2 - Primary disease (melanoma) is responsive to Cotellic therapy

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	Melanoma, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Product Name: Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Cotellic will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cotellic therapy.	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-104889 Cough and Cold Products

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/28/2022

1 . Criteria

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Under the Age of 18 Years for Cough and Cold Products
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescriber attests they are aware of Food and Drug Administration (FDA) labeled	

contraindications regarding use of opioid containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use)

AND

2 - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30)

AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Product Name: Hydromet, generic Tussigon, Z-Tuss AC, Tuzistra XR, Tussicaps, generic Tussionex, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss, generic promethazine w/codeine, generic promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP/Mar-Cof GG, Ninjacof-XG, Coditussin AC/Coditussin DAC, generic guaifenesin-codeine, generic pseudoephedrine w/codeine-guaifenesin, Tuxarin ER	
Diagnosis	Quantity Limit
Approval Length	30 Day(s)
Guideline Type	Quantity Limit*
Approval Criteria **1** - Prescriber attests that a larger quantity is medically necessary **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (See table in background section)	
Notes	*Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.

2 . Background

Benefit/Coverage/Program Information

CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Hydrocodone	None
Tapentadol	600mg IR products
Oxymorphone	None
Oxycodone	None
Codeine	360mg
Pentazocine	None
Tramadol	400mg IR products
Meperidine	600mg
Butorphanol nasal	None
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day
Acetaminophen	4g/day
Aspirin	2080mg/day
Ibuprofen	3200mg/day
Benzhydrocodone**	None

3 . Revision History

Date	Notes
3/28/2022	Updated product list, no changes to criteria.

Prior Authorization Guideline

GL-99735 Coverage of Off-Label Non-FDA Approved Indications

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits

- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehesive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

	2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
	2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
	3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the

	off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.	

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether

the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 9, 2020.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 9, 2020.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 9, 2020.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 9, 2020.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed September 9, 2020.

5 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99530 Coverage of Off-Label Non-FDA Approved Indications

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits

- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehesive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as su ch if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

	2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
	2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
	3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the

	off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.	

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether

the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed September 9, 2020.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed September 9, 2020.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed September 9, 2020.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed September 9, 2020.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed September 9, 2020.

5 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99663 Cystaran, Cystadrops

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cystaran, Cystadrops	
Diagnosis	Cystinosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona Medicaid SP to Medicaid Arizona SP for eff 7 /1

Prior Authorization Guideline

GL-99442 Daliresp

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Daliresp	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe to very severe chronic obstructive pulmonary disease (COPD) (i.e., FEV1 less than or equal to 50% of predicted)

AND

2 - COPD is associated with chronic bronchitis

AND

3 - History of COPD exacerbation(s)

Product Name: Daliresp	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Daliresp therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99605 Daraprim

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical record documentation (e.g. chart notes) of one of the following:

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary Pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of Pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 ONE of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm3 if initiating prophylaxis or CD4 100-200 cells per mm3 if reinstituting prophylaxis

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-

sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome)	
Notes	*Consider discontinuation of primary prophylaxis if CD4 greater than 2 00 cells/mm3 for greater than 3 months after institution of combination antiretroviral therapy.

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99742 Daurismo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

OR

1.2 Relapsed/refractory disease with ALL of the following:

1.2.1 Given as a component of repeating the initial successful induction regimen

AND

1.2.2 Late relapse (greater than or equal to 12 months since induction regimen)

AND

1.2.3 Initial therapy was not administered continuously

AND

1.2.4 Initial therapy was not stopped due to development of clinical resistance

AND

2 - Daurismo therapy to be given in combination with low-dose cytarabine

AND

3 - One of the following:

3.1 Patient is at least 75 years old

OR

3.2 Patient has significant comorbidities that preclude the use of intensive induction chemotherapy [e.g., severe cardiac disease, Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 2, baseline creatinine greater than 1.3 milligrams/deciliter]

Product Name: Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Daurismo therapy	

Product Name: Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Daurismo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Daurismo therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-105310 DDAVP (desmopressin) tablets - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand DDAVP tablets, generic desmopressin acetate tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of central diabetes insipidus

OR **1.2** Diagnosis of polyuria and/or polydipsia following head trauma or surgery in the pituitary region **OR** **1.3** Diagnosis of primary nocturnal enuresis **AND** **2** - For Brand DDAVP ONLY: Trial and failure to generic desmopressin tablets (verified via paid pharmacy claims or submission of medical records)

Notes	NOTE: Plan setup requires use of generic desmopressin tablets befor e Brand DDAVP

2 . Revision History

Date	Notes
3/29/2022	Added step through generic tablets for Brand.

Prior Authorization Guideline

GL-99559 Declomycin - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: demeclocycline*	
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of ONE of the following:

- Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers caused by rickettsiae
- Respiratory tract infections caused by Mycoplasma pneumoniae
- Lymphogranuloma venereum due to Chlamydia trachomatis

- Psittacosis (Ornithosis) due to Chlamydia psittaci
- Trachoma due to Chlamydia trachomatis
- Inclusion conjunctivitis caused by Chlamydia trachomatis
- Nongonococcal urethritis in adults caused by Ureaplasma urealyticum or Chlamydia trachomatis
- Relapsing fever due to Borrelia recurrentis
- Chancroid caused by Haemophilus ducreyi
- Plague due to Yersinia pestis
- Tularemia due to Francisella tularensis
- Cholera caused by Vibrio cholerae
- Campylobacter fetus infections cause by Campylobacter fetus
- Brucellosis due to Brucella species (in conjunction with streptomycin)
- Bartonellosis due to Bartonella bacilliformis
- Granuloma inguinale caused by Calymmatobacterium granulomatis
- Infection due to Escherichia coli
- Infection due to Enterobacter aerogenes
- Infection due to Shigella species
- Infection due to Acinetobacter species
- Respiratory tract infections caused by Haemophilus influenza
- Respiratory tract and urinary tract infections caused by Klebsiella species
- Upper respiratory infections caused by Streptococcus pneumoniae
- Skin and skin structure infections caused by Staphylococcus aureus.
- Uncomplicated urethritis in men due to Neisseria gonorrhoeae, and for the treatment of other uncomplicated gonococcal infections
- Infections in women caused by Neisseria gonorrhoeae
- Syphilis caused by Treponema pallidum subspecies pallidum
- Yaws caused by Treponema pallidum subspecies pertenue
- Listeriosis due to Listeria monocytogenes
- Anthrax due to Bacillus anthracis
- Vincent’s infection caused by Fusobacterium fusiforme
- Actinomycosis caused by Actinomyces israelii
- Clostridial diseases caused by Clostridium species
- Acute intestinal amebiasis, as adjunctive therapy
- Severe acne, as adjunctive therapy

OR

1.2 The medication is being prescribed by or in consultation with an Infectious Disease specialist

Notes	*Approval duration: 6 months

2 . Revision History

Date	Notes

6/23/2021	update program

Prior Authorization Guideline

GL-99526 Desonide Lotion

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Desonide Lotion	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following preferred products:

- fluocinolone acetonide
- fluticasone propionate
- hydrocortisone

- hydrocortisone acetate
- hydrocortisone-aloe vera
- mometasone furoate

2 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99444 Dificid

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Dificid	
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile- associated diarrhea]

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to Firvanq (vancomycin) oral solution

OR

2.2 History of failure, contraindication, or intolerance to oral Vancocin (vancomycin) capsules or vancomycin oral solution (NOT Firvanq) if the prescriber provides a reason or special circumstance the patient cannot use Firvanq

OR

2.3 For continuation of prior Dificid therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99445 Dofetilide - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: : Brand Tikosyn, generic dofetilide	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Atrial fibrillation
- Atrial flutter

AND

2 - Patient requires ONE of the following:

- Conversion to normal sinus rhythm
- Maintenance of normal sinus rhythm

AND

3 - Verification that the patient has already started on dofetilide while in the hospital for a minimum of 3 days

AND

4 - Patient does NOT have severe renal impairment [Creatinine Clearance (CrCl) less than 20 milliliters per minute]

AND

5 - Patient does NOT have congenital or acquired long QT syndromes

AND

6 - Patient is NOT concurrently using cimetidine, hydrochlorothiazide, ketoconazole, megestrol, prochlorperazine, trimethoprim, dolutegravir or verapamil

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99796 Doptelet - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Doptelet	
Diagnosis	Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of thrombocytopenia	

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - History of failure, contraindication, or intolerance to ALL the preferred alternatives*

- Eltrombopag Tablet (Promacta Tablet)
- Romiplostim (Nplate)

Notes	*Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. (Drugs may require PA)

Product Name: Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins

AND

2.1.2 History of failure, contraindication, or intolerance to the preferred alternatives *

- Eltrombopag Tablet (Promacta Tablet)
- Romiplostim (Nplate)

OR

2.2 Patient is currently on Doptelet therapy

Product Name: Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Doptelet therapy

Prior Authorization Guideline

GL-99558 DPP-4 Inhibitors - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tradjenta, Januvia, Onglyza, Kombiglyze XR, Jentadueto, Janumet, Janumet XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

Product Name: alogliptin, Nesina, alogliptin/metformin, Kazano, alogliptin/pioglitazone, Oseni, Jentadueto XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 History of failure to metformin at a minimum dose of 1500 milligrams daily for 90 days

OR

2.2 Contraindication or intolerance to metformin

AND

3 - ONE of the following:

3.1 History of failure for 90 days to three of the following:

- Tradjenta
- Januvia
- Onglyza

- Kombiglyze XR
- Janumet
- Janumet XR
- Jentadueto

OR

3.2 Intolerance or contraindication to THREE of the following:

- Tradjenta
- Januvia
- Onglyza
- Kombiglyze XR
- Janumet
- Janumet XR
- Jentadueto

AND

4 - If the request is for a combination product (e.g alogliptin/metformin, alogliptin/pioglitazone), the individual products have been tried and failed.

2 . Revision History

Date	Notes
6/22/2021	Updated guideline

Prior Authorization Guideline

GL-99582 Dry Eye Disease - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cequa, Xiidra	
Diagnosis	Tear deficiency associated with ocular inflammation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to ONE of the following:

- Moderate to severe keratoconjuctivitis sicca

- Moderate to severe Dry Eye Disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)

AND

3 - History of failure to at least three over-the-counter (OTC) artificial tear products (e.g.: Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP, Muro 128 2% Solution, Muro 128 5% Solution, Muro 128 5% Ointment) in the past 60 days as evidenced in the member's claim history.

AND

4 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

AND

5 - The patient has claims history indicating a minimum trial of 60 days of Restasis unless it is contraindicated.

Product Name: Cequa, Xiidra	
Diagnosis	Tear deficiency associated with ocular inflammation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated clinically significant improvement with therapy

2 . Revision History

Date	Notes
8/25/2021	Arizona Medicaid Implementation

Prior Authorization Guideline

GL-99563 Duexis and Vimovo - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Duexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer

- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE combinations of preferred NSAIDS taken with preferred H2 (histamine 2)-receptor antagonists. (Provide name and date preferred products were tried)*

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination.

Notes	*Please reference background section for preferred products table

Product Name: Brand Vimovo, generic naproxen-esomeprazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug) induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (eg, prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (eg, warfarin, heparin)
- Concurrent use of antiplatelets (eg, aspirin including low-dose, clopidogrel)

AND

2 - Documentation of history of failure, contraindication, or intolerance to THREE

combinations of preferred NSAIDS taken with preferred proton pump inhibitors (PPIs). (Provide name and date preferred products were tried)* **AND** **3** - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination.	
Notes	*Please reference background section for preferred products table

2 . Background

Benefit/Coverage/Program Information

Preferred Table

NSAIDS	Proton Pump Inhibitors (PPIs)	H2 (histamine 2)-receptor antagonists
Diclofenac DR (Generic Voltaren)	esomeprazole (Generic Nexium)	Famotidine (Generic Pepcid)
Diclofenac ER (Generic Voltaren ER)	lansoprazole (Generic Prevacid)	Nizatidine (Generic Axid)
Etodolac (Generic Lodine)	omeprazole (Generic Prilosec)	Ranitidine (Generic Zantac)
Etodolac ER (Generic Lodine ER)	pantoprazole sodium (Generic Protonix)	
Fenoprofen (Generic Nalfon)		
Flurbiprofen (Generic Ansaid)		
Ibuprofen		

Indomethacin (Generic Indocin)		
Ketorolac (Generic Toradol)		
Mefenamic (Generic Ponstel)		
Meloxicam (Generic Mobic)		
Nabumetone (Generic Relafen)		
Nabumetone DS (Generic Relafen DS)		
Naproxen (Generic Anaprox)		
Naproxen DR (Generic Anaprox DR)		
Naproxen EC (Generic Anaprox EC)		
Oxaprozin (Generic Daypro)		
Piroxicam (Generic Feldene)		
Sulindac (Generic Clinoril)		

Prior Authorization Guideline

GL-99446 Duopa

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced Parkinson's disease	

AND

2 - Patient is levodopa-responsive

AND

3 - Patient experiences disabling “off” periods for a minimum of 3 hours per day

AND

4 - Disabling “off" periods occur despite therapy with BOTH of the following:

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT [catechol-O-methyltransferase] inhibitor [entacapone, tolcapone], MAO-B [monoamine oxidase-B] inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Has undergone or has planned placement of a procedurally-placed tube

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Diagnosis	Parkinson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Duopa therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99713 Dupixent

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 6 years of age or older	

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of moderate to severe chronic atopic dermatitis

AND

2.1.2 History of failure, contraindication, or intolerance to the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- One medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] (see Table 1 in Background section)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

AND

2.2.2 History of failure, contraindication, or intolerance to BOTH of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)*

- Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] (see Table 1 in Background section)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

OR

2.3 Patient is currently on Dupixent therapy

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

4 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and/or contraindication to medication

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

AND

3 - Prescribed by one of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe asthma

AND

2 - Patient is 12 years of age or older

AND

3 - ONE of the following:

3.1 ALL of the following:

3.1.1 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following

- Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3.1.2 Dupixent will be used in combination with one of the following:

3.1.2.1 ONE high-dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)] (see Table 2 in Background section)

OR

3.1.2.2 Combination therapy including BOTH of the following:

3.1.2.2.1 ONE high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)] (see Table 2 in Background section)

AND

3.1.2.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

3.1.3 ONE of the following:

3.1.3.1 Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter within the past 6 weeks

OR

3.1.3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

OR

3.2 Patient is currently on Dupixent therapy

AND

4 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

5 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline

- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent is being used in combination with an inhaled corticosteroid (ICS)-containing controller medication (see Table 2 in Background section)

AND

3 - Patient is NOT receiving Dupixent in combination with ONE of the following:

- Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g. Xolair (omalizumab)]

AND

4 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

2.1.1.1 TWO or more of the following symptoms for greater than or equal to 12 weeks duration:

- Mucopurulent discharge
- Nasal obstruction and congestion
- Decreased or absent sense of smell
- Facial pressure or pain

AND

2.1.1.2 ONE of the following:

- Evidence of inflammation on paranasal sinus examination or computed tomography (CT)
- Evidence of purulence coming from paranasal sinuses or ostiomeatal complex

AND

2.1.1.3 The presence of nasal polyps

AND

2.1.2 ONE of the following:

- Patient has required prior sino-nasal surgery
- Patient has required systemic corticosteroids in the previous 2 years

AND

2.1.3 Patient has been unable to obtain symptom relief after trial of ALL of the following agents/classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)
- Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

OR

2.2 ALL of the following:

2.2.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2.2.2 Patient is currently on Dupixent therapy

AND

3 - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

4 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Prescribed by one of the following:

- Otolaryngologist
- Allergist
- Immunologist

Product Name: Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

AND

3 - Patient is NOT receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

4 - Prescribed by one of the following:

- Otolaryngologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information
Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	tridifloronide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1

Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids Adults and adolescents (12 years of age and older)

Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3 . Revision History

Date	Notes

6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99567 Durezol

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Durezol	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to BOTH of the following:

- prednisolone 1%
- dexamethasone ophthalmic drops and/or ointment.

2 . Revision History

Date	Notes
7/8/2021	Changed approval length to 2 months

Ecoza (econazole)

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99550 Ecoza (econazole)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Ecoza, Generic econazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- butenafine

- ciclopirox
- clotrimazole
- clotrimazole w/ betamethasone
- ketoconazole
- miconazole
- nystatin
- terbinafine
- tolnaftate

2 . Revision History

Date	Notes
6/10/2021	Update guideline

Egrifta

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99606 Egrifta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Egrifta SV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99607 Elaprase - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Elaprase	
Diagnosis	Hunter syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99447 Elidel-Protopic

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Elidel, generic pimecrolimus, Brand Protopic 0.03%, generic tacrolimus 0.03%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 2 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

Product Name: Brand Protopic 0.1%, generic tacrolimus 0.1%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 16 years of age or older

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid in the past 90 days

OR

2.2 Drug is being prescribed for the facial or groin area

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Elmiron

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99448 Elmiron

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Elmiron	
Diagnosis	Bladder pain or discomfort associated with interstitial cystitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99608 Emflaza - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Emflaza	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Duchenne muscular dystrophy	

AND

2 - Patient is 2 years of age or older

AND

3 - History of failure, contraindication, or intolerance to ONE of the following for the treatment of Duchenne muscular dystrophy:

- Prednisone
- Prednisolone

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Emflaza	
Diagnosis	Duchenne Muscular Dystrophy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician attestestation that the patient has had a positive clinical response to Emflaza therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99714 Enbrel

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderately to severely active Rheumatoid Arthritis (RA)	

AND

2 - History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel

Diagnosis	Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Active Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)

- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Moderate to Severe Chronic Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Ankylosing spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - History of failure to two non-steroidal anti-inflammatory drugs (NSAIDs: e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enbrel therapy

AND

2 - Patient is not receiving Enbrel in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Endari

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99450 Endari

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease

- Used to reduce acute complications of sickle cell disease

AND

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance

AND

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

Product Name: Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Endari therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99451 Entocort EC

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Entocort EC, generic budesonide	
Diagnosis	Chrohn's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Entocort EC is being used for the treatment of Crohn's disease	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99452 Entresto

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - As continuation of therapy initiated during an inpatient stay	

OR

2 - Both of the following:

2.1 Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

AND

2.2 Prescribed by or in consultation with a cardiologist

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 Ejection fraction is less than or equal to 40 percent

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 ONE of the following:

3.4.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following beta-blockers:

- bisoprolol
- carvedilol
- metoprolol

OR

3.4.2 Patient has a contraindication or intolerance to beta-blocker therapy

AND

3.5 Patient does not have a history of angioedema

AND

3.6 Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto*

AND

3.7 Patient is not concomitantly on aliskiren therapy

AND

3.8 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	*NOTE: ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto

Product Name: Entresto	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg (milligrams) /103 mg twice daily, or to a maximum dose as tolerated by the patient

AND

2 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99453 Epaned

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Epaned	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is less than 8 years of age

OR

1.2 BOTH of the following:

1.2.1 ONE of the following diagnoses:

- Hypertension
- Heart failure
- Asymptomatic left ventricular dysfunction, defined as left ventricular ejection fraction less than or equal to 35%

AND

1.2.2 ONE of the following:

1.2.2.1 History of failure, contraindication, or intolerance to TWO formulary oral anti-hypertensives (e.g., angiotensin-converting enzyme (ACE) inhibitor, ACE inhibitor combination, angiotensin-receptor blockers (ARB), ARB combination, thiazide diuretic)

OR

1.2.2.2 Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to ONE of the following:

- Oral/motor difficulties
- Dysphagia

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-108666 Epinephrine Pens

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Epinephrine Pens (Non-Mylan Manufacturer)	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - There is a shortage on Epinephrine Pens manufactured by Mylan.	
Notes	*Only approve other rebatable epinephrine autoinjectors if both the br anded EpiPen and authorized generic are on the FDA shortage list.

Product Name: Epinephrine Pens (Mylan Manufacturer)	
Approval Length	6 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Medication has been used or lost or the member is going on vacation.*	
Notes	Only approve other rebatable epinephrine autoinjectors if both the bra nded EpiPen and authorized generic are on the FDA shortage list

2 . Revision History

Date	Notes
6/23/2022	Updated guideline name as criteria is not specific to only non-mylan products

Prior Authorization Guideline

GL-99454 Eplerenone- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Inspra, generic eplerenone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Symptomatic heart failure with reduced ejection fraction (HFrEF) after an acute myocardial infarction

OR

1.2 Hypertension

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-108675 Epsolay (benzoyl peroxide) cream

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Epsolay	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rosacea

AND

2 - Patient has inflammatory lesions

AND

3 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance to one preferred topical product for rosacea (e.g., metronidazole cream/gel/lotion) (verified via paid pharmacy claims)

2 . Revision History

Date	Notes
6/24/2022	New Program

Prior Authorization Guideline

GL-99679 Erivedge

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Erivedge	
Diagnosis	Basal cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 ONE of the following:

- Cancer has recurred following surgery
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name: Erivedge	
Diagnosis	Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medulloblastoma

AND

2 - Patient has mutations in the sonic hedgehog pathway

AND

3 - Patient has failed prior chemotherapy

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma, Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erivedge therapy

Product Name: Erivedge	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Erivedge will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Erivedge	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erivedge therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99743 Erleada

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - One of the following:

2.1 Both of the following:

- Disease is castration-resistant or recurrent
- Disease is non-metastatic

OR

2.2 Both of the following:

- Disease is castration-sensitive or naïve
- Disease is metastatic

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name: Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erleada therapy

Product Name: Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Erleada will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erleada therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107211 Erythropoietic Agents - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/16/2022

1 . Criteria

Product Name: Aranesp, Epogen, Procrit, Mircera, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic kidney disease (CKD)	

AND

2 - Hematocrit is less than 30% at initiation of therapy

AND

3 - ONE of the following:

3.1 Patient is on dialysis

OR

3.2 ALL of the following:

3.2.1 Patient is NOT on dialysis

AND

3.2.2 The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

4 - If the request is for Aranesp, Mircera or Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

2 - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than 30% at initiation of therapy

AND

4 - If the request is for Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit less than 30% at initiation of therapy

AND

2 - There is a minimum of two additional months of planned chemotherapy

AND

3 - If the request is for Aranesp or Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Perioperative hematocrit is greater than 30% and less than or equal to 39%

AND

2 - Patient is at high risk for blood loss during surgery

AND

3 - Patient is unable or unwilling to donate autologous blood

AND

4 - Surgery procedure is elective, non-cardiac, and non-vascular

AND

5 - If the request is for Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease (MDS)

AND

2 - ONE of the following:

- Serum erythropoietin level less than or equal to 500 milliunits per milliliter
- Hematocrit is less than or equal to 30% at the initiation of therapy

AND

3 - If the request is for Aranesp or Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

AND

2 - If the request is for Aranesp or Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C virus (HCV) infection

AND

2 - Patient is receiving ribavirin and interferon therapy

AND

3 - Hematocrit is less than or equal to 30% at initiation of therapy

AND

4 - If the request is for Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Product Name: Epogen, Procrit, Retacrit*	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Hematocrit remains less than 36%

OR

1.2 Patient has demonstrated a response to therapy

AND

2 - If the request is for Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling

Notes	*NOTE: Authorization will be issued for 12 months or if patient has de monstrated response to therapy, authorization will be issued for the ful l course of ribavirin therapy.

Product Name: Aranesp, Epogen, Mircera, Procrit, Retacrit*	
Diagnosis	Erythropoietin Stimulating Agents –Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

AND

2 - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30% will not be approved

AND **3** - If the request is is for Aranesp, Mircera, or Procrit, claims history indicates either Epogen or Retacrit has been tried at maximum doses as indicated by FDA labeling	
Notes	*If the request is deemed medically necessary, the authorization will b e issued for requested length of therapy.

2 . Revision History

Date	Notes
5/16/2022	Added Epogen as preferred agent (Retacrit OOS from mfg).

Prior Authorization Guideline

GL-99609 Esbriet, Ofev

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Esbriet, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by ALL of the following criteria:

1.1 Exclusion of other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:

- ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

AND

1.2 ONE of the following:

1.2.1 In patients NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

Product Name: Esbriet or Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Esbriet or Ofev therapy

AND

2 - The agent is not being used in combination with Esbriet or Ofev

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis (SSc) - associated interstitial lung disease as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud’s phenomenon

- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on high-resolution computed tomography (HRCT), involving at least 10 percent of the lungs

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by BOTH of the following criteria:

1.1 Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10 percent of the lungs

AND

1.2 Patient is presenting with clinical signs of progression as defined by ONE of the following in the previous 24 months:

1.2.1 Forced vital capacity (FVC) decline of greater than 10 percent

OR

1.2.2 TWO of the following:

- FVC decline of greater than or equal to 5 percent, but less than 10 percent
- Patient is experiencing worsening respiratory symptoms
- Patient is exhibiting increasing extent of fibrotic changes on chest imaging

AND

2 - The agent is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease, Chronic fibrosing interstitial lung disease with a progressive phenotype
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ofev therapy

AND

2 - Ofev is not being used in combination with Esbriet

AND

3 - The prescriber is a pulmonologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99455 Estrogens- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Femring	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

OR

2 - Diagnosis of moderate to severe vulvar and vaginal atrophy due to menopause

Product Name: Premarin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of atrophic vaginitis and kraurosis vulvae	

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99540 Etoposide- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: etoposide	
Diagnosis	Small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of small cell lung cancer	

AND

2 - Used as first-line therapy with other approved chemotherapeutic agents

Product Name: etoposide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: etoposide	
Diagnosis	Small cell lung cancer, NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99456 Eucrisa

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Eucrisa	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - BOTH of the following:

1.1 History of failure, contraindication, or intolerance to ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide]

AND

1.2 ONE of the following:

1.2.1 Patient is less than 2 years of age

OR

1.2.2 Patient is greater than or equal to 2 years of age and has history of failure, contraindication, or intolerance to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99715 Evrysdi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of spinal muscular atrophy (SMA)	

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

2.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

5 - Physician attests that Evrysdi is not to be initiated in a patient less than 2 months of age

AND

6 - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

AND

7 - Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

8 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

9 - Prescribed by a neurologist with expertise in the treatment of SMA

Notes	*Baseline assessments for patients less than 2 months of age requesting Evrysdi proactively are not necessary in order not to delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy (SMA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

1.1 Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

1.1.1 Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline

OR

1.1.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

1.2.1 Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick

OR

1.2.2 Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

OR

1.2.3 The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)

OR

1.2.4 Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

1.3.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.3.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 Upper Limb Module (ULM) with ONE of the following:

1.4.1 Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline

OR

1.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:

1.5.1 Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline

OR

1.5.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

AND

3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)]

AND

5 - Patient has not previously received gene replacement therapy for the treatment of spinal muscular atrophy (SMA) [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

AND

6 - Prescribed by a neurologist with expertise in the treatment of SMA

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99457 Exondys- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Exondys	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Duchenne muscular dystrophy (DMD)	

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping

AND

3 - Patient is 7 years of age or older

AND

4 - Patient is ambulatory

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

7 - Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

Product Name: Exondys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has been on therapy for less than 12 months and all of the following:

1.1.1 Patient is maintaining ambulatory status

AND

1.1.2 Patient is tolerating therapy

AND

1.1.3 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.1.4 Prescribed by or in consultation with a neurologist who has experience treating children

AND

1.1.5 Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

OR

1.2 Patient has been on therapy for 12 months or more and all of the following:

1.2.1 Patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients)

AND

1.2.2 Patient is maintaining ambulatory status

AND

1.2.3 Patient is tolerating therapy

AND

1.2.4 Dose will not exceed 30 milligrams per kilogram of body weight once weekly

AND

1.2.5 Prescribed by or in consultation with a neurologist who has experience treating children

AND

1.2.6 Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided]

2 . Revision History

Date	Notes
3/10/2021	Bulk Copied C&S Arizona standard to Arizona Medicaid for 7/1 effect ive

Prior Authorization Guideline

GL-99610 Fabrazyme- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Fabrazyme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Fabry disease	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99744 Farydak

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Farydak	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

AND

2 - Used in combination with ONE of the following:

2.1 BOTH of the following:

- Velcade (bortezomib)
- Dexamethasone

OR

2.2 Kyprolis (carfilzomib)

OR

2.3 BOTH of the following:

- Revlimid (lenalidomide)
- Dexamethasone

AND

3 - Has received at least 2 prior treatment regimens which included BOTH of the following:

- Velcade (bortezomib)
- Immunomodulatory agent [e.g., Revlimid (lenalidomide), Thalomid (thalidomide)]

Product Name: Farydak	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Farydak therapy

Product Name: Farydak	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Farydak will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Farydak	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Farydak therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99716 Fasenra

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe asthma	

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting ONE of the following:

3.1 Asthma is an eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter within the past 6 weeks

OR

3.2 Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

AND

4 - Fasenra will be used in combination with ONE of the following:

4.1 One high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

4.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

5 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

6 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

Product Name: Fasenra Pen	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Fasenra in combination with one of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

4 - Prescribed by one of the following:

- Pulmonologist
- Allergist
- Immunologist

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99519 Fentanyl IR

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Fentanyl citrate lozenges (generic Actiq)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

Product Name: Abstral, Brand Actiq, Brand Fentora, generic fentanyl citrate buccal tablet, Lazanda, Subsys

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

AND

5 - History of failure, contraindication, or intolerance to Fentanyl citrate lozenges (generic Actiq) [Document date of trial]

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99458 Fexmid (cyclobenzaprine 7.5mg)- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Fexmid 7.5mg, generic cyclobenzaprine 7.5mg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of muscle spasm associated with acute, painful musculoskeletal conditions

AND

2 - Reason or special circumstance the patient cannot use cyclobenzaprine 5 milligram (mg) or 10mg tablet

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99611 Firazyr

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Firazyr, generic icatibant	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:	

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ruconest)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name: Brand Firazyr, generic icatibant	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

AND

2 - Prescribed for the acute treatment of hereditary angioedema (HAE) attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Ruconest)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-108661 Firdapse

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)	

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g.,Ampyra (dalfampridine), Ruzurgi (amiframpridine)]

Product Name: Firdapse	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Firdapse therapy

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g.,Ampyra (dalfampridine), Ruzurgi (amifampridine)]

2 . Revision History

Date	Notes
6/23/2022	Removed Ruzurgi as prerequisite

Prior Authorization Guideline

GL-99520 Flucytosine- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Ancobon, generic flucytosine	
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of septicemia, endocarditis or a urinary system infection caused by Candida species

OR

1.2 Diagnosis of meningitis or a pulmonary infection caused by Cryptococcus species

AND

2 - If the patient is being treated for a systemic infection, flucytosine is being used in combination with amphotericin B

Product Name: Brand Ancobon, generic flucytosine*	
Diagnosis	Infectious Diseases Society of America (IDSA) Recommended Regimens
Guideline Type	Prior Authorization
Approval Criteria **1** - The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Approval duration based on provider recommended treatment durations, up to 12 months.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99459 Fortamet, Glucophage XR, Glumetza - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Glucophage XR, generic metformin extended-release (generic for Fortamet and generic for Glumetza)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name: Brand Glumetza, Brand Fortamet	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR)

AND

1.2 ONE of the following:

1.2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.3 History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet)

AND

1.4 One of the following:

1.4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet), in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.5 History of greater than or equal to 12 week trial of metformin immediate-release

AND

1.6 One of the following:

1.6.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release, in diabetic patients, as evidenced by the hemoglobin A1c level being above the patient's goal

OR

1.6.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

1.7 Submission of article(s) published in the peer-reviewed medical literature showing that the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR)

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99790 Forteo-Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Forteo	
Diagnosis	Patients with Osteoporosis at High Risk for Fracture
Approval Length	24 months *
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of osteoporosis	

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ONE conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)**

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following:

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following FRAX 10-year probabilities:

- Major osteoporotic fracture at 20% or more
- Hip fracture at 3% or more

AND

2.3.3 History of failure, contraindication, or intolerance to one conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)**

AND

3 - Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Forteo, Tymlos) during the patient's lifetime

AND

4 - Prescriber attests to the following: the information provided is true and accurate to the best

of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided	
Notes	*Authorization will be issued for 24 months. Duration of coverage will be limited to 24 months of cumulative use of parathyroid hormone ana logs (e.g., Forteo, Tymlos) in the member's lifetime. **Note: Claims hi story may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Forteo	
Diagnosis	Glucocorticoid-Induced Osteoporosis at High Risk for Fracture
Approval Length	24 months *
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 milligrams per day for greater than or equal to 3 months

AND

3 - ONE of the following:

3.1 Bone Mineral Density (BMD) T-score less than or equal to -2.0 based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

OR

3.2 BOTH of the following:

3.2.1 BMD T-score between -1.0 and -2.0 (BMD T-score greater than -2.0 and less than or equal to -1.0) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). [Provider must submit patient specific BMD T-score]

AND

3.2.2 ONE of the following:

3.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.2.2.2 History of failure, contraindication, or intolerance to ONE conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)**

OR

3.2.3 BOTH of the following:

3.2.3.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3.2.3.2 History of failure, contraindication, or intolerance to one conventional osteoporosis therapy [e.g., bisphosphonate or selective estrogen receptor modulator (SERM)] (Document drug, date, and duration of trial)**

AND

4 - Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., Forteo, Tymlos) during the patient's lifetime **AND** **5** - Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided	
Notes	*Authorization will be issued for 24 months. Duration of coverage will be limited to 24 months of cumulative use of parathyroid hormone ana logs (e.g., Forteo, Tymlos) in the member's lifetime. **Note: Claims hi story may be used in conjunction as documentation of drug, date, and duration of trial

2 . Revision History

Date	Notes
6/10/2021	Update Guideline

Prior Authorization Guideline

GL-99613 Galafold

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Fabry disease	

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

Product Name: Galafold	
Diagnosis	Fabry disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Gattex

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99614 Gattex

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Gattex	
Diagnosis	Short Bowel Syndrome (SBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Short Bowel Syndrome (SBS)	

AND

2 - Dependent on parenteral support

Product Name: Gattex	
Diagnosis	Short Bowel Syndrome (SBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gattex therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99615 Gaucher's Disease Agents- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Cerdelga	
Diagnosis	Type 1 Gaucher’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Type 1 Gaucher’s disease	

AND

2 - Patient is one of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer,
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name: Cerezyme	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease that results in one or more of the following conditions:

- Anemia
- Thrombocytopenia
- Bone disease
- Hepatomegaly or splenomegaly

Product Name: Vpriv, Elelyso	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher's disease

Product Name: Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher's disease

AND

2 - If the request is for generic miglustat, there is a reason or special circumstance why the patient cannot use brand Zavesca

Product Name: Cerdelga, Cerezyme, Elelyso, Vpriv, Brand Zavesca, generic miglustat	
Diagnosis	Type 1 Gaucher's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99573 Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo)	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for Generic fluticasone-salmeterol diskus, Wixela Inhub (authorized generic of Advair Diskus), Airduo, fluticasone/salmeterol (authorized generic of Airduo) should be denied. The plan's preferred products are brand Advair Diskus, Advair HFA, Dulera, Symbicort.	

Prior Authorization Guideline

GL-99577 Generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for generic tretinoin cream and gel, generic Avita cream and gel, generic atralin gel should be denied. The plan's preferred product is Brand Retin-A cream or gel.*	
Notes	*Brand Retin-A cream or gel may require PA

2 . Revision History

Date	Notes
7/21/2021	7/1 Implementation

Prior Authorization Guideline

GL-99680 Gilotrif

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

- Squamous disease progressing after previous platinum-based chemotherapy
- Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations

Product Name: Gilotrif	
Diagnosis	Advanced Non-Nasopharyngeal Head and Neck Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, non-nasopharyngeal head and neck cancer

AND

2 - Disease has progressed on or after platinum-containing chemotherapy

Product Name: Gilotrif	
Diagnosis	Extensive Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastasis due to EGFR (epidermal growth factor receptor)-sensitizing mutation positive non-small cell lung cancer

AND

2 - Disease is one of the following:

- Recurrent
- Relapsed

Product Name: Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Advanced Non-Nasopharyngeal Head and Neck Cancer, Extensive Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gilotrif therapy

Product Name: Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Gilotrif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Gilotrif therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Gleevec - Arizona

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99805 Gleevec - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic imatinib	
Diagnosis	Chronic myelogenous or myeloid leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelogenous or myeloid leukemia (CML)	

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS) or Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic disease or myeloproliferative disease (MDS/MPD)

AND

2 - ONE of the following:

- Disease is associated with 5q31-33 (gene) translocations
- Disease is associated with platelet-derived growth factor receptor (PDGRF) beta gene re-arrangements

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - ONE of the following:

- Patient is without the D816V c-Kit (gene)mutation
- c-Kit mutational status unknown

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) / Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least ONE of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatofibrosarcoma protuberans (DFSP)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gastrointestinal stromal tumors (GIST)
- Desmoid tumors / aggressive fibromatosis
- Pigmented villonodular synovitis (PVNS) or tenosynovial giant cell tumor (TGCT)

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec

Product Name: Generic imatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma:

AND

2 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Patient has C-KIT (gene) mutation

AND

3 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Generic imatinib	
Diagnosis	AIDS-Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

AND

4 - History of failure, intolerance, or contraindication to Brand Gleevec.

Product Name: Brand Gleevec, generic imatinib

Diagnosis	Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is currently being treated with systemic corticosteroids

AND

3 - Patient had no response to first-line therapy options

AND

4 - If the request is for generic imatinib, there is a reason or special circumstance the patient cannot use brand Gleevec

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - One of the following:

- FIP1L1-PDGFRA rearrangement
- PDGFRB rearrangement
- ABL1 rearrangement

AND

3 - If the request is for generic imatinib, there is a reason or special circumstance the patient cannot use brand Gleevec

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	All Indications except NCCN
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gleevec therapy

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gleevec therapy

2 . Revision History

Date	Notes
7/21/2021	Updated Gpi

Prior Authorization Guideline

GL-99460 Global Quantity Limits

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is permitted

Product Name: Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-107456 GLP-1 Agonists - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Byetta, Victoza, Bydureon,Trulicity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

Product Name: Adlyxin, Bydureon BCise, Ozempic	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - History of a 90 day trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following:

- Byetta
- Victoza
- Trulicity

Product Name: Rybelsus	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Diagnosis of type 2 diabetes mellitus

AND

1.2 History of failure to metformin at a minimum dose of 1500 milligrams (mg) daily for 90 days, or contraindication or intolerance to metformin (verified via paid pharmacy claims or submission of medical records)

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 History of a 90 day trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the following:

- Byetta
- Victoza
- Trulicity

OR

2.2 BOTH of the following:

2.2.1 The patient is unable to self-inject due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

2.2.2 History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana
- Invokamet
- Synjardy
- Xigduo XR

2 . Revision History

Date	Notes
5/24/2022	Added new strength of Ozempic. Removed Bydureon as prereq. Add ed submission of medical records to all sections.

Prior Authorization Guideline

GL-108674 Glycopyrrolate Products

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Brand Cuvposa oral solution, Dartisla ODT, Brand Robinul, Brand Robinul Forte	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting requested drug is being used for a Food and Drug Administration (FDA)-approved indication	

AND

2 - Trial and failure or intolerance to generic glycopyrrolate tablets or oral solution (verified via pharmacy paid claims or submission of medical records/chart notes)

Product Name: Glycopyrrolate injection 0.6mg/3ml	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure or intolerance to preferred glycopyrrolate injection strengths (e.g., 0.2 mg/ml, 0.4mg/2ml, 1 mg/5ml, 4mg/20ml) (verified via pharmacy paid claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
6/24/2022	Added NP glycopyrrolate inj as target. Changed guideline name to Gl ycopyrrolate Products.

Prior Authorization Guideline

GL-99798 Gonadotropin-Releasing Hormone Agonists

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: leuprolide acetate, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of central precocious puberty (idiopathic or neurogenic)	

AND

2 - Onset of secondary sexual characteristics in one of the following:

2.1 Females less than or equal to 8 years of age

OR

2.2 Males less than or equal to 9 years of age

AND

3 - Confirmation of diagnosis as defined by one of the following:

3.1 Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)

OR

3.2 A pubertal luteinizing hormone response to a gonadotropin releasing hormone (GnRH) stimulation test

OR

3.3 Bone age advanced one year beyond the chronological age

AND

4 - If the request is for Triptodur or Fensolvi, history of failure, contraindication, or intolerance to Lupron-Depot Ped

Product Name: leuprolide acetate, Lupron Depot Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving therapy for central precocious puberty

AND

2 - Documentation of positive clinical response to therapy

AND

3 - Patient is ONE of the following (younger than the appropriate time point for the onset of puberty):

3.1 Female younger than 11 years of age

OR

3.2 Male younger than 12 years of age

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to both of the following:

2.1.1 Oral contraceptives or depot medroxyprogesterone (e.g., Depo- Provera)

AND

2.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.2 Patient has had surgical ablation to prevent recurrence

AND

3 - If the request is for Lupaneta Pack, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupaneta Pack, Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - Recurrence of symptoms following an initial course of therapy

AND

3 - Concurrently to be used with add-back therapy (e.g., progestin, estrogen, or bone sparing agents)

Product Name: Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Uterine Leiomyomata (Fibroids)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 For the treatment of uterine leiomyomata-related anemia

AND

1.1.2 Patient did not respond to iron therapy of 1 month duration

AND

1.1.3 For use prior to surgery

OR

1.2 For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi	
Diagnosis	Gender dysphoria in adolescents

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

3 - Patient has experienced puberty development to at least Tanner stage 2

AND

4 - One of the following laboratory tests, based upon the laboratory reference range, confirming:

- Pubertal levels of estradiol in females
- Pubertal levels of testosterone in males
- Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
- A pubertal luteinizing hormone response to a gonadotropin-releasing hormone (GnRH) stimulation test

AND

5 - A letter from the prescriber and/or formal documentation stating all of the following:

5.1 Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning

AND

5.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

5.3 Both of the following:

5.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

5.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

5.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

6 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi	
Diagnosis	Gender dysphoria in adolescents
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

4 - A letter from the prescriber and/or formal documentation stating all of the following:

4.1 Patient continues to meet their individual goals of therapy for gender dysphoria

AND

4.2 Patient continues to have a strong affinity for the desired (opposite of natal) gender

AND

4.3 Discontinuation of treatment and subsequent pubertal development would interfere with or impair psychological functioning and well-being

AND

4.4 Coexisting psychiatric and medical comorbidities or social problems that may interfere with treatment continue to be addressed or removed

AND

4.5 Both of the following:

4.5.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

4.5.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

4.6 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

3 - Gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing)

AND

4 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

5 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

6 - A letter from the prescriber and/or formal documentation stating all of the following:

6.1 Transgender patient has identified goals of gender-affirming hormone therapy

AND

6.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

6.3 Both of the following:

6.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

6.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

6.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

AND

7 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot

Product Name: Lupron Depot, Lupron Depot-Ped, Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Documentation (within the last 6 months) of appropriate luteinizing hormone (LH) suppression
- Change in dosing

AND

2 - Documented diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

3 - Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

4 - Gonads (i.e., testes, ovaries) are intact

AND

5 - Patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

6 - Inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

7 - A letter from the prescriber and/or formal documentation stating all of the following:

7.1 Transgender patient continues to meet goals of gender-affirming hormone therapy

AND

7.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment continue to be addressed or removed

AND

7.3 Both of the following:

7.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

7.3.2 Patient will continue enrollment, attendance and active participation in psychological and social support throughout the course of treatment

AND

7.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Product Name: Lupron Depot, Lupron Depot Ped, Lupaneta Pack, Triptodur, generic leuprolide acetate solution for injection, Fensolvi	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in pre-menopausal women

AND

2 - Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

AND

3 - If the request is for Lupaneta Pack, leuprolide acetate, Triptodur, Fensolvi, history of failure, contraindication, or intolerance to Lupron Depot.

Product Name: Lupron Depot, Lupron Depot Ped, Lupaneta Pack, Triptodur, generic leuprolide acetate solution for injection, Fensolvi	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy for the purpose of fertility preservation

AND

2 - Patient continues to receive a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name: Lupron Depot 7.5 mg, 22.5 mg, 30 mg and 45 mg, generic leuprolide acetate solution for injection	
Diagnosis	Advanced or Metastatic Prostate Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

2 . Revision History

Date	Notes
7/1/2021	Updated Guideline

Prior Authorization Guideline

GL-99461 Gralise, Horizant - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Gralise	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of postherpetic neuralgia (PHN)	

Product Name: Horizant	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of postherpetic neuralgia (PHN)

OR

1.2 Diagnosis of restless legs syndrome

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-105179 Growth Hormone, Growth Stimulating Agents - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: All products	
Diagnosis	Idiopathic Short Stature (ISS)
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for coverage for diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved	
Notes	Approval Length: N/A - Requests for Idiopathic Short Stature (ISS) sh ould not be approved. Deny as a benefit exclusion.

Product Name: Non Preferred* Humatrope, Nutropin AQ NuSpin, Omnitrope, Saizen, Saizen Click Easy, Zomacton, Zorbitive, Serostim*	
Approval Length	month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed the 2 preferred products listed below.

- Brand Genotropin/Genotropin Miniquick
- Brand Norditropin Flexpro

Notes	*The Patient must use one of the preferred products listed above. All Non preferred products will be denied for appeals process.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following:

1.1.1 All of the following:

- Infant is less than 4 months of age
- Infant has growth deficiency
- Prescribed by an endocrinologist

OR

1.1.2 BOTH of the following:

- History of neonatal hypoglycemia associated with pituitary disease
- Prescribed by an endocrinologist

OR

1.1.3 BOTH of the following:

- Diagnosis of panhypopituitarism
- Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric growth hormone (GH) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.2.3.1 BOTH of the following:

1.2.3.1.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

AND

1.2.3.1.2 BOTH GH response values are less than 10 micrograms per liter

OR

1.2.3.2 BOTH of the following:

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 ONE of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

1.2.4 ONE of the following:

1.2.4.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

1.2.4.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

1.2.5 Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:**

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:**

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

4.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

5 - ONE of the following:

5.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

5.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

6 - Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency. ** Documentation of previous height, current height and goa l expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome

AND

2 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 BOTH of the following:

1.1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

AND

1.1.2 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

1.2.3 Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small for gestational age (SGA) based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by documentation that ONE of the following is below the third percentile for gestational age (more than 2 standard deviations [SD] below population mean):

- Birth weight
- Birth length

AND

2 - Documentation that height remains less than or equal to the third percentile (more than 2 SD below population mean)

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with ONE of the following:

1.1 BOTH of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 BOTH of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 ONE of the following:

1.2.2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the fifth percentile on growth charts for age and gender

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)

Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 BOTH of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 BOTH of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has undergone ONE of the following GH (growth hormone) stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- Glucagon
- ARG

AND

2.1.2 ONE of the following peak GH values:

2.1.2.1 ITT less than or equal to 5 micrograms per liter

OR

2.1.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

2.1.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

2.1.2.4 ARG less than or equal to 0.4 micrograms per liter

OR

2.2 BOTH of the following:

2.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of THREE of the following anterior pituitary hormones:

- Prolactin
- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

2.2.2 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis and not used in combination with BOTH of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole),Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

5 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of Insulin-like Growth Factor 1 (IGF-1)/Somatomedin C level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis and not used in combination with BOTH of the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

4 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

2 - Documentation of ONE of the following:

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

3.1 BOTH of the following:

3.1.1 Documentation of high risk of growth hormone (GH) deficiency due to GH deficiency in childhood from ONE of the following:

3.1.1.1 Embryopathic/congenital defects

OR

3.1.1.2 Genetic mutations

OR

3.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

3.1.1.4 Panhypopituitarism

OR

3.1.1.5 Deficiency of THREE of the following anterior pituitary hormones:

- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- Prolactin
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

3.1.2 ONE of the following:

3.1.2.1 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

3.1.2.2 ALL of the following:

3.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

3.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

3.1.2.2.3 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- ARG
- Glucagon

AND

3.1.2.2.4 ONE of the following peak GH values:

3.1.2.2.4.1 ITT less than or equal to 5 micrograms per liter

OR

3.1.2.2.4.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.1.2.2.4.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.1.2.2.4.4 ARG less than or equal to 0.4 micrograms per liter

OR

3.2 ALL of the following:

3.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

3.2.2 Discontinued GH therapy for at least 1 month

AND

3.2.3 BOTH of the following:

3.2.3.1 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH and ARG
- ARG
- Glucagon

AND

3.2.3.2 ONE of the following peak GH values:

3.2.3.2.1 ITT less than or equal to 5 micrograms per liter

OR

3.2.3.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared

- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.2.3.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.2.3.2.4 ARG less than or equal to 0.4 micrograms per liter

AND

4 - Prescribed by an endocrinologist

Product Name: Preferred (Brand Genotropin/Genotropin Miniquick, Brand Norditropin Flexpro)	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 [Insulin-like Growth Factor 1] and IGFBP-3 [Insulin-like growth factor binding protein 3] levels)

AND

2 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

3 - Prescribed by an endocrinologist

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV)-associated wasting syndrome or cachexia

AND

2 - Documentation of ONE of the following:

2.1 Unintentional weight loss of greater than 10 percent over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5 percent over the last 6 months

OR

2.3 Loss of 5 percent body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kilograms per meter squared

OR

2.5 ONE of the following:

2.5.1 ALL of the following:

- Patient is male
- BCM less than 35 percent of total body weight
- BMI less than 27 kilograms per meter squared

OR

2.5.2 ALL of the following:

- Patient is female
- BCM less than 23 percent of total body weight
- BMI less than 27 kilograms per meter squared

AND

3 - A nutritional evaluation has been completed since onset of wasting first occurred

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes)

AND

5 - Patient's anti-retroviral therapy has been optimized to decrease the viral load

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2 percent increase in body weight and/or body cell mass [BCM])

AND

2 - ONE of the following targets or goals has not been achieved:

- Weight
- BCM
- Body Mass Index (BMI)

Product Name: Zorbtive*	
Diagnosis	Short Bowel Syndrome
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive*

Notes	*Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 Documentation of ALL of the following:

1.1.1 Diagnosis of severe primary Insulin-like Growth Factor 1 (IGF-1) deficiency

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone levels

AND

1.1.5 Documentation of open epiphyses on last bone radiograph

AND

1.1.6 The patient will not be treated with concurrent growth hormone therapy

AND

1.1.7 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

1.2.2 Documentation of open epiphyses on last bone radiograph

AND

1.2.3 The patient will not be treated with concurrent growth hormone therapy

AND

1.2.4 Prescribed by an endocrinologist

Product Name: Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not obtained
- Expected adult height goal

AND

3 - Patient is not treated with concurrent growth hormone therapy

AND

4 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

2 . Background

Benefit/Coverage/Program Information

Human Growth Hormone:

Preferred Agents:

Somatropin (Genotropin®, Genotropin Miniquick®, or Norditropin Flexpro®)

Nonpreferred Agents:

Somatropin (Humatrope®, Nutropin AQ Nuspin®, Omnitrope®, Saizen®, Serostim®, Zomacton®, and Zorbtive®)

Growth Stimulating Products :

Mecasermin (Increlex®)

Preferred and Non-Preferred Agents

Preferred		
GPI Number		**MSC**
30100020002121	GENOTROPIN INJ 5MG	N
30100020002134	GENOTROPIN INJ 12MG	N
30100020002166	GENOTROPIN MINIQUICK INJ 0.2MG	N
30100020002168	GENOTROPIN MINIQUICK INJ 0.4MG	N
30100020002170	GENOTROPIN MINIQUICK INJ 0.6MG	N
30100020002172	GENOTROPIN MINIQUICK INJ 0.8MG	N
30100020002174	GENOTROPIN MINIQUICK INJ 1MG	N
30100020002176	GENOTROPIN MINIQUICK INJ 1.2MG	N
30100020002178	GENOTROPIN MINIQUICK INJ 1.4MG	N
30100020002180	GENOTROPIN MINIQUICK INJ 1.6MG	N
30100020002182	GENOTROPIN MINIQUICK INJ 1.8MG	N
30100020002184	GENOTROPIN MINIQUICK INJ 2MG	N
3010002000D212	NORDITROPIN FLEXPRO 5MG	N
3010002000D230	NORDITROPIN FLEXPRO 10MG	N
3010002000D240	NORDITROPIN FLEXPRO 15MG	N

3010002000D260	NORDITROPIN FLEXPRO 30MG	N

Non-Preferred		
GPI Number	**Drug Name and Strength**	**Drug Name**
30100020002125	HUMATROPE INJ 6MG	HUMATROPE
30100020002132	HUMATROPE INJ 12MG	HUMATROPE
30100020002150	HUMATROPE INJ 24MG	HUMATROPE
30160045002020	MECASERMIN INJ 40 MG/4ML	INCRELEX
3010002000D220	NUTROPIN AQ INJ 10MG/2ML	NUTROPIN AQ NUSPIN 10
3010002000D250	NUTROPIN AQ INJ 20MG/2ML	NUTROPIN AQ NUSPIN 20
3010002000D207	NUTROPIN AQ INJ NUSPIN 5	NUTROPIN AQ NUSPIN 5
30100020002123	OMNITROPE INJ 5.8MG	OMNITROPE
3010002000E210	OMNITROPE INJ 5/1.5ML	OMNITROPE
3010002000E213	OMNITROPE INJ 10/1.5ML	OMNITROPE
30100020102120	SAIZEN INJ 5MG	SAIZEN
30100020102130	SAIZEN INJ 8.8MG	SAIZEN
30100020102130	SAIZENPREP INJ 8.8MG	SAIZENPREP RECONSTITUTIONKIT
30100020102118	SEROSTIM INJ 4MG	SEROSTIM
30100020102121	SEROSTIM INJ 5MG	SEROSTIM
30100020102125	SEROSTIM INJ 6MG	SEROSTIM
30100020002121	ZOMACTON INJ 5MG	ZOMACTON
30100020002140	ZOMACTON INJ 10MG	ZOMACTON
30100020102132	ZORBTIVE INJ 8.8MG	ZORBTIVE

3 . Revision History

Date	Notes
3/28/2022	Added ISS indication criterion, to be denied as benefit exclusion.

Prior Authorization Guideline

GL-99616 Haegarda - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Haegarda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and one of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - For prophylaxis against HAE attacks

AND

3 - Not used in combination with other approved C1 esterase inhibitors indicated for prophylaxis against HAE attacks (e.g. Cinryze)

AND

4 - Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Haegarda

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name: Haegarda	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response, defined as a clinically significant reduction in the rate and/or number of hereditary angioedema (HAE) attacks, while on Haegarda therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Haegarda therapy

AND

3 - Prescribed for the prophylaxis of HAE attacks

AND

4 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Takhzyro)

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99463 HCG

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Novarel, Ovidrel, Brand Pregnyl, generic chorionic gonadotropin	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99464 Hemangeol

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Hemangeol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of proliferating infantile hemangioma

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use generic propranolol oral solution

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99717 Hemlibra

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Hemlibra	
Diagnosis	Hemophilia A with Factor VIII Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hemophilia A	

AND

2 - Patient has factor VIII inhibitors

AND

3 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name: Hemlibra	
Diagnosis	Hemophilia A with Factor VIII Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

Product Name: Hemlibra	
Diagnosis	Hemophilia A without Factor VIII Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of severe hemophilia A

AND

1.1.2 Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (less than 0.01 international units per milliliter)

OR

1.2 BOTH of the following:

1.2.1 ONE of the following

1.2.1.1 BOTH of the following

1.2.1.1.1 Diagnosis of moderate hemophilia A

AND

1.2.1.1.2 Documentation of endogenous factor VIII level greater than or equal to 1% and less than 5% (greater than or equal to 0.01 international units per milliliter [IU/mL] to less than 0.05 IU/mL)

OR

1.2.1.2 BOTH of the following

1.2.1.2.1 Diagnosis of mild hemophilia A

AND

1.2.1.2.2 Documentation of endogenous factor VIII level greater than 5% (greater than or equal to 0.05 international units per milliliter)

AND

1.2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve

appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

OR

1.3 BOTH of the following:

1.3.1 Patient is currently on Hemlibra therapy

AND

1.3.2 Diagnosis of hemophilia A

AND

2 - Hemlibra is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

AND

3 - Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes

Product Name: Hemlibra	
Diagnosis	Hemophilia A without Factor VIII Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Hemlibra in combination with an extended half-life factor VIII replacement product (e.g., Eloctate, Adynovate, Afstyla, Jivi) for the treatment of breakthrough bleeding episodes. [Prescription claim history that does not show any concomitant extended half-life factor VIII replacement product claim within 60 days of reauthorization request may be used as documentation]

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99617 Hemophilia- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Eloctate, Adynovate, Afstyla, Idelvion, Alprolix, Tretten	
Diagnosis	Hemophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hemophilia	

AND

2 - Prescribing physician attests patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Kogenate FS, Kovaltry, Novoeight, or Nuwiq

AND

3 - One of the following:

3.1 Patient is not to receive routine infusions more frequently than 3 times per week

OR

3.2 Both of the following:

3.2.1 Patient is less than 12 years of age

AND

3.2.2 PK (pharmacokinetic) testing results suggest that more frequent than 3 times per week dosing is required

Product Name: Eloctate, Adynovate, Afstyla, Idelvion, Alprolix, Tretten	
Diagnosis	Hemophilia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient is not to receive routine infusions more frequently than 3 times per week

OR

2.2 Both of the following:

2.2.1 Patient is less than 12 years of age

AND

2.2.2 PK (pharmacokinetic) testing results suggest that more frequent than 3 times per week dosing is required

Product Name: Jivi	
Diagnosis	Hemophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Patient is 12 years of age or older

AND

3 - Patient has previously received Factor VIII replacement therapy

AND

4 - Prescribing physician attests patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [Kogenate FS, Kovaltry, Novoeight, or Nuwiq]

AND

5 - Patient is not to receive routine infusions more frequently than 2 times per week

Product Name: Jivi	
Diagnosis	Hemophilia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not to receive routine infusions more frequently than 2 times per week

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona SP to Medicaid Arizona SP for 7/1 eff

Prior Authorization Guideline

GL-99815 Hepatitis C - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Preferred: sofosbuvir-velpatasvir (authorized generic of Epclusa)**, Mavyret**	
Diagnosis	Hepatitis C
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic Hepatitis C infection status which has been confirmed by detectable serum hepatitis C virus (HCV) RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request

AND

2 - Age of the patient is Food and Drug Administration (FDA) approved for the specific HCV DAA (Direct Acting Antiviral) product

AND

3 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV medicine

AND

4 - The prescribing provider assesses the patient's ability to adhere to the HCV DAA treatment plan and attests the assessment has been documented within the clinical record. For patients that would benefit from adherence aids, the treating provider shall refer the patient to a treatment adherence program

AND

5 - Patient agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program

AND

6 - One of the following:

6.1 Patient has been screened for Hepatitis A and B and has received one Hepatitis A and one Hepatitis B vaccine prior to requesting treatment

OR

6.2 Patient demonstrates laboratory evidence of immunity to Hepatitis A and B

AND

7 - The Prescriber must submit the following information with the request for HCV DAA medications to be considered:

7.1 HCV treatment history and responses to treatment

AND

7.2 Current medication list

AND

7.3 Laboratory results for all of the following:

- HCV screen test results
- Genotype and current baseline HCV viral load
- Total bilirubin
- Albumin level
- International Normalized Ratio (INR)
- Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR)
- Liver Function Tests (LFTs)
- Complete Blood Count (CBC)
- Viral resistance status (when applicable)
- Hepatic status (Child Pugh Score)

AND

8 - If the HCV DAA product is being used in combination with ribavirin, the prescribing provider attests to monitoring hemoglobin levels periodically

AND

9 - The prescribing provider attests to monitoring HCV RNA levels obtained at 12- and 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR)

AND

10 - DAA HCV treatment coverage is NOT provided for ANY of the following:

10.1 DAA dosages greater than the FDA approved maximum dosage

OR

10.2 Patients whose comorbidities are such that their life expectancy is one year or less

OR

10.3 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

10.4 Lost or stolen medication absent of good cause

OR

10.5 Fraud, waste, or misuse of HCV DAA medications

Notes	*Approval length Mavyret: 8 Week(s)*, sofosbuvir-velpatasvir (authorized generic of Epclusa): 12 Weeks(s). **Mavyret and sofosbuvir-velpatasvir (authorized generic of Epclusa) may be approved for approval durations beyond listed duration depending on regimen. Refer to AASLD for specific approval durations AASLD: https://www.hcvguidelines.org/contents

Product Name: Non-Preferred: Brand Epclusa, Brand Harvoni, ledipasvir-sofosbuvir (authorized generic of Harvoni), Sovaldi, Vosevi, Zepatier	
Diagnosis	Hepatitis C
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient was adherent to previous DAA therapy as evidenced by submission of medical records and/or pharmacy prescription claims

OR

1.2 If prior therapy was discontinued due to adverse effects from the DAA, the medical record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider

AND

2 - The patient's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record

AND

3 - Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when BOTH of the following are true

- Required for regimens whereby the FDA (Food and Drug Administration) requires such testing prior to treatment to ensure clinical appropriateness
- Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen

AND

4 - HCV retreatment with a DAA shall NOT be approved for ANY of the following:

4.1 The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy

OR

4.2 Is considered an experimental service

OR

4.3 Monotherapy of Sofosbuvir (Sovaldi)

OR

4.4 DAA dosages greater than the FDA approved maximum dosage

OR

4.5 Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request

OR

4.6 Patients whose comorbidities are such that their life expectancy is one year or less

OR

4.7 Patients currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.)

OR

4.8 Lost or stolen medication absent of good cause

OR

4.9 Fraudulent use of HCV DAA medications

AND

5 - If the request if for brand Epclusa or brand Harvoni BOTH of the following:

5.1 The patient has a therapeutic failure, contraindication, or intolerance to the generic as evidenced by submission of medical records or claims history

AND

5.2 The prescriber must submit the FDA MedWatch form

Notes	*NOTE: The approval length should be as recommended per AASLD. Refer to AASLD for specific approval durations. AASLD: https://www.hcvguidelines.org/contents

Product Name: Pegasys, PegIntron	
Diagnosis	Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Will be used as part of a combination antiviral treatment regimen

Product Name: Ribavirin tablets and capsules	
Diagnosis	Hepatitis C

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Used in combination with a direct-acting agent

2 . Revision History

Date	Notes
12/6/2021	Updated prescriber requirement

Prior Authorization Guideline

GL-108664 Hetlioz, Hetlioz LQ (tasimelteon)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-

running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient is totally blind (has no light perception)

AND

3 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

Product Name: Hetlioz capsule	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

2 . Revision History

Date	Notes
6/23/2022	New Program

Prior Authorization Guideline

GL-99816 Humira

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Humira	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderately to severely active rheumatoid arthritis	

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira

Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of

failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)

- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Humira

Diagnosis	Adult Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

OR

2.2 Patient has lost response or intolerant to infliximab (e.g., Remicade, Inflectra, Renflexis)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Pediatric Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist	
Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Adult Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Hidradenitis Suppurativa
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as ONE of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated

dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at a maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

5 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

6 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Humira	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Humira therapy

AND

2 - Patient is NOT receiving Humira in combination with ANY of the following:

- Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

2 . Revision History

Date	Notes
12/6/2021	Added "history of paid claims or submission of medical records (e.g., chart notes)" to all t/f criteria. Changed concomitant use criteria from ' one' to ALL.

Hycamtin

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99745 Hycamtin

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Hycamtin	
Diagnosis	Small cell lung cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of small cell lung cancer (SCLC)	

AND

2 - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Product Name: Hycamtin	
Diagnosis	Merkel cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma

AND

2 - BOTH of the following:

- Disseminated disease
- Clinical M1 disease

AND

3 - Patient has a contraindication to checkpoint immunotherapy [e.g., Bavencio (avelumab), Keytruda (pembrolizumab), Opdivo (nivolumab)]

Product Name: Hycamtin	
Diagnosis	Small cell lung cancer (SCLC), Merkel cell carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin therapy

Product Name: Hycamtin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hycamtin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Hycamtin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hycamtin therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99465 Hydroxychloroquine

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Plaquenil, generic hydroxychloroquine	
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 Treatment of chronic discoid lupus erythematosus or systemic lupus erythematosus

OR

1.2 Treatment of rheumatoid arthritis **OR** **1.3** Prophylaxis of malaria in geographic areas where chloroquine resistance is not reported **OR** **1.4** Treatment of uncomplicated malaria	
Notes	Authorization will be issued for 6 months up to a quantity of 120 tablet s per 30 days.

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99746 Ibrance

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ibrance	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

- Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Used in combination with Faslodex (fulvestrant)

Product Name: Ibrance	
Diagnosis	Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable well-differentiated/dedifferentiated liposarcoma (WD-DDLS)

Product Name: Ibrance	
Diagnosis	Breast Cancer, Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ibrance therapy

Product Name: Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ibrance will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ibrance therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99747 Iclusig

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelogenous/ myeloid leukemia (CML)	

AND

2 - ONE of the following:

- Patient is unable to take or has failed treatment with TWO or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]
- Confirmed documentation of T315I mutation

Product Name: Iclusig	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)

AND

2 - ONE of the following:

2.1 Patient is unable to take or has failed treatment with two or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

OR

2.2 Confirmed documentation of T315I mutation

OR

2.3 Used as a component of Hyper-CVAD (chemotherapy) regimen induction or consolidation

Product Name: Iclusig	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

2.1 Patient has FGFR1 (fibroblast growth factor receptor 1) rearrangement

OR

2.2 Patient has ABL1 (gene) rearrangement

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML), Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL), Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iclusig therapy

Product Name: Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Iclusig will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iclusig therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99681 Idhifa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acute myeloid leukemia (AML)	

AND

2 - AML is IDH2 (isocitrate dehydrogenase 2) mutation-positive

AND

3 - ONE of the following:

3.1 Disease is relapsed or refractory

OR

3.2 BOTH of the following:

3.2.1 Patient is 60 years of age or older

AND

3.2.2 ONE of the following:

- Patient is not a candidate for intensive induction therapy
- Used for post remission therapy following response to low intensity induction therapy

Product Name: Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Idhifa therapy

Product Name: Idhifa	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Idhifa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Idhifa	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Idhifa therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99618 Ilaris

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)

- Muckle-Wells Syndrome (MWS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FCAS and MWS

Product Name: Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

AND

2 - Documentation of positive clinical response to Ilaris therapy

Product Name: Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS

Product Name: Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name: Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)

- Mevalonate Kinase Deficiency (MKD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of HIDS or MKD

Product Name: Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)
- Mevalonate Kinase Deficiency (MKD)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name: Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Familial Mediterranean Fever (FMF)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF

AND

3 - History of failure, contraindication, or intolerance to colchicine

Product Name: Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Familial Mediterranean Fever (FMF)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined by a decrease in index disease flare or normalization of CRP (C-reactive protein)

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Still’s Disease [Adult-Onset Still’s Disease (AOSD)]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Adult Onset Still's Disease (AOSD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of Still's Disease

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Product Name: Ilaris	
Diagnosis	Still's Disease [Adult-Onset Still's Disease (AOSD)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Adult Onset Still's Disease (AOSD)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99718 Ilumya - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure, to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Ilumya therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Ilumya	
Diagnosis	Chronic Moderate to Severe Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ilumya therapy

AND

2 - Patient is NOT receiving Ilumya in combination with ONE of the following:

- Biologic DMARD (disease modifying anti-rheumatic drug) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99748 Imbruvica

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Imbruvica	
Diagnosis	B-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of mantle cell lymphoma (MCL)

AND

1.1.2 ONE of the following:

- Patient has received at least one prior therapy for MCL
- Used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

OR

1.2 Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of ONE of the following:

- Follicular lymphoma (grade 1-2)
- Diffuse large B-cell lymphoma [non-GCB DLBCL (non-germinal center B-cell diffuse large B-cell) and non-candidate for transplant]
- Acquired immune deficiency syndrome (AIDS)-related B-cell lymphoma
- Post-transplant lymphoproliferative disorders
- Histologic transformation to diffuse large B-cell lymphoma
- Hairy cell leukemia
- Nodal or splenic marginal zone lymphoma (MZL)
- Gastric MALT (mucosa-associated lymphoid tissue) lymphoma
- Nongastric MALT lymphoma
- High grade B-cell lymphoma

AND

1.3.2 Used as second-line or a subsequent therapy

Product Name: Imbruvica	
Diagnosis	Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Product Name: Imbruvica	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - ONE of the following:

2.1 Used as second-line or a subsequent therapy

OR

2.2 Used as induction therapy if the patient is unsuitable or intolerant to high-dose methotrexate

Product Name: Imbruvica	
Diagnosis	B-Cell Lymphoma, Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Primary CNS Lymphoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Imbruvica therapy

Product Name: Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft versus host disease

AND

2 - History of failure of at least one other systemic therapy [e.g. corticosteroids, mycophenolate, etc.]

Product Name: Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response while on Imbruvica therapy

Product Name: Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Imbruvica will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Imbruvica therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99783 Immune Globulin- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following diagnoses:	

- Severe asthma
- Persistent asthma
- High-dose steroid-dependent asthma

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is receiving optimal conventional asthma therapy (e.g., high-dose inhaled glucocorticoids, short- and long-acting inhaled β agonists)

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

AND

5 - Patient has required continuous oral glucocorticoid therapy for a minimum of 2 months prior to the decision to initiate immune globulin therapy

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - Prescribed by or in consultation with a pulmonologist or allergist or immunologist

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Asthma (severe, persistent, high-dose steroid-dependent)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Extensive and debilitating disease

AND

4 - History of failure, contraindication, or intolerance to systemic corticosteroids with concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil)

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 to 2,000 milligrams (mg) per kilogram (kg) per month divided into 3 equal doses, each given over 3 consecutive days or 400 mg per kg per day given over 5 consecutive days per month. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify

Diagnosis	Autoimmune Bullous Disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following uses:

- Prevention of acute graft vs. host disease (GVHD)
- Prevention of infection

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Confirmed allogeneic bone marrow transplant within the last 100 days

AND

4 - Documented severe hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 500 mg per kilogram (kg) once weekly for the first 90 days of therapy, then monthly up to 360 days after transplantation

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Bone Marrow Transplant (BMT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: : HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by ALL of the following:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb

AND

1.3 Electrodiagnostic findings [consistent with European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) guidelines for definite chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)] indicating at least ONE of the following criteria are present:

- Motor distal latency prolongation in 2 nerves
- Reduction of motor conduction velocity in 2 nerves
- Prolongation of F-wave latency in 2 nerves
- Absence of F-waves in at least 1 nerve
- Partial motor conduction block of at least 1 motor nerve
- Abnormal temporal dispersion in at least 2 nerves
- Distal compound muscle action potential (CMAP) duration increase in at least 1 nerve

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with B-cell CLL

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in B-cell Chronic Lymphocytic Leukemia (CLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatomyositis or polymyositis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per

kilogram (kg) per month given over 2 to 5 consecutive days administered as monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Dermatomyositis or polymyositis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is newly diagnosed with insulin dependent (type 1) diabetes mellitus

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient is not a candidate for or is refractory to insulin therapy

AND

4 - If the request is for a non-preferred product, there must be a history of failure,

contraindication or intolerance to ALL the following products.(Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For pregnant women all of the following:

1.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia (AIT)

AND

1.2 ONE of the following:

- Previously affected pregnancy
- Family history of the disease
- Platelet alloantibodies found on screening

AND

1.3 ONE of the following:

1.3.1 Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) once weekly until delivery

OR

1.3.2 BOTH of the following:

- Fetus or newborn is considered to be at high risk for developing intracranial hemorrhage or other severe complication of AIT
- IVIG dose does not exceed 2,000 mg/kg once weekly until delivery

AND

2 - For newborns all of the following:

2.1 Diagnosis of feto-neonatal alloimmune thrombocytopenia

AND

2.2 Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

AND

3 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Feto-neonatal Alloimmune Thrombocytopenia (AIT)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barré Syndrome

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Severe disease requiring aid to walk

AND

4 - Onset of neuropathic symptoms within the last four weeks

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Graves' ophthalmopathy Guillain-Barré syndrome (GBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV disease

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Patient age less than or equal to 13 years of age

AND

4 - ONE of the following:

- Documented hypogammaglobulinemia [Immunoglobulin (IgG) less than 400 milligrams (mg) per deciliter (dL)]
- Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 28 days

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of bacterial infection in pediatric HIV
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

- Diagnosis of acute thrombocytopenic purpura (ITP)

- Documented platelet count less than 50 x 10^9 per Liter (L) (obtained within the past 30 days)
- Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram(kg) per day for 1 to 2 days

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic thrombocytopenic purpura (ITP)

AND

1.2.2 History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Splenectomy

AND

1.2.3 IVIG dose does not exceed 2,000 mg per kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there is a history of failure, contraindication or intolerance to 3 preferred products.* (Note: In instances where there are fewer than three

preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to all of the preferred products

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Immune thrombocytopenia [Idiopathic thrombocytopenic purpura (ITP)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki disease

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 4,000 milligrams (mg) per kilograms (kg) for five consecutive days or a single dose of 2,000 mg per kg

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma

- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Kawasaki Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids)

AND

4 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous Immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

8 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication or intolerance to initial treatment with traditional anti-epileptic pharmacotherapy (e.g., lamotrigine, phenytoin, valproic acid)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 milligrams (mg) per kilogram (kg) per day given for 4 to 5 consecutive days. IVIG administration may be repeated monthly as needed in patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

5 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Lennox Gastaut Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy as confirmed by ALL of the following:

- Weakness with slowly progressive or stepwise progressive course over at least one month
- Asymmetric involvement of two or more nerves
- Absence of motor neuron signs and bulbar signs

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Multifocal Motor Neuropathy (MMN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,400 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - ONE of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with multiple myeloma

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 3 to 4 weeks

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Prevention of infection in Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary- progressive MS with relapses, progressive-relapsing MS with relapses)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy

AND

4 - History of failure, contraindication, or intolerance to at least TWO of the following agents:

- Aubagio (teriflunomide)
- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Copaxone/Glatopa (glatiramer acetate)
- Extavia (interferon beta-1b)
- Gilenya (fingolimod)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Mayzent (siponimod)
- Ocrevus (ocrelizumab)
- Plegridy (peginterferon beta-1a)
- Rebif (interferon beta-1a)
- Tecfidera (dimethyl fumarate)
- Tysabri (natalizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Induction, when indicated, does not exceed a dose of 400 milligrams (mg) per kilogram (kg) daily for up to five days

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C

- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Relapsing Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Medical records, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Scale (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy

AND

4 - Diagnosis continues to be the relapsing forms of multiple sclerosis (MS)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligram (mg) per kilogram (kg) monthly

AND

7 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis - Exacerbation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Evidence of myasthenia exacerbation, defined by at least ONE of the following symptoms in the last month

- Difficulty swallowing
- Acute respiratory failure
- Major functional disability responsible for the discontinuation of physical activity
- Recent immunotherapy treatment with a checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)]

AND

4 - ONE of the following:

- History of failure, contraindication, or intolerance to immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis
- Currently receiving immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe

- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory generalized myasthenia gravis by or in consultation with a physician or center with expertise in management of myasthenia gravis

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documentation that the disease status is unchanged or worsening (persistent or worsening symptoms that limit functioning) despite failure, contraindication, or intolerance to BOTH of the following (used in adequate doses and duration):

- Corticosteroids
- Two immunomodulator therapies (e.g., azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus)

AND

4 - Currently receiving immunomodulator therapy (e.g., corticosteroids, azathioprine,

mycophenolate mofetil, cyclosporine, methotrexate, tacrolimus), used in adequate doses, for long-term management of myasthenia gravis

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Myasthenia Gravis –Exacerbation and Refractory Myasthenia Gravis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Neuromyelitis Optica
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist confirming ALL of the following:

1.1 Serologic testing for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) or Neuromyelitis optica immunoglobulin G (NMO-IgG) antibodies has been performed

AND

1.2 ONE of the following:

1.2.1 If AQP4-IgG/NMO-IgG positive, past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis

- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

OR

1.2.2 If AQP4-IgG/NMO-IgG negative, past medical history of TWO of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication, or intolerance to at least TWO of the following:

- Azathioprine
- Corticosteroids
- Mycophenolate mofetil
- Rituximab

- Soliris (eculizumab)

AND

4 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

5 - Prescribed by or in consultation with a neurologist

AND

6 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

7 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Neuromyelitis Optica

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with immune globulin

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting immune globulin. (NOTE: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on immune globulin therapy will be considered as treatment failure.)

AND

3 - Patient is not receiving immune globulin in combination with either of the following:

- Rituximab
- Soliris (eculizumab)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of posttransfusion purpura

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) for 2 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Posttransfusion Purpura
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation confirming previous treatment of B-cell targeted therapy within the last 100 days [e.g., CAR-T (e.g., Kymriah), Rituxan (rituximab), Besponsa (inotuzumab ozogamicin)]

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - BOTH of the following:

- Documented hypogammaglobulinemia [immunoglobulin (IgG) less than 500 milligrams (mg) per deciliter (dL)]
- History of bacterial infection(s) associated with B-cell depletion

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 400 mg per kilogram (kg) every 4 weeks, up to 360 days after discontinuation of B-cell depleting therapy

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D

- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Post B-Cell Targeted Therapies
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunodeficiency

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by ONE of the following:

- Documented failure to produce antibodies to specific antigens
- History of significant recurrent infections

AND

4 - Initial intravenous immunoglobulin (IVIG) dose is 200 to 800 milligrams (mg) per kilogram (kg) every 3 to 4 weeks, based on product prescribing information, and titrated based upon patient response (For subcutaneous immune globulin (SCIG) products, FDA-labeled dosing and conversion guidelines will used to determine benefit coverage.)

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe

- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Primary Immunodeficiency Syndromes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following demonstrating that:

- Short term amelioration of encephalitis is needed prior to definitive surgical therapy
- Disease symptoms (e.g., seizures) persist despite surgical treatment
- The patient is not a candidate for surgical treatment

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days

AND

4 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products.* (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Rasmussen Syndrome
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable

- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - History of failure, contraindication or intolerance to GABAergic (gamma-aminobutyric acid analogs) medication (e.g., baclofen, benzodiazepines)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

6 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Stiff-Person Syndrome

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical improvement from baseline

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligrams (mg) per kilogram (kg) per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities

AND

4 - For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - Documented platelet count less than 50 x 10^9 per liter (L) (obtained within the past 30 days)

AND

4 - Intravenous immunoglobulin (IVIG) dose does not exceed 1,000 milligrams (mg) per kilogram (kg) per day for 1 to 2 days

AND

5 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	Thrombocytopenia, secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Diagnosis of thrombocytopenia secondary to Hepatitis C Virus (HCV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.2 Both of the following:

- Diagnosis of thrombocytopenia secondary Human Immunodeficiency Virus (HIV) infection
- Patient is receiving concurrent antiviral therapy, unless contraindicated

OR

1.3 Diagnosis of thrombocytopenia secondary to pregnancy

AND

2 - Intravenous immunoglobulin (IVIG) dose does not exceed 2,000 milligram (mg) per kilogram (kg) per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Autoimmune Uveitis
- Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants
- Enteroviral Meningoencephalitis
- IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Lymphoproliferative disease (treatment of bacterial infections)
- Monoclonal gammopathy
- Paraproteinemic neuropathy
- Renal transplantation (prevention or treatment of acute humoral rejection)
- Severe Rheumatoid arthritis
- Rotaviral enterocolitis
- Staphylococcal toxic shock

- Toxic epidermal necrolysis or Stevens-Johnson syndrome
- Urticaria (delayed pressure)

AND

2 - Medical records documenting BOTH of the following:

- History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
- Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested

AND

3 - If the request is for a non-preferred product, there must be a history of failure, contraindication or intolerance to ALL the following products. (Note: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products)

- Flebogamma
- Gammagard Liquid
- Gammagard S-D
- Gammaked
- Gamunex-C
- Hizentra Vial & Syringe
- Privigen

Product Name: HyQvia, Gammagard S-D, Gammagard liquid, Cuvitru, Gamastan, Gamastan S-D, Gamunex-C, Carimune NF Nanofiltered, Privigen, Hizentra, Bivigam, Flebogamma Dif, Gammaplex, Octagam, Panzyga, Gammaked, Xembify	
Diagnosis	All other indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to immune globulin therapy

AND

2 - Statement of expected frequency and duration of proposed immune globulin treatment

AND

3 - For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response

2 . Revision History

Date	Notes
6/28/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99466 Inbrija

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Inbrija	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Parkinson’s disease	

AND

2 - Inbrija will be used as intermittent treatment for OFF episodes

AND

3 - Prescribed by, or in consultation with, a neurologist or specialist in the treatment of Parkinson's disease

AND

4 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

5 - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

6 - History of failure, contraindication, or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

Product Name: Inbrija

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inbrija therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99807 Ingrezza

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia (TD) secondary to a centrally acting dopamine receptor blocking agent (DRBA).

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist.

AND

3 - Age ≥ 18 years.

AND

4 - Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of the AIMS items 1 through 9.

AND

5 - Failure of tetrabenazine as indicated by utilization per patient's pharmacy claims or clinically significant adverse effects are experienced:

AND

6 - Ingrezza is not prescribed concurrently with Austedo® or tetrabenazine.

AND

7 - Dose does not exceed 80 mg (1 capsule) per day.

Product Name: Ingrezza	
Diagnosis	Moderate to Severe Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is responding positively to therapy as evidenced by a reduction in the baseline AIMS score in any one of the AIMS items 1 through 9.

AND

2 - Ingrezza is not prescribed concurrently with Austedo or tetrabenazine.

AND

3 - Dose does not exceed 80 mg (1 capsule) per day.

2 . Revision History

Date	Notes
8/25/2021	Arizona Medicaid Implementation

Prior Authorization Guideline

GL-105180 Inhaled Corticosteroids - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Alvesco, Arnuity Ellipta, Asmanex HFA, Qvar Redihaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - History of failure, contraindication, intolerance to a majority (not more than 3) of the preferred inhaled corticosteroids:

- Asmanex Twisthaler (mometasone)
- Flovent Diskus (fluticasone)
- Flovent HFA (fluticasone)
- Pulmicort Flexhaler (budesonide)
- budesonide respule (generic)

2 . Revision History

Date	Notes
3/24/2022	Removed Pulmicort and budesonide respules as targets

Prior Authorization Guideline

GL-108679 Injectable Oncology Agents

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

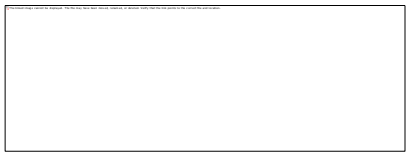
Effective Date:	7/1/2022

1 . Criteria

Product Name: Non-Preferred Injectable Oncology Drugs	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B	

2 . Revision History

Date	Notes
6/24/2022	Changed from Admin guideline to PA guideline



Prior Authorization Guideline

GL-108679 Injectable Oncology Agents

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Non-Preferred Injectable Oncology Drugs	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
6/24/2022	Changed from Admin guideline to PA guideline

Prior Authorization Guideline

GL-99682 Inlyta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of renal cell cancer

AND

2 - One of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

Product Name: Inlyta	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnosis:

- Follicular Carcinoma
- Hürthle Cell Carcinoma
- Papillary Carcinoma

AND

2 - ONE of the following:

- Unresectable recurrent
- Persistent locoregional disease
- Metastatic disease

AND

3 - Disease is refractory to radioactive iodine treatment

Product Name: Inlyta	
Diagnosis	Advanced Renal Cell Carcinoma, Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Inlyta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inlyta therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99719 Inrebic

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

1.1 Primary myelofibrosis

OR

1.2 Post-polycythemia vera myelofibrosis

OR

1.3 Post-essential thrombocythemia myelofibrosis

Product Name: Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has evidence of symptom improvement or reduction in spleen volume while on Inrebic

Product Name: Inrebic	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Inrebic

Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Inrebic therapy	

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99580 Insulins, Concentrated- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Humulin R U-500 vial and kwikpen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, intolerance, or contraindication to ALL of the following:

- Novolog or Humalog
- Lantus
- Levemir

OR **2** - There is a reason or special circumstance the patient needs to use a concentrated insulin product

2 . Revision History

Date	Notes
8/4/2021	Update guideline

Prior Authorization Guideline

GL-99683 Iressa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Iressa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Iressa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iressa therapy

Product Name: Iressa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central nervous system (CNS) cancer with metastatic lesions

AND

2 - Iressa is active against primary (NSCLC) tumor with a known epidermal growth factor receptor (EGFR) sensitizing mutation

Product Name: Iressa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iressa therapy

Product Name: Iressa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Iressa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Iressa	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to Iressa therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-104870 Iron Chelators

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/17/2022

1 . Criteria

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion	

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of transfusional iron overload due to thalassemia syndromes

AND

1.2 Current chelation therapy is inadequate [e.g., Desferal (deferoxamine), Exjade (deferasirox)]

Product Name: Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome

AND

1.2 Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade or Jadenu

AND

1.3 Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with Exjade or Jadenu

Product Name: Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/16/2022	Added new generic deferiprone tabs

Prior Authorization Guideline

GL-99468 Irritable Bowel Syndrome-Diarrhea

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)	

AND

2 - Symptoms for at least 6 months

AND

3 - Patient was female at birth

AND

4 - Age greater than or equal to 18 years

AND

5 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Brand Lotronex, generic alosetron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lotronex therapy

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - History of failure, contraindication, or intolerance to TWO of the following:

- Antispasmodic agent (e.g. dicyclomine)
- Antidiarrheal agents (e.g. loperamide)
- Tricyclic antidepressant (e.g. amitriptyline)

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Viberzi therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99562 Isotretinoin

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Absorica, Absorica LD, generic Amnesteem, generic Claravis, generic isotretinoin, generic Myorisan, generic Zenatane	
Diagnosis	Oncology Uses (Off Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for oncology indication meeting National Comprehensive Cancer Network (NCCN) with a Category of Evidence and Consensus of 1, 2A, or 2B. or from ONE of the following appropriate compendia of current literature: American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex, or Clinical Pharmacology

Product Name: Absorica, Absorica LD, generic Amnesteem, generic Claravis, generic isotretinoin, generic Myorisan, generic Zenatane	
Approval Length	5 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

OR

1.2 Diagnosis of treatment resistant acne

AND

2 - History of failure, contraindication, or intolerance to an adequate trial on TWO of the following conventional therapy regimens:

- Topical retinoid or retinoid-like agent [eg,Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

AND

3 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (see table in Background section)

Product Name: Absorica, Absorica LD, generic Amnesteem, generic Claravis, generic isotretinoin, generic Myorisan, generic Zenatane

Diagnosis	Persistent or Recurring Acne After 2 Months Off Therapy
Approval Length	5 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - After greater than or equal to 2 months OFF therapy, persistent or recurring severe recalcitrant nodular acne is still present	
Notes	Authorization will be given only by clinical pharmacist review for up to 5 months.

Product Name: Absorica, Absorica LD, generic Amnesteem, generic Claravis, generic isotretinoin, generic Myorisan, generic Zenatane	
Diagnosis	Dose Titration
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Confirmation that the cumulative dose is less than 150 mg/kg (there is little therapeutic benefit to be gained by increasing the cumulative dose beyond 150 mg/kg)*	
Notes	Authorization will be given only by clinical pharmacist review for 1 mo nth to allow for titration up to the target dose *See background section for dosing regimens

2 . Background

Benefit/Coverage/Program Information
Formulary **Preferred Agents:**

Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin), generic isotretinoin

Non-Preferred Agents:

Absorica (isotretinoin)

Absorica LD (isotretinoin)

Dosing by Body Weight (based on administration with food):

Body Weight		Daily Dose		
Kg	Lbs	0.5 mg/kg/day	1 mg/kg/day	2 mg/kg/day
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200

3 . Revision History

Date	Notes
6/25/2021	Updated program

Prior Authorization Guideline

GL-99684 Isturisa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Isturisa	
Diagnosis	Cushing’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Both of the following:

1.1 Diagnosis of Cushing's disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Isturisa	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

Product Name: Isturisa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Isturisa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Isturisa

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Isturisa therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99749 Jakafi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Primary myelofibrosis

OR

1.2 Post-polycythemia vera myelofibrosis

OR

1.3 Post-essential thrombocythemia myelofibrosis

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi*	
Notes	* NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of polycythemia vera	

AND

2 - History of failure, inadequate response, contraindication, or intolerance to ONE of the following:

2.1 Hydroxyurea

OR

2.2 Interferon therapy (e.g., Intron A, Pegasys, PegIntron)

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi*	
Notes	* NOTE: If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name: Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of graft versus host disease (GVHD)

AND

2 - Disease is steroid refractory

Product Name: Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has symptom improvement while on Jakafi

Product Name: Jakafi	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Jakafi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Jakafi	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jakafi therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99791 Juxtapid - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment low density lipoprotein cholesterol (LDL-C) greater than 500 milligrams per deciliter
- Treated LDL-C greater than 300 milligrams per deciliter

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Patient has tried, failed or intolerant to Repatha and Praluent

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Notes	Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, low density lipoprotein [LDL] apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Juxtapid therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

2 . Revision History

Date	Notes
7/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-100644 Jynarque

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)

Product Name: Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jynarque therapy	

2 . Revision History

Date	Notes
12/16/2021	Added new Jynarque GPIs

Prior Authorization Guideline

GL-99620 Kalydeco

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kalydeco, Kalydeco packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory results confirming that patient has ONE of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene listed in the table in the Background section:

AND

3 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Kalydeco, Kalydeco packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Kalydeco therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information

CFTR Gene Mutations

CFTR Gene Mutations					
A1067T	*E56K*	*G1244E*	*R1070Q*	*S1251N*	*2789+5G→A*
A455E	*E193K*	*G1349D*	*R1070W*	*S1255P*	*3272-26A→G*
D110E	*E831X*	*G178R*	*R117C*	*S549N*	*3849+10kbC→T*
D110H	*F1052V*	*G551S*	*R117H*	*S549R*	
D1152H	*F1074L*	*K1060T*	*R347H*	*S945L*	
D1270N	*G1069R*	*L206W*	*R352Q*	*S977F*	
D579G	*G551D*	*P67L*	*R74W*	*711+3A→G*	

3 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-102888 Kerendia (finerenone)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) defined by one of the following:

1.1 Both of the following:

- Urinary albumin-to-creatinine ratio (UACR) of 30 to 300 mg/g
- Estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m2

OR

1.2 Both of the following:

- UACR of greater than or equal to 300 mg/g
- eGFR of 25 to 75 mL/min/1.73 m2

AND

2 - One of the following:

2.1 Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following [2]:

- Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

2 . Revision History

Date	Notes
2/3/2022	New Program

Prior Authorization Guideline

GL-99621 Keveyis

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of primary hyperkalemic periodic paralysis or related variant

OR **1.2** Diagnosis of primary hypokalemic periodic paralysis or related variant

Product Name: Keveyis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Keveyis therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99720 Kevzara- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.1.4 Patient is NOT receiving Kevzara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.5 Prescribed by or in consultation with a rheumatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Kevzara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of moderately to severely active RA

AND

1.2.3 Patient is not receiving Kevzara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Kevzara	
Diagnosis	Moderately to Severely Active Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kevzara therapy

AND

2 - Patient is not receiving Kevzara in combination with ONE of the following:

- Biologic diease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-104978 Kimmtrak (tebentafusp-tebn)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of uveal melanoma

AND

2 - Disease is unresectable or metastatic

AND

3 - Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test [2]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Kimmtrak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on therapy

2 . Revision History

Date	Notes
3/22/2022	New Program mirrors ORx with Submission of Records added to initi al and reauth

Prior Authorization Guideline

GL-99721 Kineret - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Kineret therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active (RA)

AND

2.3 Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA) (formerly Still's Disease)

AND

2 - Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Kineret	
Diagnosis	Adult Onset Still's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult onset Still's Disease

AND

2 - Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Kineret	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kineret therapy

AND

2 - Patient is NOT receiving Kineret in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND **3** - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99750 Kisqali

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kisqali	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced, recurrent, or metastatic breast cancer	

AND

2 - BOTH of the following:

- Disease is hormone receptor (HR)-positive
- Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3 - BOTH of the following:

3.1 ONE of the following:

- Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)]
- Used in combination with Faslodex (fulvestrant)

AND

3.2 ONE of the following:

- History of failure, contraindication, or intolerance to Verzenio (abemaciclib)
- Patient is currently on Kisqali therapy

Product Name: Kisqali	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali therapy

Product Name: Kisqali

Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Kisqali will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Kisqali	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kisqali therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99728 Kisqali Femara Co-Pack

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced or metastatic breast cancer	

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 History of failure, contraindication, or intolerance to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole)

OR

4.2 Patient is currently on Kisqali Femara Co-Pack therapy

Product Name: Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Product Name: Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimen

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Kisqali Femara Co-Pack will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kisqali Femara Co-Pack therapy

2 . Revision History

Date	Notes
5/14/2021	Arizona Medicaid 7.1 Implementation

Korlym

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99622 Korlym

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ALL of the following:	

1.1 Diagnosis of Endogenous Cushing's Syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

1.3 ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name: Korlym	
Diagnosis	Endogenous Cushing's Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of ONE of the following:

- Patient has improved glucose tolerance while on Korlym therapy
- Patient has stable glucose tolerance while on Korlym therapy

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-107424 Korsuva (difelikefalin)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Korsuva	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of chronic kidney disease (CKD)

AND

1.2 Patient is currently undergoing hemodialysis (HD) at an optimal dialysis dose (e.g., Kt/V greater than or equal to 1.2)

AND

1.3 Patient is experiencing moderate to severe pruritus associated with CKD (CKD-aP)

AND

1.4 Exclusion of other causes of pruritus (e. g., eczema, infections, drug-induced skin dryness)

AND

1.5 Trial and failure, contraindication, or intolerance to ONE topical anti-pruritic treatment:

- emollient cream
- analgesics (e.g., pramoxine lotion, capsaicin)
- corticosteroids (e.g., hydrocortisone, triamcinolone)

AND

1.6 Trial and failure, contraindication, or intolerance to ONE oral treatment*:

- antihistamine (e.g., diphenhydramine, hydroxyzine, loratadine)
- gabapentin
- pregabalin

AND

2 - Prescribed by or in consultation with one of the following:

- Nephrologist

• Dermatologist	
Notes	*PA may be required

Product Name: Korsuva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Patient is currently undergoing hemodialysis

AND

1.2 Documentation of positive clinical response to therapy (e.g., improved quality of life, improved worst itching intensity numerical rating score from baseline)

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

GL-99685 Koselugo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are BOTH of the following:

- Inoperable
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Koselugo therapy

Product Name: Koselugo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Koselugo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Koselugo

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Koselugo therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99623 Kuvan

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Kuvan	
Diagnosis	Phenylketonuria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99506 LAMA-LABA- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Bevespi, Stiolto	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - One of the following:

2.1 History of failure, contraindication, or intolerance to treatment with a 30 day trial of a long-acting beta-agonist (e.g. Foradil, Serevent, Striverdi, Arcapta)

OR

2.2 History of failure, contraindication, or intolerance to treatment with a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza)

2 . Revision History

Date	Notes
5/21/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99556 Lansoprazole/Amoxicillin/Clarithromycin

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lansoprazole/Amoxicillin/Clarithromycin	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for Lansoprazole/Amoxicillin/Clarithromycin should be denied. These medications are available as individual prescriptions (lansoprazole, amoxicillin, and clarithromycin).	

2 . Revision History

Date	Notes
6/29/2021	7/1 Implementation

Lenvima

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99751 Lenvima

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of advanced renal cell cancer	

AND

2 - History of failure, contraindication, or intolerance to prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]

AND

3 - Used in combination with Afinitor (everolimus)

Product Name: Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Afinitor (everolimus)

Product Name: Lenvima	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable or locally recurrent disease
- Metastatic disease
- Persistent locoregional disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 ONE of the following:

- Disease is refractory to radioactive iodine
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of anaplastic thyroid carcinoma

AND

1.3.2 Disease is metastatic

Product Name: Lenvima	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Disease is ONE of the following:

- Unresectable
- Metastatic

Product Name: Lenvima	
Diagnosis	Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent adenoid cystic carcinoma

Product Name: Lenvima	
Diagnosis	Thyroid Cancer, Hepatocellular Carcinoma, Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name: Lenvima	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lenvima will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Lenvima

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lenvima therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-104974 Leqvio (inclisiran)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:	

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:

1.1.1 Both of the following: [5]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.1.2 One of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following: [5]

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [2,4]

- Acute coronary syndromes

- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [4]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

- Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose
- Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [4]

AND

3 - One of the following:

3.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Patient is unable to maintain adherence to proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy

AND

5 - Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 70 mg/dL for diagnosis of ASCVD [2]
- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH [3]

AND

6 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

7 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting LDL-C reduction from baseline while on therapy

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

2 . Revision History

Date	Notes
3/22/2022	New program, mirrors ORx with Submission of Records requirement

Prior Authorization Guideline

GL-99469 Leucovorin- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Leucovorin tabs	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Methotrexate toxicity prophylaxis

OR

1.2 Treatment of hematologic toxicity from folic acid antagonists (i.e., pyrimethamine toxicity treatment or trimethoprim toxicity treatment)

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99575 Lidocaine - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lidocaine 2% Gel	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Used with catheters or open mucus membrane areas.	

Product Name: Lidocaine 4 or 5% ointment	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Lidocaine 4 or 5% ointment should be denied. The plan's preferred product is Aspercreme with Lidocaine 4%.

2 . Revision History

Date	Notes
7/14/2021	Updated guideline

Prior Authorization Guideline

GL-103328 Livtencity (maribavir)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Livtencity	
Diagnosis	CMV infection/disease
Approval Length	8 Week(s) [1]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cytomegalovirus (CMV) infection/disease as confirmed by one of the following methods: [2, 3]

- quantitative polymerase chain reaction (qPCR)

- CMV pp65 antigenemia

AND

2 - Patient is a recipient of one of the following:

- Hematopoietic stem cell transplant
- Solid organ transplant

AND

3 - Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose:

- Intravenous (IV) ganciclovir
- Oral valganciclovir
- IV foscarnet
- IV cidofovir

AND

4 - Patient is 12 years of age or older

AND

5 - Patient weighs greater than or equal to 35kg

AND

6 - Prescribed by or in consultation with a provider who specializes in one of the following areas:

- Transplant
- Infectious Disease

2 . Endnotes

A. A one-log decline in CMV viral load is the anticipated outcome after at least 2 weeks of appropriately dosed antiviral therapy. [2]

3 . References

1. Livtencity Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. November 2021.
2. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clinical Transplantation. 2019;33(9).
3. ClinicalTrials.gov [Internet]. U.S. National Library of Medicine. Identifier NCT02931539. Efficacy and Safety Study of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir; October 13, 2016. Available from: https://clinicaltrials.gov/ct2/show/NCT02931539.

4 . Revision History

Date	Notes
2/3/2022	New Program

Prior Authorization Guideline

GL-99583 Long-Acting Opioid Products- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	PA REQUIRED for use of MAT and other Opioids (Reject 88)
Guideline Type	DUR
Approval Criteria	

1 - Provider attests to notify the prescriber of the MAT therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy.

AND

2 - The days supply does not exceed 14 days for a surgical procedure.

AND

3 - The days supply does not exceed 5 days for all other requests.

AND

4 - There has not been a previous approval in the last 6 months.

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other requests

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

Notes	*Note: If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity author

	ization criteria requirements for treatment with an opioid, a denial sho uld be issued and a maximum 30 day authorization may be authorized one time for the requested drug/strength combination up to the reque sted quantity for transition to an alternative treatment.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication or intolerance to a trial of at least THREE of the following (Document drugs and date of trials):*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

- FENTANYL PATCH 72-HOUR 12mcg, 25mcg, 50mcg, 75mcg & 100mcg

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment. **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are n on-preferred. *Note: Claims history may be used in conjunction as doc umentation of drug, date, and duration of trial.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Cancer related pain/Hospice care/end-of-life care*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer

OR

1.2 Patient is receiving hospice or end-of-life care

AND

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 The patient has a history of failure, contraindication or intolerance to a trial of BOTH of the following (Document drugs and date of trials):*

- tramadol immediate release (IR)
- tramadol extended release tablets (non-biphasic release tablets)

OR

2.1.2 Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care pain (Document date regimen was started)

AND

2.2 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz ed one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: Claim s history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR **2.3** Postoperative pain is expected to be moderate to severe and persist for an extended period of time **AND** **3** - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following: **3.1** Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)* **AND** **3.2** Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial)*

Notes	*Note: If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5 mcg/hr are non-preferred.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - The patient has a history of failure, contraindication or intolerance to at least THREE of the following (Document drugs and date of trials):)*

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal**
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)
- FENTANYL PATCH 72-HOUR 12mcg, 25mcg, 50mcg, 75mcg & 100mcg

AND

4 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

4.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial))*

AND

4.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial))*

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment. Additionall y **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5 m cg/hr are non-preferred. *Note: Claims history may be used in conjunc tion as documentation of drug, date, and duration of trial.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

AND

2 - ONE of the following:

2.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days (Document drug(s) and date of trial)*

OR

2.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

2.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), BOTH of the following:

3.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document date of trial)*

AND

3.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug and date of trial)*

AND

3.3 The patient has a history of failure, contraindication or intolerance to BOTH of the following (Document drugs and date of trials):)*

- tramadol immediate release (IR)**
- tramadol extended release tablets (non-biphasic release tablets)**

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for tramadol extended release capsules or tramadol extend ed release biphasic release tablets and the member is currently taking th e requested long-acting opioid for at least 30 days and has met the m edical necessity authorization criteria requirements for treatment wi th an opioid, but has not tried the preferred alternatives a denial shoul d b e issued and a maximum 30-day authorization may be authorized

	one time for the requested drug/strength combination up to the reques ted quantity for transition to an alternative treatment. *Drug may requir e prior authorization *Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial.

Product Name: Generic morphine sulfate ER tablets, generic fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, Xtampza, generic tramadol ER tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic

• Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time) • Pain management is required around the clock with a long-acting opioid	
Notes	*Note: If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. *Note: If the request is for a non-preferred product and the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. **NOTE: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred.

Product Name: Generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, generic fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Duragesic	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- • The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for a non-preferred product and the member is currently ta kin g the requested long-acting opioid for at least 30 days and has me t th e medical necessity authorization criteria requirements for treatme nt w ith an opioid, but has not tried the preferred alternatives a denial shoul d be issued and a maximum 30-day authorization may be autho rized one time for the requested drug/strength combination up to the r eques ted quantity for transition to an alternative treatment.**NOTE: F entanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5m cg/hr are non -preferred.

Product Name: Brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets	
Diagnosis	Non-cancer pain/Non-hospice care/Non-end-of-life care pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time)
- Pain management is required around the clock with a long-acting opioid

Notes	*Note: If the member is currently taking the requested long-acting opio id for at least 30 days and does not meet the medical necessity autho r ization criteria requirements for treatment with an opioid, a denial sh o uld be issued and a maximum 30-day authorization may be authoriz e d one time for the requested drug/strength combination up to the req u ested quantity for transition to an alternative treatment. *Note: If the re quest is for tramadol extended release capsules or tramadol extend ed release biphasic release tablets and the member is currently taking th e requested long-acting opioid for at least 30 days and has met the m edical necessity authorization criteria requirements for treatment wi

	th an opioid, but has not tried the preferred alternatives a denial shoul d b e issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the reques ted quantity for transition to an alternative treatment.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, brand Zohydro ER, hydrocodone ER capsules (generic Zohydro ER), generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, hydrocodone ER tablets (generic Hysingla ER), brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Criteria for Quantity Limit Reviews*
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (see Table 1 in the Background section)	
Notes	*Note: Authorization will be issued for • Cancer pain/hospice/end-of-lif e related pain: 12 months • All Tramadol ER requests: 12 months • No n-cancer pain/non-hospice/non-end-of-life related pain: 6 months

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Opioid Naïve (Not having filled an opioid in the past 120 days)*
Guideline Type	Morphine Milligram Equivalents (MME)** MME 50.00 exceeded; PA Required for dosage above 50 MEDD

Approval Criteria

1 - Opioid naïve members may receive greater than 50 morphine milligram equivalent (MME) based on the following:

1.1 If the request is for 50 MME to 90 MME, ONE of the following (NOTE: If the request exceeds 90 MME please skip this section and proceed to the Exceeding the 90 MME Cumulative Threshold Reviews section):

1.1.1 Diagnosis of ONE of the following:

- Cancer
- End of life pain (including hospice care)
- Palliative care
- Sickle cell anemia

OR

1.1.2 Patient is currently exceeding 50 MME and prescriber attests patient has been on a short-acting opioid in the past 120 days

OR

1.1.3 Document ALL of the following:

- The diagnosis associated with the need for pain management with opioid
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment
- Prescriber attests the member requires more than 50 MME per day to adequately control pain

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets

Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Cancer/Hospice/End-of-Life/Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain*
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalent (MME)** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Doses exceeding the cumulative morphine milligram equivalent (MME) of 90 milligrams will be approved up to the requested amount for ALL opioid products if the patient has one of the following conditions:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedure

Notes	*Note: Authorization will be issued for 12 months for one of the above conditions. The authorization should be entered for an MME of 9999 s o as to prevent future disruptions in therapy if the patient's dose is inc r eased.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets	
Diagnosis	Doses- Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled Nursing Facility/Traumatic Injury Related Pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalent (MME)** MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

2.1 Patient has tried and failed non-opioid pain medication (document drug name and date of trial)

AND

2.2 Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

Notes	*Note: If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose. **Note: Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

Product Name: Generic morphine sulfate ER tablets, brand Duragesic, generic fentanyl, Xtampza, generic morphine sulfate beads cap ER, generic hydromorphone ER, brand Kadian, generic morphine sulfate ER capsules, brand MS Contin, Zohydro ER, generic oxymorphone ER (non-crush resistant), brand Methadose, brand Dolophine, generic methadone, Arymo ER, Morphabond ER, Hysingla ER, brand Oxycontin, generic oxycodone ER, Nucynta ER, brand Conzip, generic tramadol ER 24HR biphasic capsules, generic tramadol ER biphasic release tablets, generic tramadol ER tablets

Diagnosis	Doses Exceeding the Cumulative MME of 90 mg - Non-cancer/non-hospice/non-end-of-life/non-palliative Nursing Facility/Traumatic Injury Related Pain* care/non-skilled
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalent (MME)** MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- if used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

AND

3 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)

Notes	*Note: If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose. **Note: Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain up to the current requested MME plus 90 MME.

2 . Background

Benefit/Coverage/Program Information

Table 1. CDC Recommended Long-Acting Opioid Maximum Milligram Morphine Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Fentanyl transdermal, mcg/hr	None
Hydrocodone	None
Methadone	None
Tapentadol	500mg ER
Oxymorphone	None
Oxycodone	Xtampza Only =288mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

Max MME is the maximum dose per day based on morphine milligram equivalents allowed without consultation or prescription by a pain specialist. Max MME is based upon the CDC guidelines and adjusted for currently available product strengths. Fentanyl is dosed in mcg/hr rather than mg/day

3 . Revision History

Date	Notes
9/1/2021	updated guideline

Prior Authorization Guideline

GL-99470 Lonhala and Yupelri- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lonhala Magnair, Yupleri	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD	

AND

2 - ONE of the following:

2.1 History of failure, contraindication or intolerance to Spiriva Handihaler (tiotropium)

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Handihaler) to control his/her COPD due to ONE of the following

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 Liters per minute)

AND

2.2.2 History of failure, contraindication or intolerance to ipratropium nebulized solution (generic Atrovent)

Product Name: Lonhala Magnair, Yupleri	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99752 Lonsurf

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lonsurf	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic colorectal cancer (mCRC)	

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:

- Fluoropyramidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Anti-vascular endothelial growth factor (VEGF) biological therapy

AND

3 - ONE of the following:

3.1 Tumors is RAS mutant-type

OR

3.2 BOTH of the following:

- Tumor is RAS wild-type
- History of failure, contraindication, or intolerance to anti-EGRF therapy

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Metastatic gastric cancer
- Metastatic gastroesophageal junction adenocarcinoma

AND

2 - History of failure, contraindication, or intolerance to treatment with at least TWO prior lines of chemotherapy that consisted of the following agents:

- Fluoropyrimidine (e.g., fluorouracil)
- Platinum (e.g., carboplatin, cisplatin, oxaliptalin)
- Taxene (e.g., docetaxel, paclitaxel) or irinotecan
- Human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

Product Name: Lonsurf	
Diagnosis	Colorectal Cancer, Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lonsurf therapy

Product Name: Lonsurf	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lonsurf will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Lonsurf

Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lonsurf therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99753 Lorbrena

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Disease is BOTH of the following:

- Advanced, metastatic, or recurrent
- Anaplastic lymphoma kinase (ALK)-positive

AND

2.1.2 Metastatic disease has progressed on at least ONE of the following therapies:

- Xalkori (crizotinib)
- Alecensa (alectinib)
- Zykadia (ceritinib)
- Alunbrig (brigatinib)

OR

2.2 Both of the following:

2.2.1 Disease is BOTH of the following:

- Advanced, metastatic, or recurrent
- ROS proto-oncogene 1 (ROS1)-positive

AND

2.2.2 Disease has progressed on at least ONE of the following therapies:

- Xalkori (crizotinib)
- Rozlytrek (entrectinib)
- Zykadia (ceritinib)

Product Name: Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lorbrena therapy

Product Name: Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Lorbrena will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lorbrena therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-104515 Lucemyra

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/9/2022

1 . Criteria

Product Name: Lucemyra	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For symptoms of abrupt opioid withdrawal

AND

2 - Opioids have been discontinued

AND

3 - BOTH of the following:

3.1 History of failure, contraindication, or intolerance to clonidine as verified by recent clonidine claims history in the past 180 days

AND

3.2 Lucemyra was initiated in the inpatient setting*

AND

4 - Prescriber must verify patient has been screened for hepatic and renal impairment and that dosing is appropriate for the patient's degree of hepatic and renal function

AND

5 - Prescriber must verify patient's vital signs have been monitored and that the patient is capable of and has been instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms

AND

6 - Patient does not have severe coronary insufficiency, a recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia

AND

7 - Patient does not have congenital long QT syndrome

Notes	*NOTE: Authorization will be issued for 14 days of therapy. If Lucemyra was initiated in the inpatient setting, the total course of therapy should not exceed 14 days.

2 . Revision History

Date	Notes
3/9/2022	Updated with patient safety criteria

Prior Authorization Guideline

GL-99471 Lumizyme -Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lumizyme	
Diagnosis	Pompe disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency)	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-107445 Lynparza (olaparib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Lynparza	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is advanced or recurrent

AND

3 - ONE of the following:

3.1 Patient has had a complete or partial response to platinum-based chemotherapy

OR

3.2 BOTH of the following:

3.2.1 Patient has had a complete or partial response to first-line platinum-based chemotherapy

AND

3.2.2 ONE of the following:

3.2.2.1 Presence of deleterious or suspected deleterious germline or somatic BRCA (breast cancer gene)-mutations

OR

3.2.2.2 BOTH of the following:

- Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability
- Used in combination with bevacizumab (e.g., Avastin, Mvasi)

AND

4 - Request is for maintenance therapy

Product Name: Lynparza	
Diagnosis	Ovarian Cancer (Treatment)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of advanced, persistent, or recurrent ovarian cancer

AND

2 - Presence of deleterious or suspected deleterious germline BRCA (breast cancer gene)-mutation

AND

3 - Patient has been treated with two or more prior lines of chemotherapy

Product Name: Lynparza	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

AND

3 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - ONE of the following:

5.1 Disease is hormone receptor (HR) negative

OR

5.2 BOTH of the following:

5.2.1 Disease is hormone receptor (HR) positive

AND

5.2.2 ONE of the following:

- Disease has progressed on previous endocrine therapy

- Provider attestation that treatment with endocrine therapy is inappropriate for the patient's disease

Product Name: Lynparza	
Diagnosis	High Risk Early Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of high risk early breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Patient has been previously treated with neoadjuvant or adjuvant chemotherapy (e.g., anthracycline, taxane)

Product Name: Lynparza	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of deleterious or suspected deleterious germline BRCA1/2 (breast cancer gene)-mutation

AND

4 - Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name: Lynparza	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of metastatic castration-resistant prostate cancer

AND

2 - Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

AND

3 - Disease has progressed following prior treatment with ONE of the following:

- Enzalutamide (Xtandi)
- Abiraterone (e.g., Zytiga, Yonsa)

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name: Lynparza	
Diagnosis	Ovarian Cancer (Maintenance and Treatment), Breast Cancer, High Risk Early Breast Cancer, Pancreatic Cancer, Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Lynparza will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lynparza therapy

2 . Revision History

Date	Notes
5/24/2022	Added criteria for new indication of High Risk Early Breast Cancer

Prior Authorization Guideline

GL-105529 Lyrica

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Lyrica	
Diagnosis	Seizure Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of seizure disorder	

AND

2 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Brand Lyrica	
Diagnosis	Neuropathic Pain Associated with Spinal Cord Injury
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain associated with spinal cord injury

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Fibromyalgia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fibromyalgia

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Brand Lyrica	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - One of the following:

- History of failure to generic pregabalin immediate-release capsules or solution at a minimum dose of 300mg daily for 4 weeks
- Contraindication or intolerance to generic pregabalin immediate-release capsules or solution

Product Name: Lyrica CR	
Diagnosis	Diabetic peripheral neuropathy (DPN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to treatment with ONE of the following:

- Tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks, or intolerance to a tricyclic antidepressant
- Serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressant (i.e. duloxetine, venlafaxine)

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

Product Name: Lyrica CR	
Diagnosis	Post herpetic neuralgia (PHN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post herpetic neuralgia (PHN)

AND

2 - History of failure, contraindication, or intolerance to gabapentin (generic Neurontin) at a minimum dose of 1800 milligrams daily for 4 weeks

AND

3 - History of failure, contraindication, or intolerance to a tricyclic antidepressant at the maximum tolerated dose for 6 to 8 weeks

AND

4 - History of failure, contraindication, or intolerance to generic pregabalin immediate-release capsules or generic pregabalin solution

2 . Revision History

Date	Notes

3/31/2022	Added step through generic for seizure indication. Updated all indicat ions to allow for any manufacturer of generic immediate-release caps ules or solution.

Prior Authorization Guideline

GL-99473 Lysteda

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Lysteda, generic tranexamic acid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cyclic heavy menstrual bleeding	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99670 Makena- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Makena*, generic hydroxyprogesterone caproate*	
Guideline Type	Prior Authorization

Approval Criteria

1 - Current singleton pregnancy

AND

2 - History of a prior spontaneous preterm birth of a singleton pregnancy

AND **3** - Treatment is initiated between 16 weeks, 0 days of gestation and 26 weeks, 6 days of gestation **AND** **4** - Administration is to continue weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first **AND** **5** - If the request is for a non-preferred product, patient has a history of failure, contraindication or intolerance to Makena ** • Brand Makena	
Notes	*NOTE: Approval duration is up to 21 weeks; approval duration should take into account gestation week when Makena wil be started and onl y authorized up to week 37. Drugs may require PA)*

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-108625 Marinol, Syndros

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Brand Marinol, Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is receiving cancer chemotherapy	

AND

2 - ONE of the following:

2.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

2.2 Patient is unable to swallow capsules

AND

3 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydroxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

4 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Generic Dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - History of failure, contraindication, or intolerance to a 5HT-3 (5-hydoxytriptamine) receptor antagonist [eg, Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)]

AND

3 - History of failure, contraindication, or intolerance to ONE of the following:

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol, Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

AND

4 - ONE of the following:

4.1 History of failure, contraindication, or intolerance to formulary generic dronabinol

OR

4.2 Patient is unable to swallow capsules

Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

- Patient is less than 65 years of age
- History of failure, contraindication, or intolerance to Megace (megestrol)

2 . Revision History

Date	Notes
6/23/2022	Removed cesamet from guideline name. Added Brand Marinol as NP target

Prior Authorization Guideline

GL-99624 Mavenclad - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

AND

2 - Prescribed by, or in consultation with, a specialist in the treatment of MS (e.g., neurologist)

AND

3 - ONE of the following:

3.1 Trial and failure (after trial of at least 4 weeks), contraindication, or intolerance to TWO of the following disease-modifying therapies for MS (document medication used, dose, and duration):

- Interferon beta-1a (Avonex, Rebif)
- Interferon beta-1b (Betaseron, Extavia)*
- Peginterferon beta-1a (Plegridy)
- Glatiramer acetate products (e.g., Copaxone, Glatopa)*
- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Aubagio (teriflunomide)
- Gilenya (fingolimod)
- Mayzent (siponimod)
- Tysabri (natalizumab)**
- Ocrevus (ocrelizumab)**
- Lemtrada (alemtuzumab)**
- Zeposia (ozanimod)*
- Kesimpta (ofatumumab)*
- Bafiertam (monomethyl fumarate)*

OR

3.2 Patient is currently on Mavenclad

AND

4 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

Notes	*Copaxone 40mg, Glatopa 20mg, glatiramer acetate, Bafiertam, Kesi mpta, Zeposia, and Extavia are non-preferred and should not be inclu

	ded in denial to provider. **Tysabri, Ocrevus, and Lemtrada are medic al benefit and should not be included in denial to provider.

Product Name: Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Mavenclad treatment **AND** **2** - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)] **AND** **3** - Patient has not exceeded the FDA (Food and Drug Administration)-recommended limit of 2 treatment courses (4 treatment cycles) of Mavenclad	
Notes	Duration of coverage will be limited to 1 reauthorization to allow 2 cum ulative treatment courses (4 treatment cycles) of Mavenclad therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99755 Mekinist

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mekinist	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

- Prescribed as adjuvant therapy for melanoma involving the lymph nodes
- Used in combination with Tafinlar (dabrafenib)

OR

2 - Cancer is positive for BRAF V600 mutation

Product Name: Mekinist	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic thyroid cancer (ATC)

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - ONE of the following:

4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced

- Unresectable

OR

4.2 Prescribed as adjuvant therapy following resection

Product Name: Mekinist	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has metastatic brain lesions

AND

2 - Mekinist is active against primary tumor (melanoma)

AND

3 - Used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Melanoma, Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Product Name: Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Mekinist will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mekinist therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99756 Mektovi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Unresectable melanoma

- Metastatic melanoma

AND

2 - Patient is positive for BRAFV600 mutation

AND

3 - Used in combination with Braftovi (encorafenib)

AND

4 - ONE of the following:

4.1 Patient has a contraindication or history of intolerance to ONE of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

4.3 For continuation of prior Mektovi therapy

Product Name: Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with Braftovi (encorafenib)

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Mektovi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mektovi therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99474 Mepron

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Mepron, generic atovaquone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 The patient has a diagnosis (e.g. human immunodeficiency virus [HIV]) warranting Pneumocystis jirovecii pneumonia (PCP) infection prophylaxis

AND

1.1.2 The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone

OR

1.2 BOTH of the following:

1.2.1 The patient has a diagnosis of mild to moderate pneumonia caused by P. jirovecii

AND

1.2.2 The patient has a documented intolerance, contraindication, or history of treatment failure to TMP-SMX

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99475 Migranal

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Migranal, Generic dihydroergotamine mesylate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - History of failure, contraindication, or intolerance to TWO preferred 5-HT1 (5-hydroxytryptamine-1) receptor agonist (triptan) alternatives [eg, Imitrex (sumatriptan), Maxalt or Maxalt-MLT (rizatriptan)]

Product Name: Brand Migranal*, Generic dihydroergotamine mesylate*	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by, or in consultation with, ONE of the following:

- Neurologist
- Pain management specialist

AND

3 - ONE of the following:

3.1 Currently receiving prophylactic therapy with at least ONE of the following agents in patients experiencing two or more migraines monthly:

- Amitriptyline (Elavil)
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol**
- Divalproex sodium (Depakote/Depakote ER)
- Topiramate (Topamax)
- Venlafaxine (Effexor/Effexor XR)

OR

3.2 Patient has a contraindication or intolerance to ALL of the following, in patients experiencing two or more migraines monthly:

- Amitriptyline (Elavil)
- ONE of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol**
- Divalproex sodium (Depakote/Depakote ER)
- Topiramate (Topamax)
- Venlafaxine (Effexor/Effexor XR)

AND

4 - BOTH of the following:

4.1 ONE of the following:

4.1.1 Higher dose or quantity is supported by the manufacturer's prescribing information

OR

4.1.2 Higher dose or quantity is supported by ONE of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System
- Clinical pharmacology

OR

4.1.3 Physician provides evidence to support safety and additional efficacy at higher than maximum doses as documented in published biomedical literature demonstrating safety and efficacy of doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

4.2 Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	*Quantity requests exceeding the limited amount per month for frequently occurring migraines will be approved by a clinical pharmacist. **Nadolol and timolol are non-preferred and should not be included in denial to provider

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-108624 Monurol

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/23/2022

1 . Criteria

Product Name: Monurol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The provider has submitted labs showing the culture and sensitivity is positive for Monural and negative to Ciprofloxacin or Nitrofurantoin

OR

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Ciprofloxacin
- Nitrofurantoin

2 . Revision History

Date	Notes
6/23/2022	Added product name to criteria section, no change to criteria

Prior Authorization Guideline

GL-99625 Mozobil

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mozobil	
Approval Length	4 Days*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Patients with non-Hodgkin’s lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation

• Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation **AND** **2** - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)] **AND** **3** - Prescribed by, or in consultation with, a hematologist/oncologist	
Notes	*Authorization will be issued for 1 course of therapy (up to four days of therapy).

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-105532 MS Agents - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Gilenya, Brand Copaxone 20 mg, Brand Glatopa 40 mg, Avonex, Rebif, Betaseron, Extavia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS)	

Product Name: GLATIRAMER 20mg, Brand GLATOPA 20mg, GLATIRAMER 40mg, Brand COPAXONE 40mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of one of the preferred alternatives * NOTE: Drug May Require PA

- Interferon Beta-1B (Extavia)
- Fingolimod (Gilenya)
- Interferon Beta-1A (Refib, Avonex)

AND

3 - If the request is for GLATIRAMER 20mg or brand GLATOPA 20mg, patient must have tried and failed brand COPAXONE 20mg If the request is for GLATIRAMER 40mg or brand COPAXONE 40mg, patient must have tried and failed brand GLATOPA 40mg.

Notes	* Note: Preferred Drug may require PA

Product Name: Vumerity, Bafiertam, Kesimpta, Tecfidera, Plegridy, Aubagio, Mayzent	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred alternatives * NOTE: Drug May Require PA

- Interferon Beta-1B (Extavia)
- Fingolimod (Gilenya)
- Brand Copaxone 20mg
- Brand Glatopa 40mg
- Interferon Beta-1A (Refib, Avonex)

Notes	* Note: Preferred Drug may require PA

Product Name: Gilenya, Brand Copaxone 20 mg, Brand Glatopa 40 mg, Avonex, Rebif, Betaseron, Extavia, GLATIRAMER 20mg, Brand GLATOPA 20mg, GLATIRAMER 40mg, Brand COPAXONE 40mg, Vumerity, Bafiertam, Kesimpta, Tecfidera, Plegridy, Aubagio, Mayzent	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/31/2022	Added new GPI for Mayzent starter pack

Prior Authorization Guideline

GL-99521 Mulpleta

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mulpleta	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of thrombocytopenia	

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - History of failure, contraindication, or intolerance to the preferred alternatives

- Nyplate (romiplostim)*
- Promacta (eltrombopag olamine)*

Notes	*Drugs may require PA

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Multaq

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99476 Multaq

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Multaq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)
- Persistent AF defined as AF less than 6 months duration

AND

1.1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.1.3 Patient does not have New York Heart Association (NYHA) Class IV heart failure

AND

1.1.4 Patient does not have symptomatic heart failure with recent decompensation requiring hospitalization

OR

1.2 For continuation of current therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99626 Myalept

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Congenital generalized lipodystrophy associated with leptin deficiency

- Acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Documentation demonstrates that patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (triglycerides greater than 250 milligrams per deciliter) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99477 Mytesi

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Mytesi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) associated diarrhea	

2 . Revision History

Date	Notes
3/11/2021	Bulk copy C&S Arizona standard to Medicaid Arizona

Prior Authorization Guideline

GL-99542 Nadolol

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nadolol	
Diagnosis	PA required for children over the age of 18
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to 3 of the following:

- atenolol
- atenolol/chlorthalidone
- bisoprolol fumarate

- bisoprolol/hydrochlorothiazide
- carvedilol
- labetalol HCl
- metoprolol succinate
- metoprolol tartrate
- metoprolol/hydrochlorothiazide
- propranolol HCl
- propranolol/hydrochlorothiazide
- sotalol HCl

2 . Revision History

Date	Notes
6/7/2021	7/1 Implementation

Prior Authorization Guideline

GL-99478 Namzaric

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Namzaric	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 History of BOTH of the following:

1.1.1 Memantine (generic Namenda)

AND

1.1.2 Donepezil (generic Aricept)

AND

1.2 Patient is stabilized on 10mg of donepezil once daily

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99627 Natpara

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

AND

1.2 25-hydroxy vitamin D level is above the lower limit of the normal laboratory reference range

AND

1.3 Patient is currently on active vitamin D (calcitriol) therapy

AND

1.4 Total serum calcium level (albumin corrected) is above 7.5 milligrams per deciliter

AND

2 - ONE of the following:

2.1 Patient is currently on calcium supplementation of 1-2 grams per day of elemental calcium in divided doses

OR

2.2 Patient has a contraindication to calcium supplementation

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Product Name: Natpara	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 milligrams per deciliter)

AND

2 - Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99479 Nayzilam and Valtoco

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of epilepsy	

AND

2 - Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

Product Name: Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Valtoco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

AND

4 - One of the following:

4.1 Patient is less than 12 years of age

OR

4.2 History of failure, contraindication, or intolerance to Nayzilam

Product Name: Valtoco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99757 Nerlynx

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nerlynx	
Diagnosis	Early-Stage Breast Cancer
Approval Length	12 Months*
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of early-stage breast cancer	

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Patient has received adjuvant trastuzumab-based therapy (e.g., Herceptin, Kanjinti)

Notes	Authorization will be issued for 12 months. Duration of coverage is limi ted to 12 months per occurence

Product Name: Nerlynx	
Diagnosis	Breast Cancer with Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient has brain metastases

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with ONE of the following:

- Xeloda (capecitabine)
- Paclitaxel

Product Name: Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Patient has received two or more prior anti-HER2 based regimens in metastatic setting

AND

4 - Will be used in combination with Xeloda (capecitabine)

Product Name: Nerlynx	
Diagnosis	Breast Cancer with Brain Metastases; or Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nerlynx therapy

Product Name: Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nerlynx will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nerlynx therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99758 Nexavar

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nexavar	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell carcinoma (RCC)	

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following:

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

Product Name: Nexavar	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

2.1 Patient has metastatic disease

OR

2.2 Patient has extensive liver tumor burden

OR

2.3 Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only)

OR

2.4 BOTH of the following:

- Patient is not a transplant candidate
- Disease is unresectable

Product Name: Nexavar	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease

- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Nexavar	
Diagnosis	Soft Tissue Sarcoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of angiosarcoma

OR

2 - Diagnosis of desmoid tumors / aggressive fibromatosis

OR

3 - BOTH of the following:

3.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

3.2 History of failure, contraindication, or intolerance to ONE of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

OR

4 - Diagnosis of solitary fibrous tumor/hemangiopericytoma

Product Name: Nexavar	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of chordoma

AND

1.2 Disease is recurrent

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of osteosarcoma
- Diagnosis of dedifferentiated chondrosarcoma
- Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

AND

2.2 Not used as first-line therapy

Product Name: Nexavar	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has FLT3-ITD mutation-positive disease

AND

3 - ONE of the following:

- Patient has relapsed disease
- Patient has refractory disease

AND

4 - Used in combination with ONE of the following:

- Vidaza (azacitidine)
- Dacogen (decitabine)

AND

5 - Patient is unable to tolerate more aggressive treatment regimens

Product Name: Nexavar	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ovarian cancer
- Fallopian tube cancer

- Primary peritoneal cancer

AND

2 - ONE of the following:

- Patient has persistent disease
- Patient has recurrent disease

AND

3 - Disease is platinum-resistant

AND

4 - Used in combination with topotecan

Product Name: Nexavar	
Diagnosis	Renal Cell Carcinoma (RCC), Hepatocellular Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma, Bone Cancer, Acute Myeloid Leukemia, Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nexavar therapy

Product Name: Nexavar	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nexavar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Nexavar	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nexavar therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107439 Nexiclon XR (clonidine ER)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Nexiclon XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure, contraindication, or intolerance to one of the following (verified via paid pharmacy claims or submitted chart notes):

- generic clonidine oral tablet
- generic clonidine topical patch

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

GL-99480 Nexletol, Nexlizet

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)

- Atherosclerotic cardiovascular disease (ASCVD)

AND

2 - ONE of the following:

2.1 Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e. atorvastatin 40-80 mg (milligrams), rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate- intensity statin therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK [creatine kinase] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Documentation of ONE of the following LDL-C (low-density lipoprotein cholesterol) values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL (milligrams per deciliter) with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Documentation of ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Documentation of ONE of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

AND

2 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99628 Nityr- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

AND

2 - Prescriber provides a reason or special circumstance the patient cannot use Orfadin (nitisinone) capsules or suspension

Product Name: Nityr	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response (e.g. decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Nityr therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99505 Nocdurna

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nocdurna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name: Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient has routine monitoring for serum sodium levels

AND

3 - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

2 . Revision History

Date	Notes
3/11/2021	Bulk copy from C&S Medicaid to Arizona Medicaid for 7/1 eff

Prior Authorization Guideline

GL-104403 Non-Preferred Drugs - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/4/2022

1 . Criteria

Product Name: Non-Preferred Drugs	
Approval Length	12 months*
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

- If there are at least three preferred alternatives, history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to at least

THREE preferred alternatives (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*

- If there are fewer than three preferred alternatives, the patient must have a history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*
- There are no preferred formulary alternatives for the requested drug*

AND

1.2 If the request is for a multi-source brand medication (i.e., MSC O) ONE of the following:

1.2.1 BOTH of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications.
- If there are generic product(s), the member has tried at least three (if available)

OR

1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure).
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.
- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program**

OR

2 - If the requested medication is a behavioral health medication, ONE of the following:

- The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days).
- The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge.

Notes	*Anti-infectives: Approve for the requested time frame, or if duration is not specified approve the request for 30 days. *Controlled Substances shall be approved for the requested time. If there is not a requested time period and it is not clear in the directions, approve for one time only. *Other medications: Approved for the requested time frame, or if duration is not specified, approve for 12 months. * For Non-Preferred Generics (i.e. MSC=Y) approvals: Please approve at MSC=Y only. For preferred alternatives, use the non-preferred alternatives grid to identify appropriate alternatives: https://uhgazure.sharepoint.com/sites/CST/

	CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FAZM%2FNF%20Alt%20Tables **Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, or sexual dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
3/4/2022	Updated MSC criterion verbiage. Attached to Specialty formulary.

Prior Authorization Guideline

GL-104403 Non-Preferred Drugs - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/4/2022

1 . Criteria

Product Name: Non-Preferred Drugs	
Approval Length	12 months*
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

- If there are at least three preferred alternatives, history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to at least THREE preferred alternatives (Prior trials of formulary/preferred drug list (PDL)

alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*

- If there are fewer than three preferred alternatives, the patient must have a history of trial per member's pharmacy claims resulting in a therapeutic failure, contraindication, or intolerance to ALL of the preferred products (Prior trials of formulary/preferred drug list (PDL) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)*
- There are no preferred formulary alternatives for the requested drug*

AND

1.2 If the request is for a multi-source brand medication (i.e., MSC O) ONE of the following:

1.2.1 BOTH of the following:

- The brand is being requested because of an adverse reaction, allergy or sensitivity to the generic and the prescriber must attest to submitting the FDA MedWatch Form for allergic reactions to the medications.
- If there are generic product(s), the member has tried at least three (if available)

OR

1.2.2 ONE of the following:

- The brand is being requested due to a therapeutic failure with the generic (please provide reason for therapeutic failure).
- The brand is being requested because transition to the generic could result in destabilization of the patient (rationale must be provided)
- Special clinical circumstances exist that preclude the use of the generic equivalent of the multi-source brand medication for the patient (rationale must be provided)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- The requested drug must be used for a Food and Drug Administration (FDA)-approved indication.
- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program**

OR

2 - If the requested medication is a behavioral health medication, ONE of the following:

- The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days).
- The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge.

Notes	*Anti-infectives: Approve for the requested time frame, or if duration is not specified approve the request for 30 days. *Controlled Substances shall be approved for the requested time. If there is not a requested time period and it is not clear in the directions, approve for one time only. *Other medications: Approved for the requested time frame, or if duration is not specified, approve for 12 months. * For Non-Preferred Generics (i.e. MSC=Y) approvals: Please approve at MSC=Y only. For preferred alternatives, use the non-preferred alternatives grid to identify appropriate alternatives: https://uhgazure.sharepoint.com/sites/CST/

	CSDM/Shared%20Documents/Forms/AllItems.aspx?FolderCTID=0x01200027C80175A8369D44AC45A99A99328B80&View=%7B4B6D25AD%2D6A95%2D496D%2D9937%2D65CECD43AFE7%7D&viewid=c2ad0afa%2D814c%2D499e%2Dbf25%2D3411fac9171f&id=%2Fsites%2FCST%2FCSDM%2FShared%20Documents%2FAZM%2FNF%20Alt%20Tables **Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, or sexual dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
3/4/2022	Updated MSC criterion verbiage. Attached to Specialty formulary.

Prior Authorization Guideline

GL-99528 Non-Preferred Prenatal Vitamins

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Non-Preferred Prenatal Vitamins	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - History of failure, contraindication, or intolerance to ALL of the following preferred products:*	
Notes	*Please refer to the background table for the alternatives

2 . Background

Benefit/Coverage/Program Information

Preferred Products:

GPI-14	Product ID	Product Label	GPI-14 Description
78512000000315	73317105009	PRENATVITE TAB RX	*PRENATAL MULTIVITAMINS & MINERALS W/IRON & FA TAB 0.8 MG***
78512010000330	69543026790	PNV TABS TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	60258019309	PRENATABS RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070510	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070516	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	42937070518	PRENATAL+FE TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	58657013390	THRIVITE RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	71186001924	VIL-RX TAB 29-1MG	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000330	13811051690	VOL-TAB RX TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 29-1 MG***
78512010000352	13811002710	ELITE-OB TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512010000352	68025001010	OB COMPLETE TAB	*PRENATAL VIT W/ IRON CARBONYL-FA TAB 50-1.25 MG***
78512015000324	58657017001	M-NATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	12830080001	M-VIT TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	70898022001	NEONATAL TAB COMPLTE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***

78512015000324	70898011501	NEONATAL PLS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	75834005001	NIVA-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	00813931601	O-CAL FA TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	71399624609	ONE VITE TAB 1MG PLUS	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010610	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	39328010650	PRENATAL TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015001	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	63044015005	PRENATAL VIT TAB LOW IRON	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025810	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69543025850	PREPLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	67112010100	TRICARE TAB PRENATAL	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	17139080030	VITATHELY TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051910	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	13811051950	VOL-PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000324	69367026701	WESTAB PLUS TAB 27-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 27-1 MG***
78512015000329	60258019201	TRINATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***
78512015000329	13811051410	VOL-NATE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 28-1 MG***

78512015000332	10267227001	CO-NATAL FA TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000332	73317828601	NEONATAL TAB COMPLETE	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000332	69543025910	PRETAB TAB 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 29-1 MG***
78512015000360	13811000710	TRINATAL RX TAB 1	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000360	51991056601	VINATE ONE TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 60-1 MG***
78512015000366	58607081120	MYNATAL PLUS TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	58607010565	MYNATAL-Z TAB	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000366	00642007912	VITAFOL-OB TAB 65-1MG	*PRENATAL VIT W/ FE FUMARATE-FA TAB 65-1 MG***
78512015000530	13811001490	COMPLETENATE CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070710	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070716	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	42937070718	PRENATAL 19 CHW 29-1MG	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	60258019701	PRENATAL 19 CHW TAB	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***
78512015000530	13925011701	SE-NATAL 19 CHW	*PRENATAL VIT W/ FE FUMARATE-FA CHEW TAB 29-1 MG***

78512016000130	13811004930	ULTIMATECARE CAP ONE	*PRENATAL VIT W/ FE CBN-FE ASP GLYC-FA-OMEGA 3 CAP 27-1MG***
78512018000116	23359010530	C-NATE DHA CAP 28-1-200	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	23359020030	RELNATE DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	69543037030	VIRT-NATE CAP DHA	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512018000116	64661008030	VIVA DHA CAP	*PRENATAL VIT W/ FE FUM-FA-OMEGA 3 CAP 28-1-200 MG***
78512022000320	69543024190	VIRT-PN TAB	*PRENATAL VIT W/ FE FUM-METHYLFOLATE-FA TAB 27-0.6-0.4 MG***
78512046000330	55495012501	ATABEX OB TAB 29-1MG	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512046000330	51991017801	VINATE II TAB	*PRENATAL VIT W/ FE BISGLYCINATE CHELATE-FA TAB 29-1 MG***
78512051000327	00178085890	CITRANATAL TA B RX	*PRENATAL W/O A W/ FE CARBONYL-FE GLUC-DSS-FA TAB 27-1MG***
78512058000150	52747062030	CONCEPT OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512058000150	13811053530	FOLIVANE-OB CAP	*PRENATAL W/O A W/FE FUM-FE POLY-FA CAP 130-92.4-1 MG***
78512060000325	51991015501	VINATE M TAB	*PRENATAL VIT W/ SEL-FE FUMARATE-FA TAB 27-1 MG***
78512070000330	42937070610	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070616	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512070000330	42937070618	PRENATAL 19 TAB 29-1MG	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***

78512070000330	13925011601	SE-NATAL 19 TAB	*PRENATAL VIT W/ DSS-FE FUMARATE-FA TAB 29-1 MG***
78512091000135	52747062130	CONCEPT DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	58657012130	DOTHELLE DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	13811053630	TARON-C DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78512091000135	76439033130	VIRT-C DHA CAP	*PRENATAL W/FE FUM-FE POLY -FA-OMEGA 3 CAP 53.5-38-1 MG***
78516020006330	00642007630	VITAFOL-OB PAK +DHA	*PRENATAL MV W/FE FUM-FA TAB 65-1 MG & DHA CAP 250 MG PACK *
78516032000130	00642007030	VITAFOL-ONE CAP	*PRENATAL MV W/ FE POLYSAC CMPLX-FA-DHA CAP 29-1-200 MG***
78516032006325	00642007530	SELECT-OB+ PAK DHA	*PRENATAL MV W/FE POLY-FA CHW 29-1 MG & DHA CAP 250 MG PAK *

3 . Revision History

Date	Notes
5/18/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107420 Norliqva (amlodipine oral solution)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/25/2022

1 . Criteria

Product Name: Norliqva	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to generic amlodipine tablets (verified via paid pharmacy claims or submitted chart notes)

OR

2.2 One of the following:

- Patient is 8 years of age or younger
- Patient is unable to swallow oral tablets/capsules

2 . Revision History

Date	Notes
5/23/2022	New Program

Prior Authorization Guideline

GL-99629 Northera

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Northera	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

- At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure

- At least a 10 mm Hg fall in diastolic pressure

AND

2 - nOH caused by ONE of the following:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

AND

4 - The patient has tried at least TWO of the following non-pharmacologic interventions:

- Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
- Raising the head of the bed 10 to 20 degrees
- Compression garments to the lower extremities or abdomen
- Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
- Increased salt and water intake, if appropriate
- Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

AND

5 - No previous diagnosis of supine hypertension

AND

6 - Prescribed by, or in consultation with, ONE of the following specialists:

- Cardiologist

- Neurologist
- Nephrologist

AND

7 - History of failure (after a trial of at least 30 days), contraindication or intolerance to BOTH of the following medications:

- Florinef (fludrocortisone)
- ProAmatine (midodrine)

Product Name: Northera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Northera therapy

AND

2 - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99481 Nourianz

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nourianz	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Parkinson’s disease	

AND

2 - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing “off” episodes

AND

3 - History of failure, contraindication, or intolerance to TWO anti-Parkinson’s disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name: Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nourianz therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99760 Nubeqa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nubeqa	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - Disease is castration-resistant or recurrent

AND

3 - Disease is non-metastatic

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name: Nubeqa	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nubeqa therapy

Product Name: Nubeqa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nubeqa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Nubeqa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nubeqa therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-108527 Nucala (mepolizumab)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims):

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications (verified via paid pharmacy claims)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone)

AND

3 - Used in combination with another agent for CRSwNP

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])

AND

2 - Used in combination with another agent for CRSwNP

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient has been diagnosed for at least 6 months

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

2 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320

Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	200		400
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

***This is not a table of equivalence**,* but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

3 . Revision History

Date	Notes
6/22/2022	Updated criteria for all approved indications

Prior Authorization Guideline

GL-99482 Nuedexta

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuedexta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pseudobulbar affect (PBA)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99483 Nuplazid

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Parkinson’s disease	

AND

2 - Patient is currently experiencing hallucinations and delusions associated with Parkinson's disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

Product Name: Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nuplazid therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99586 Nurtec Ubrelvy - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to FOUR of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)
- Imitrex nasal spray (Brand only)

AND

3 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain specialist
- Headache specialist*

AND

4 - One of the following:

4.1 Patient is currently treated with TWO of the following prophylactic therapies as evidenced by submission of medical records or claims history:

- amitriptyline (Elavil)
- A beta-blocker (i.e., atenolol, metoprolol, or propranolol)
- divalproex sodium [(Depakote/Depakote ER (extended release)]
- topiramate (Topamax)
- venlafaxine [Effexor/Effexor XR (extended release)]

OR

4.2 The patient has less than 4 migraine days per month

OR

4.3 Both of the following:

4.3.1 The patient has greater than or equal to 4 migraine days per month

AND

4.3.2 Patient has a history of failure, contraindication, or intolerance to TWO of the following prophylactic therapies as evidenced by submission of medical records or claims history:

- amitriptyline (Elavil)
- A beta-blocker (i.e., atenolol, metoprolol, or propranolol)
- divalproex sodium (Depakote/Depakote ER)
- topiramate (Topamax)
- venlafaxine (Effexor/Effexor XR)

AND

5 - Patient has tried ALL of the following calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine:

- Ajovy (fremanezumab)
- Emgality (galacanezumab)
- Aimovig (erenumab-aooe)

AND

6 - This medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (i.e., Nurtec)

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS)

Product Name: Nurtec ODT	
Diagnosis	Migraine
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnosis:

1.1 Used for acute treatment of migraine

OR

1.2 Used for preventive treatment of episodic migraine

AND

2 - BOTH of the following:

2.1 Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to TWO of the following as evidenced by submission of medical records or claims history:

- naratriptan tablets
- rizatriptan tablets/ODT (Oral Disintegrating Tablets)
- sumatriptan auto injection/cartridge
- Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT
- Zomig nasal spray (Brand only)

AND

2.2 Patient has a history of a one-month trial resulting in therapeutic failure, contraindication, or intolerance to Ubrelvy as evidenced by submission of medical records or claims history

AND

3 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist

- Pain specialist
- Headache specialist*

AND

4 - One of the following:

4.1 Patient is currently treated with TWO of the following prophylactic therapies as evidenced by submission of medical records or claims history:

- amitriptyline (Elavil)
- A beta-blocker (i.e., atenolol, metoprolol, or propranolol
- divalproex sodium [(Depakote/Depakote ER (extended release)]
- topiramate (Topamax)
- venlafaxine [Effexor/Effexor XR (extended release)]

OR

4.2 The patient has less than 4 migraine days per month

OR

4.3 Both of the following:

4.3.1 The patient has greater than or equal to 4 migraine days per month

AND

4.3.2 Patient has a history of failure, contraindication, or intolerance to TWO of the following prophylactic therapies as evidenced by submission of medical records or claims history:

- amitriptyline (Elavil)
- A beta-blocker (i.e., atenolol, metoprolol, or propranolol)
- divalproex sodium (Depakote/Depakote ER)
- topiramate (Topamax)
- venlafaxine (Effexor/Effexor XR)

AND

5 - Patient has tried ALL of the following calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine:

- Ajovy (fremanezumab)
- Emgality (galacanezumab)
- Aimovig (erenumab-aooe)

AND

6 - This medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (i.e., Ubrelvy)

Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS) ***CGRP antagonists for preven tive treatment of migraines require a prior authorization.

Product Name: Ubrelvy, Nurtec ODT	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - This medication will not be used in combination with another calcitonin gene-related peptide receptor (CGRP) antagonist (i.e., Nurtec ODT for Ubrelvy requests, Ubrelvy for Nurtec ODT requests, Aimovig, Ajovy, & Emgality)

2 . Revision History

Date	Notes
9/30/2021	UM criteria update per SN TSK003786763 eff 10.15.2021

Prior Authorization Guideline

GL-99522 Nuzyra

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Nuzyra	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.3.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics or antibiotic regimens:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Nuzyra	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 ALL of the following:

1.3.1 ONE of the following diagnoses:

1.3.1.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.1.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.3 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline

- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

1.4.3 History of failure, contraindication, or intolerance to THREE of the following antibiotics:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

Product Name: Nuzyra	
Diagnosis	Off-Label Uses*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist.	
Notes	*Note: Authorization duration based on provider treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-100643 OAB Agents- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Product Name: Oxytrol (Rx) patch, trospium ER, brand Enablex, generic darifenacin ER, Brand Vesicare, generic solifenacin, Myrbetriq, Gelnique, brand Ditropan XL, Flavoxate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient has a history of failure, contraindication, or intolerance to a trial of THREE preferred products

- oxybutynin (generic Ditropan)
- oxybutynin ER (generic Ditropan XL)
- Brand Detrol
- Brand Detrol LA
- Toviaz (fesoterodine)

2 . Revision History

Date	Notes
12/16/2021	update guideline for new formulary no changes to criteria

Prior Authorization Guideline

GL-99630 Ocaliva

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of primary biliary cholangitis (aka primary biliary cirrhosis)	

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid(e.g., Urso, ursodiol)

AND

2.1.2 Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

3 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in

alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy) while on Ocaliva therapy

AND

2 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99686 Odomzo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of metastatic basal cell carcinoma (BCC)

OR

2 - Both of the following:

2.1 Diagnosis of locally advanced basal cell carcinoma

AND

2.2 ONE of the following:

- Cancer has recurred following surgery
- Cancer has recurred following radiation
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name: Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Odomzo therapy.

Product Name: Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Odomzo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Odomzo therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99723 Olumiant- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Olumiant	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (document drug, date, and duration of trial)*

AND

1.3 History of failure, contraindication, or intolerance to ALL of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving Olumiant in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Olumiant therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis moderately to severely active rheumatoid arthritis RA

AND

2.3 Patient is not receiving Olumiant in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Olumiant	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Olumiant therapy

AND

2 - Patient is not receiving Olumiant in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Xeljanz/Xeljanz XR (tofacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-102887 Opzelura (ruxolitinib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of mild to moderate atopic dermatitis	

AND

2 - One of the following:

- Greater than or equal to 3% body surface area (BSA) involvement
- Involvement of sensitive body areas (e.g., face, hands, feet, scalp, groin)

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply of non-pharmacologic topical therapies (e.g., moisturizers) [2]

AND

6 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least TWO of the following:

- Medium or higher potency topical corticosteroid
- Elidel (pimecrolimus) cream*
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment*

AND

7 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

8 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

Notes	*Product may require step therapy

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in pruritus severity from baseline
- Improvement in quality of life from baseline

AND

2 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

3 - Opzelura will only be used for short-term and/or non-continuous chronic treatment

2 . Background

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005

	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium	Hydrocortisone butyrate	Cream, ointment, solution	0.1
potency	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Endnotes

A. Opzelura should be discontinued when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be reexamined by their healthcare provider.

4 . References

1. Opzelura Prescribing Information. Incyte Corp. Wilmington, DE. September 2021.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.

5 . Revision History

Date	Notes

2/3/2022	New Program

Prior Authorization Guideline

GL-108949 Oral Oncology Agents

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Non-Preferred Oral Oncology Drugs	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B	

2 . Revision History

Date	Notes
7/1/2022	Updated product list to contain only oral oncology agents.

Prior Authorization Guideline

GL-108949 Oral Oncology Agents

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Non-Preferred Oral Oncology Drugs	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
7/1/2022	Updated product list to contain only oral oncology agents.

Orencia- Arizona

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99812 Orencia- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Orencia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderately to severely active rheumatoid arthritis	

AND

2 - Patient is not receiving Orencia in combination with ALL of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 History of failure to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial and claims history must be verified)

AND

3.1.2 History of failure, contraindication, or intolerance as verified by claims history to ALL of the following

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Orencia therapy as documented by 3 months of prior claims history or submission of medical records (document drug, date, and duration of therapy)

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Orencia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is not receiving Orencia in combination with ALL of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 History of failure to a 3-month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial, claims history must be verified)

AND

3.1.2 History of failure, contraindication, or intolerance as verified by claims history to THREE of the following

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Orencia therapy as documented by 3 months of prior claims history or submission of medical records (document drug, date, and duration of therapy)

AND

4 - Prescribed by or consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Orencia	
Diagnosis	Juvenile Idiopathic Arthritis (JIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active juvenile idiopathic arthritis

AND

2 - Patient is not receiving Orencia in combination with ALL of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - ONE of the following:

3.1 History of failure, contraindication, or intolerance as verified by claims history to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

OR

3.2 Patient is currently on Orencia therapy as documented by 3 months of prior claims history or submission of medical records (document drug, date, and duration of therapy)

AND

4 - Prescribed by or consultation with a rheumatologist

Product Name: Orencia	
Diagnosis	Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orencia therapy

AND

2 - Patient is not receiving Orencia in combination with ALL of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Orencia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orencia therapy

AND

2 - Patient is not receiving Orencia in combination with ALL of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

2 . Revision History

Date	Notes

11/11/2021	Specified paid claims/submission of records where applicable, changed concomitant tx criterion to ALL.

Orfadin- Arizona

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99631 Orfadin- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hereditary tyrosinemia type 1	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Oriahnn

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99484 Oriahnn

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Oriahnn	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of uterine fibroids (leiomyomas)	

AND

2 - Used for the management of heavy menstrual bleeding

AND

3 - Patient is premenopausal

AND

4 - History of trial and failure, contraindication, or intolerance after a three-month trial to ONE of the following:

- Estrogen/progestin contraceptive (e.g., Loestrin FE)
- Progestin-releasing intrauterine devices (IUDs) (e.g., Mirena)*
- Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

AND

5 - History of trial and failure, contraindication or intolerance after a three-month trial of tranexamic acid (e.g., Lysteda)

AND

6 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes	*This is a medical benefit, should not be included in denial to provider

Product Name: Oriahnn	
Approval Length	6 months*
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy **AND** **2** - Impact to bone mineral density has been considered **AND** **3** - Treatment duration has not exceeded a total of 24 months**	
Notes	*Authorization will be issued for 6 months up to a maximum of 24 months **Oriahnn is indicated for a maximum of 24 months

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7/1 go live

Orilissa

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99485 Orilissa

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe pain associated with endometriosis	

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Product Name: Orilissa 150 mg	
Approval Length	6 months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months**

Notes	*NOTE: Authorization for Orilissa 150 mg will be issued for 6 months up to a maximum of 24 months. **NOTE: Orilissa 150 mg once daily i s indicated for a maximum of 24 months.

Product Name: Orilissa 200 mg	
Approval Length	6 months*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Patient is premenopausal

AND

3 - History of trial and failure (e.g., inadequate pain relief), contraindication or intolerance after a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen)

AND

4 - History of trial and failure, contraindication, or intolerance after a three month trial to ONE of the following:

• Hormonal contraceptives • Progestins [e.g., norethindrone (generic Aygestin)] **AND** **5** - Prescribed by or in consultation with ONE of the following: • Obstetrics/Gynecologist (OB/GYN) • Reproductive endocrinologist	
Notes	*NOTE: Orilissa 200 mg twice daily is indicated for a maximum of 6 m onths.

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99632 Orkambi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

AND

3 - The patient is greater than or equal to 2 years of age

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Orkambi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99486 Osphena - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*

AND **2** - History of failure, contraindication, or intolerance to BOTH of the following: • Estradiol vaginal cream • Estradiol vaginal tablet

Notes	*Treatment of dyspareunia is a benefit exclusion.

Product Name: Osphena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Otezla

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99724 Otezla

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of active psoriatic arthritis	

AND

2 - History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behcet's Disease

AND

2 - Patient has active oral ulcers

AND

3 - History of failure, contraindication, or intolerance to one non-biologic (e.g., corticosteroids, colchicine) within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis, Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

3 - Both of the following:

3.1 History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

4 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/13/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-102750 Oxbryta (voxelotor)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/3/2022

1 . Criteria

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of sickle cell disease	

AND

2 - Patient is 4 years of age or older

AND

3 - One of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin (Hb) less than or equal to 10.5 grams per deciliter

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Oxbryta	
Diagnosis	Sickle Cell Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least one of the following:

1.1 Increase in hemoglobin (Hb) by greater than or equal to 1 gram per deciliter from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

4 - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
2/3/2022	Updated age criterion due to expanded indication

Prior Authorization Guideline

GL-99634 Oxervate

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Oxervate	
Diagnosis	Neurotrophic keratitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Stage 2 or 3 neurotrophic keratitis	

AND

2 - History of failure to at least one OTC ocular artificial tear product (e.g., Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe® XP)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99635 Palforzia

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L (kilo units of allergen per liter)

AND

1.2 A meal wheal diameter that is at least 3mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have one of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist or immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist or immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes

3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99636 Palynziq

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - Physician attestation that the patient will not be receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride)

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles per liter

Product Name: Palynziq	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles per liter

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting that the

patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 BOTH of the following:

2.3.1 Patient is in initial titration/maintenance phase of dosing regimen (week 1-33)

AND

2.3.2 Patient will receive maximum labeled dosage of 40 milligrams (mg) once daily if response has not been obtained after 24 weeks of 20 mg once daily maintenance dosing

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) [Prescription claim history that does not show any concomitant Kuvan claim within 60 days of reauthorization request may be used as documentation]

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99511 Panretin

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Panretin	
Diagnosis	AIDS-related Kaposi's Sarcoma (KS)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acquired immunodeficiency syndrome (AIDS)-related Kaposi's Sarcoma (KS)	

AND

2 - Patient is not receiving systemic anti-KS treatment

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Panretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Panretin therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-105258 Pediculicides - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Sklice, Brand Natroba, generic spinosad susp	
Diagnosis	Head lice
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of topical treatment of head lice infestations	

AND

2 - For Brand Natroba requests ONLY: Trial and failure to generic spinosad suspension (verified via paid pharmacy claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
3/28/2022	Added step through generic for Brand Natroba.

Prior Authorization Guideline

GL-99687 Pemazyre

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cholangiocarcinoma	

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

AND

4 - Patient has been previously treated

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pemazyre therapy

Product Name: Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Pemazyre will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pemazyre therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Piqray

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99688 Piqray

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Piqray	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA mutations

AND

6 - Patient is ONE of the following:

- Postmenopausal
- Male

AND

7 - Used in combination with fulvestrant

AND

8 - Disease has progressed on or after an endocrine-based regimen

Product Name: Piqray	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Piqray therapy

Product Name: Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Piqray will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Piqray therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Pomalyst

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99761 Pomalyst

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

AND

2 - History of failure, contraindication, or intolerance to BOTH of the following:

- Immunomodulatory agent [e.g. Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g., Velcade (bortezomib)]

Product Name: Pomalyst	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with dexamethasone

Product Name: Pomalyst	
Diagnosis	AIDS-Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired immunodeficiency syndrome (AIDS)-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - NOT used as first-line therapy

Product Name: Pomalyst	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - Used as second-line or subsequent therapy

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma, Systemic Light Chain Amyloidosis, AIDS-Related Kaposi Sarcoma, Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pomalyst therapy

Product Name: Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Pomalyst will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pomalyst therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-102901 Praluent

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/3/2022

1 . Criteria

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of ONE of the following:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) of ONE of the following:

- Greater than 190 milligrams per deciliter (mg/dL)
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C of ONE of the following:

- Greater than 190 mg/dL
- Greater than 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low density lipoprotein), apoB (apolipoprotein B), or PCSK9 (proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata

- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy [i.e. atorvastatin 40-80 milligrams (mg), rosuvastatin 20-40mg] and will continue to receive high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without creatine kinase [CK] elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to

20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Note: Results of prior genetic testing can be submitted as confirmation of diagnosis of HeFH.

Product Name: Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha (evolocumab))

2 . Revision History

Date	Notes
2/3/2022	Added criteria for HoFH indication, removed 'prescriber attestation' cr iterion from all sections

Prior Authorization Guideline

GL-99782 Preferred Drugs- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Diagnosis	Prior Authorization Administrative Guideline for Preferred Drugs Without Drug-Specific Criteria
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

1.3 If the patient is less than FDA minimum age, the prescriber attests they are aware of FDA labeling and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Notes	Medications used solely for anti-obesity/weight loss, cosmetic (e.g., al opecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysf unction purposes are NOT medically accepted indications and are NO T recognized as a covered benefit. Erectile dysfunction drugs (Cialis/T adalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99538 Preferred Drugs- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Diagnosis	Prior Authorization Administrative Guideline for Preferred Drugs Without Drug-Specific Criteria
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

1.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

1.3 If the patient is less than FDA minimum age, the prescriber attests they are aware of FDA labeling and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Notes	Medications used solely for anti-obesity/weight loss, cosmetic (e.g., al opecia, actinic keratosis, vitiligo), erectile dysfunction, and sexual dysf unction purposes are NOT medically accepted indications and are NO T recognized as a covered benefit. Erectile dysfunction drugs (Cialis/T adalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99488 Pretomanid

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pretomanid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

OR

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

AND

2 - Pretomanid will be used in combination with bedaquiline and linezolid

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99507 Prevymis

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Prevymis	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a recipient of an allogeneic hematopoietic stem cell transplant

AND

2 - Patient is cytomegalovirus (CMV)-seropositive

AND

3 - Provider attests that Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

2 . Revision History

Date	Notes
5/21/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99725 Procysbi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of nephropathic cystinosis	

AND **2** - Patient is 1 year of age or older **AND** **3** - History of failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)*

Notes	*Note: AZM generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity

Product Name: Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Procysbi therapy

2 . Revision History

Date	Notes
5/14/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99489 Progesterone - Non-Oral

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Crinone, Endometrin	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99637 Promacta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Promacta	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP)	

AND

2 - History of failure, contraindication, or intolerance to at least ONE of the following:

- Corticosteroids
- Immunoglobulins
- Splenectomy

Product Name: Promacta	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - ONE of the following:

- Planning to initiate and maintain interferon-based treatment

- Currently receiving interferon-based treatment

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C

Product Name: Promacta	
Diagnosis	Aplastic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - One of the following:

2.1 Used in combination with standard immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

OR

2.2 History of failure, contraindication, or intolerance to at least one course of immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

Product Name: Promacta	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99490 Provigil, Nuvigil

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Narcolepsy, Obstructive Sleep Apnea, Shift Work Disorder, Idiopathic Hypersomnia (off label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Narcolepsy
- Excessive sleepiness due to obstructive sleep apnea

- Excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)
- Idiopathic hypersomnia

AND

2 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Fatigue due to Multiple Sclerosis (off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is experiencing fatigue

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment-resistant depression, defined as BOTH of the following:

1.1 Diagnosis of ONE of the following:

- Major depressive disorder (MDD)
- Bipolar depression

AND

1.2 History of failure, contraindication, or intolerance to at least TWO antidepressants from different classes (e.g., SSRIs [selective serotonin reuptake inhibitors], SNRIs [serotonin-norepinephine reuptake inhibitors], bupropion)

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Product Name: Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Diagnosis	Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99809 Pulmonary Arterial Hypertension Agents

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Preferred Products brand Adcirca brand Letairis brand Revatio Suspension brand Tracleer, Sildenafil Citrate Tablets (Generic Revatio). Non Preferred: Generic Alyq tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Veletri injection, or Ventavis inhalation solution, Brand Revatio Injection, Generic Sildenafil injection, Uptravi	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - If the patient is requesting a non preferred product, patient has a history of failure, contraindication or intolerance to at least THREE preferred alternatives.* (NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products.)

- brand Adcirca
- brand Letairis
- brand Revatio Suspension
- brand Tracleer

- Sildenafil Citrate Tablets (Generic Revatio)

AND

6 - If the request is for generic Adcirca, patient must have tried and failed brand Adcirca. If the request is for generic LETAIRIS, patient must have tried and failed brand LETAIRIS. If the request is for generic TRACLEER, patient must have tried and failed brand TRACLEER

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist

- Cardiologist

Product Name: Preferred Products brand Adcirca brand Letairis brand Revatio Suspension brand Tracleer, Sildenafil Citrate Tablets (Generic Revatio). Non Preferred: Generic Alyq tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Veletri injection, or Ventavis inhalation solution, Brand Revatio Injection, Generic Sildenafil injection, Uptravi	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Endnotes

A. Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

3 . References

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. November 2019.
2. Revatio Prescribing Information. Pfizer Inc. New York, NY. February 2020.
3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. December 2019.
4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. October 2017.
5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. July 2018.
6. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
7. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.

8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. May 2019.
9. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. October 2020.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. April 2019.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. January 2018.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. November 2020.
13. Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. September 2019.
14. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. January 2019.

Pulmozyme

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99638 Pulmozyme

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Pulmozyme	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Cystic Fibrosis	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-107467 Pyrukynd (mitapivat)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)

AND

1.2 Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene:

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant
- Patients is not homozygous for the c.1436G>A (p.R479H) variant
- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

1.3 Hemoglobin is less than or equal to 10g/dL

AND

1.4 Patient has symptomatic anemia or is transfusion dependent

AND

1.5 Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs)

AND

2 - Prescribed by or in consultation with a hematologist

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy [e.g., hemoglobin greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)] **AND** **2** - Prescribed by or in consultation with a hematologist	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 1-month authorization should be issued one time for Pyrukynd gradual therapy discontinuation.

2 . Revision History

Date	Notes
5/24/2022	New Program

Qinlock

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99762 Qinlock

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic
- Unresectable

AND

3 - History of failure to ALL of the following:

- imatinib (Gleevec)
- sunitinib (Sutent)
- regorafenib (Stivarga)

Product Name: Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Qinlock therapy

Product Name: Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Qinlock will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Qinlock therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-105259 Ranexa (ranolazine)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Brand Ranexa, generic ranolazine	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of ONE of the following standard anti-angina treatments:

1.1 One beta-blocker [e.g. Lopressor (metoprolol), Inderal (propranolol)]

OR

1.2 One calcium channel blocker [e.g. Procardia XL (nifedipine ER), Cardizem LA/Cardizem CD (diltiazemER)]

OR

1.3 One long acting nitrate therapy [e.g. Imdur (isosorbide mononitrate), Isordil (isosorbide dinitrate), Nitro-Time/Nitro-Dur/Nitro-Bid (nitroglycerin ER)]

AND

2 - For Brand Ranexa requests ONLY: Trial and failure to generic ranolazine (verified via paid pharmacy claims or submission of medical records/chart notes)

2 . Revision History

Date	Notes
3/28/2022	Added step through generic ranolazine for Brand Ranexa

Prior Authorization Guideline

GL-99671 Ravicti

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs)	

AND

2 - Inadequate response to ONE of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

3 - Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

4 - History of failure, contraindication, or intolerance to sodium phenylbutyrate [Buphenyl] *

Notes	*Note: AZM generally does not consider frequency of dosing and or lack of compliance to dosing regimens an indication of medical necessity

Product Name: Ravicti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ravicti therapy

AND

2 - Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

2 . Revision History

Date	Notes
5/21/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99523 Rayos

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rayos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program*

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) or claims history documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

AND

4 - History of failure, contraindication, or intolerance to TWO the following:

- Dexamethasone tablet, oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet, oral solution

Notes	*Note: Medications used solely for anti-obesity/weight loss, cosmetic (e.g., alopecia, actinic keratosis, vitiligo), erectile dysfunction, and sexu al dysfunction purposes are NOT medically accepted indications and are NOT recognized as a covered benefit. Erectile dysfunction drugs (Cialis/Tadalafil) are covered for clinical diagnoses other than ED.

2 . Revision History

Date	Notes
5/14/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99808 Reblozyl (luspatercept-aamt) AZ Medicaid

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia** Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. October 2020.
2. Piga A, Perrotta S, Gamberini M, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β-thalassemia. Blood 2019; 133 (12): 1279–1289.
3. Per clinical consult with oncologist, December 19, 2019.
4. Fenaux P, Platzbecker U, Ghulam J, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med 2020; 382:140-151.

Prior Authorization Guideline

GL-102891 Recorlev (levoketoconazole)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Recorlev	
Diagnosis	Cushing’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Cushing’s disease

AND

1.2 ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name: Recorlev	
Diagnosis	Cushing's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recorlev will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Recorlev	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
2/3/2022	New Program (mirrors Isturisa PA criteria)

Prior Authorization Guideline

GL-99492 Rectiv

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rectiv	
Diagnosis	Pain Associated with Chronic Anal Fissures
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe pain associated with chronic anal fissures	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-102898 Regranex

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/3/2022

1 . Criteria

Product Name: Regranex	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a lower extremity diabetic neuropathic ulcer	

2 . Revision History

Date	Notes
2/3/2022	Removed t/f Santyl prerequisite

Prior Authorization Guideline

GL-99493 Relistor

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Relistor Injection	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation (e.g. chart notes) demonstrating ONE of the following:

1.1 Diagnosis of opioid induced constipation in a patient with advanced illness receiving palliative care

OR

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 Diagnosis of opioid induced constipation with chronic, non-cancer pain

OR

1.2.1.2 Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

1.2.2 ONE of the following:

1.2.2.1 The patient is not able to swallow oral medications

OR

1.2.2.2 BOTH of the following:

- History of failure, contraindication or intolerance to an over-the-counter (OTC) laxative (document name and date tried)
- History of failure, contraindication or intolerance to Movantik

Product Name: Relistor Injection	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Relistor Injection therapy

Product Name: Relistor tabs	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of opioid induced constipation with chronic, non-cancer pain

OR

1.2 Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - BOTH of the following:

2.1 History of failure, contraindication or intolerance to an over-the-counter (OTC) laxative (document name and date tried)

AND

2.2 History of failure, contraindication or intolerance to Movantik

Product Name: Relistor tabs	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Relistor Tablet therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-103331 Repatha

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/3/2022

1 . Criteria

Product Name: Repatha	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following diagnoses:	

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following*:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 190 milligrams per deciliter (mg/dL) (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first degree relative less than 60 years of age
- Family history of myocardial infarction in second degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first or second degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first or second degree relative
- Family history of tendinous xanthomata and or arcus cornealis in first or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low-density lipoprotein), apoB (Apolipoprotein B), or PCSK9 (Proprotein convertase subtilisin/kexin type 9) gene*
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 ONE of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 20 mg, pravastatin greater than or equal to 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 2 mg] and will continue to receive a moderate-intensity statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity statin [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] therapy and will continue to receive a low-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate, and high intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate, and high intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD

- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Used as an adjunct to a low-fat diet and exercise

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HeFH .

Product Name: Repatha	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH), Atherosclerotic cardiovascular disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

AND

2 - Patient is continuing a low-fat diet and exercise regimen

AND

3 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:*

1.1 ONE of the following:

- Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 500 mg/dL (milligrams per deciliter)
- Treated LDL-C greater than 300 mg/dL

AND

1.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Used as an adjunct to a low-fat diet and exercise

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL [low-density lipoprotein] apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HoFH.

Product Name: Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is continuing a low-fat diet and exercise regimen

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

AND

3 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid Specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent (alirocumab))

2 . Revision History

Date	Notes
2/3/2022	Added effective date to guideline details, no change to criteria

Retevmo

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99793 Retevmo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Retevmo therapy

Product Name: Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Retevmo therapy

Product Name: Retevmo

Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.1.2 Disease is ONE of the following:

- Advanced
- Metastatic

AND

1.1.3 Disease has presence of RET gene mutation

AND

1.1.4 Disease requires treatment with systemic therapy

OR

1.2 ALL of the following:

1.2.1 Diagnosis of thyroid cancer

AND

1.2.2 Disease is ONE of the following:

- Advanced
- Metastatic

AND

1.2.3 Disease is RET gene fusion-positive

AND

1.2.4 Disease requires treatment with systemic therapy

AND

1.2.5 One of the following:

- Patient is radioactive iodine-refractory
- Treatment with radioactive iodine is not appropriate

Product Name: Retevmo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Retevmo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Retevmo	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Retevmo therapy

2 . Revision History

Date	Notes
6/11/2021	7/1 Implementation

Prior Authorization Guideline

GL-108673 Retinal Vascular Disease Agents

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Beovu	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)

- Diabetic macular edema (DME)

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Compounded Avastin* prepared by a 503(B) Outsourcing Facility [B]
- Lucentis (ranibizumab)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Notes	*Note: Trial and failure of compounded bevacizumab can be accepted as meeting the trial and failure of compounded Avastin requirement

Product Name: Eylea	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Compounded Avastin* prepared by a 503(B) Outsourcing Facility [B]
- Lucentis (ranibizumab)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Notes	*Note: Trial and failure of compounded bevacizumab can be accepted as meeting the trial and failure of compounded Avastin requirement

Product Name: Lucentis 0.5mg, Byooviz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Lucentis 0.3mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Susvimo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of neovascular (wet) age-related macular degeneration (nAMD)

AND

2 - Trial and positive response to at least 2 intravitreal injections of ONE of the following:

- Compounded Avastin* prepared by a 503(B) Outsourcing Facility [B]
- Lucentis (ranibizumab)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Notes	*Note: Trial of compounded bevacizumab can be accepted as meetin g the trial of compounded Avastin requirement

Product Name: Vabysmo	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting one of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD)
- Diabetic macular edema (DME)

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Compounded Avastin* prepared by a 503(B) Outsourcing Facility [B]
- Lucentis (ranibizumab)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Notes	*Note: Trial and failure of compounded bevacizumab can be accepted as meeting the trial and failure of compounded Avastin requirement

Product Name: Beovu, Byooviz, Eylea, Lucentis, Susvimo, Vabysmo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

2 . Revision History

Date	Notes
6/24/2022	New Program

Prior Authorization Guideline

GL-99639 Revcovi - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe combined immunodeficiency disease (SCID)	

AND

2 - Deficiency of adenosine deaminase is confirmed by one of the following:

- Deficiency or absence of adenosine deaminase (ADA) in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus
- Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates compared to laboratory standard
- Decrease in ATP (Adenosine triphosphate) concentration in erythrocytes
- Molecular genetic confirmation of mutations in both alleles of the ADA1 gene
- Positive screening by T cell receptor excision circles (TRECs)

AND

3 - One of the following:

- Patient is not a suitable candidate for hematopoietic cell transplantation (HCT)
- Patient has failed HCT
- Patient is awaiting HCT

AND

4 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Revcovi (elapegademase) therapy

AND

2 - Patient has experienced a positive clinical response to therapy (e.g., normalization of plasma ADA activity, erythrocyte dATP levels, improvement of disease symptoms, etc.)

AND

3 - Dosing is in accordance with the United States Food and Drug Administration approved labeling

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-105276 Revlimid (lenalidomide)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: generic lenalidomide	
Diagnosis	All indications, Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Trial and failure to Brand Revlimid (verified via paid pharmacy claims or submission of medical records)	

Product Name: Brand Revlimid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of multiple myeloma

Product Name: Brand Revlimid	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

2.1 Patient has a diagnosis of anemia due to myelodysplastic syndrome WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 Serum erythropoetin levels greater than 500 mU (milliunits)/mL (milliliter)

OR

2.2.2 ALL of the following:

2.2.2.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.2.2 Ring sideroblasts less than 15%

AND

2.2.2.3 ONE of the following:

- Revlimid therapy is in combination with an erythropoietin [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]
- History of failure, contraindication, or intolerance to erythropoietins [e.g., Epogen, Procrit, Retacrit (epoetin alfa)]

OR

2.2.3 ALL of the following:

2.2.3.1 Serum erythropoetin levels less than or equal to 500 mU/mL

AND

2.2.3.2 Ring sideroblasts greater than or equal to 15%

AND

2.2.3.3 No response to an erythropoietin in combination with a granulocyte-colony stimulating factor (G-CSF)

OR

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

3.1 Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

AND

3.2 Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Product Name: Brand Revlimid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Diffuse large B-cell lymphoma (patients 60 to 80 years old)
- Follicular lymphoma
- Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
- Nodal marginal zone lymphoma
- Non-gastric MALT lymphoma
- Splenic marginal zone lymphoma

OR

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

2.1 ONE of the following diagnoses:

- Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
- Castleman's Disease (CD)
- Diffuse large B-cell lymphoma (patients who are less than 60 years old)
- High-grade B-cell lymphoma
- Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

2.2 NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of Hodgkin lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Used as third-line or subsequent therapy

Product Name: Brand Revlimid	
Diagnosis	Systemic Light Chain Amyloidosis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of systemic light chain amyloidosis

AND

2 - ONE of the following:

2.1 Used in combination with dexamethasone

OR

2.2 Used in combination with dexamethasone and cyclophosphamide

Product Name: Brand Revlimid	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND

2 - ONE of the following:

- Used post first-line chemoimmunotherapy maintenance therapy

- Used post second-line maintenance therapy
- Used for relapsed or refractory disease

Product Name: Brand Revlimid	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of ONE of the following:

- Mycosis Fungoides (MF) / Sezary Syndrome (SS)
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders

Product Name: Brand Revlimid	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has ONE of the following diagnoses:

- Peripheral T-cell lymphoma
- T-cell leukemia/lymphoma
- Hepatosplenic gamma-delta T-cell lymphoma

AND

2 - NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of primary central nervous system lymphoma

Product Name: Brand Revlimid	
Diagnosis	AIDS–Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has diagnosis of AIDS-related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - NOT used as first line therapy

Product Name: Brand Revlimid	
Diagnosis	*

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on Revlimid therapy

Notes	*Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Primary Cutaneous Lymphomas, T-Cell Lymphomas, Primary CNS Lymphomas, AIDS-Related Kaposi Sarcoma

Product Name: Brand Revlimid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient has a diagnosis of myelofibrosis

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Serum erythropoietin levels less than 500 mU (milliunits)/mL (milliliter)

AND

2.1.2 History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Brand Revlimid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting the patient has evidence of symptom improvement or reduction in spleen/liver volume while on Revlimid

Product Name: Brand Revlimid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Revlimid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Revlimid therapy	

2 . Revision History

Date	Notes
3/28/2022	Added criteria for Non-Preferred generic lenalidomide. Added submis sion of records where applicable.

Prior Authorization Guideline

GL-99548 Reyvow - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe migraine headaches with or without aura	

AND

2 - Used for acute treatment of migraine

AND

3 - Patient is 18 years of age or older

AND

4 - Documentation of a one month trial resulting in therapeutic failure, contraindication, or intolerance to THREE ofthe following:

- naratriptan tablets
- rizatriptan tablets/ODT (oral disintegrating tablets)
- sumatriptan tablets/auto injection/cartridge or Imitrex nasal spray (Brand only)
- zolmitriptan tablets/ODT

AND

5 - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist*

AND

6 - Prescriber attests to ALL of the following:

- Patient has been informed the use of Reyvow may result in significant CNS impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose
- If used concurrently with a benzodiazepine or other drugs that could potentially cause central nervous system (CNS) depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

AND

7 - Both of the following:

7.1 One of the following

7.1.1 The patient must have a history of therapeutic failure, contraindication, or intolerance to THREE of the following:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- VENLAFAXINE [EFFEXOR/EFFEXOR XR (EXTENDED-RELEASE)]**

OR

7.1.2 The patient must be currently treated with one of the following prophylactic therapies unless there is a contraindication or intolerance to ALL:

- Amitriptyline (Elavil)**
- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)**
- Divalproex sodium [Depakote/Depakote ER (extended-release)]**
- Topiramate (Topamax)**
- Venlafaxine [Effexor/Effexor XR (extended-release)]**

AND

7.2 Both of the Following

7.2.1 History of a therapeutic failure after 3 month trial, contraindication, or intolerance to two of the following biologic calcitonin gene-related peptide receptor (CGRP) antagonists for preventive treatment of migraine

- Ajovy (fremanezumab)
- Emgality (galcanezumab)
- Aimovig (erenumab)

AND **7.2.2** History of a therapeutic failure, contraindication, or intolerance to Ubrelvy	
Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS) **Drugs may require PA

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy **AND** **2** - Prescribed by or in consultation with one of the following specialists with expertise in the acute treatment of migraine: • Neurologist • Pain Specialist • Headache Specialist*	
Notes	*Headache specialists are physicians certified by the United Council f or Neurologic Subspecialties (UCNS)

2 . Revision History

Date	Notes
7/13/2021	Updated Guideline

Prior Authorization Guideline

GL-103329 Rezurock (belumosudil)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic graft-versus-host disease	

AND

2 - Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease - Twice daily (BID) Therapy
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Patient is using medication concomitantly with one of the following:

- Strong CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin)

- Proton pump inhibitor (e.g., omeprazole, pantoprazole, lansoprazole)

2 . Revision History

Date	Notes
2/3/2022	New Program

Prior Authorization Guideline

GL-99494 Rhofade

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of persistent erythema associated with rosacea	

AND

2 - ONE of the following:

2.1 History of a 30 day or longer trial and failure of one of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

OR

2.2 Contraindication or intolerance to both of the following:

- metronidazole cream, gel, or lotion
- azelaic acid gel

Product Name: Rhofade	
Diagnosis	Persistent erythema associated with rosacea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Rhofade therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-108351 Rinvoq (upadacitinib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/24/2022

1 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting one of the following:

3.1 Both of the following:

3.1.1 History of failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

3.1.2 History of failure, contraindication or intolerance to ALL of the following preferred drugs**:

- 2 preferred TNF inhibitors [e.g., Avsola (infliximab), Enbrel (etanercept), Humira (adalimumab)]
- Orencia (abatacept)
- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)***

AND

4 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (eq

	uivalent to 10 mg or less of prednisone daily). **PA may be required ** *Patients requesting initial authorization who were established on ther apy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer spons ored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)* **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting one of the following:

3.1 History of failure, contraindication or intolerance to ALL of the following preferred drugs**:

- 2 preferred TNF inhibitors [e.g., Avsola (infliximab), Enbrel (etanercept), Humira (adalimumab)]
- Orencia (abatacept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)***

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ***Patients requesting initial authorization who were established on ther

	apy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer spons ored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhale d corticosteroids, and/or low stable dosages of oral corticosteroids (eq uivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting one of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3.1.2 History of failure, contraindication or intolerance to ALL of the following preferred drugs**:

- 2 preferred TNF inhibitors [e.g., Avsola (infliximab), Enbrel (etanercept), Humira (adalimumab)]
- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)***

AND

4 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required ** *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)* **AND** **3** - Prescribed by or in consultation with a rheumatologist	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - Submission of medical records documenting one of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting one of the following:

5.1 Both of the following:

5.1.1 Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following**:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream

- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

5.1.2 Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)**

OR

5.2 Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)***

AND

6 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). ** PA may be required. ***Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

3 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging, paid claims history) documenting one of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies:**

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

3.1.2 History of failure to ALL of the following preferred drugs**:

- 2 preferred TNF inhibitors [e.g., Avsola (infliximab), Enbrel (etanercept), Humira (adalimumab)]
- Xeljanz (tofacitinib)

OR

3.2 Patient is currently on Rinvoq therapy as documented by claims history or medical records (document drug, date, and duration of trial)***

AND

4 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily). **PA may be required *** *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from manufacturer sponsored programs shall be required to meet initial authorization criteria as if patient were new to therapy.

Product Name: Rinvoq

Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting positive clinical response to therapy

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

2 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [5]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05

	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
	Alclometasone dipropionate	Cream, ointment	0.05

Low potency	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
6/23/2022	Updated criteria to include all approved indications.

Prior Authorization Guideline

GL-99689 Rozlytrek

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Rozlytrek	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Disease is ROS1 (gene)-positive

Product Name: Rozlytrek	
Diagnosis	NTRK gene fusion-positive solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumors (e.g., sarcoma, non-small cell lung cancer [NSCLC], salivary, breast, thyroid, colorectal, neuroendocrine, pancreatic, gynecological, cholangiocarcinoma, etc.)

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic

- Unresectable

AND

5 - ONE of the following:

5.1 Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)

OR

5.2 Disease has no satisfactory alternative treatments

Product Name: Rozlytrek	
Diagnosis	Non-small cell lung cancer (NSCLC), NTRK gene fusion-positive solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Product Name: Rozlytrek	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Rozlytrek	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rozlytrek therapy	

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99764 Rubraca

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of one of the following:	

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - One of the following:

2.1 Both of the following

2.1.1 Cancer has a deleterious BRCA mutation

AND

2.1.2 History of failure, contraindication, or intolerance to two or more chemotherapies (e.g., carboplatin or cisplatin)

OR

2.2 To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy

Product Name: Rubraca	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic, castration-resistant prostate cancer

AND

2 - Cancer has a deleterious BRCA mutation

AND

3 - History of failure, contraindication, or intolerance to both of the following:

3.1 Androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)]

AND

3.2 Taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)]

AND

4 - One of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name: Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rubraca therapy

Product Name: Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rubraca therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Ruconest-Arizona

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99640 Ruconest-Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ruconest	
Diagnosis	Hereditary Angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and one of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g. Berinert, Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name: Ruconest	
Diagnosis	Hereditary Angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99641 Ruzurgi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ruzurgi	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)	

AND

2 - Patient is not receiving Ruzurgi in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine), Firdapse (amifampridine)]

Product Name: Ruzurgi	
Diagnosis	Lambert-Eaton myasthenic syndrome (LEMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ruzurgi therapy

AND

2 - Patient is not receiving Ruzurgi in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine), Firdapse (amifampridine)]

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99690 Rydapt

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FLT3 mutation-positive

AND

3 - Rydapt will be used in combination with standard induction and consolidation therapy

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rydapt therapy

Product Name: Rydapt	
Diagnosis	Aggressive systemic mastocytosis, systemic mastocytosis with associated hematologic neoplasm, mast cell leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)

- Mast cell leukemia (MCL)

Product Name: Rydapt	
Diagnosis	Aggressive systemic mastocytosis, systemic mastocytosis with associated hematologic neoplasm, mast cell leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rydapt therapy

Product Name: Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rydapt therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Samsca

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99642 Samsca

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Samsca, generic tolvaptan	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99705 Sandostatin

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acromegaly	

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for all of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is surgically inaccessible

AND

3 - One of the following:

- Disease is recurrent
- Disease is progressive

AND

4 - Additional radiation is not possible

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine tumors, Pheochromocytoma, Paraganglioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has neuroendocrine tumors [e.g., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI (gastrointestinal) tract, lung and thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

OR

2 - All of the following:

- Diagnosis of Pheochromocytoma or Paraganglioma
- Disease is locally unresectable or distant metastases
- Disease is somatostatin receptor positive
- Presence of symptomatic disease

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine tumors, Pheochromocytoma, Paraganglioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

OR

2 - Documentation of positive clinical response (e.g. suppression of severe diarrhea, flushing, etc.) to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Thymoma or Thymic Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymoma or thymic carcinoma

AND

2 - Used as a second-line therapy for one of the following:

2.1 Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis

OR

2.2 Extrathoracic metastatic disease

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of malignant bowel obstruction

AND

2 - Gut function cannot be maintained

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Diarrhea due to concurrent cancer chemotherapy and/or radiation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation

AND

2 - One of the following:

2.1 Presence of Grade 3 or 4 severe diarrhea

OR

2.2 Patient is in palliative or end of life care

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Diarrhea due to concurrent cancer chemotherapy and/or radiation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	HIV/AIDS-Related Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)/AIDS (acquired immunodeficiency syndrome)-related diarrhea

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	HIV/AIDS-Related Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bleeding gastroesophageal varices associated with liver disease

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to the requested therapy	

2 . Revision History

Date	Notes
5/11/2021	7/1 Implementation

Prior Authorization Guideline

GL-108663 Sedative Hypnotics - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/24/2022

1 . Criteria

Product Name: Brand Rozerem, generic ramelteon	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, intolerance, or contraindication to two preferred medications*

- Eszopiclone (Generic Lunesta)
- Zolpidem (Generic Ambien)
- Temazepam 15/30mg capsules (Generic Restoril)

AND

2 - If the request is for generic ROZEREM, patient must have tried and failed brand ROZEREM

Product Name: Brand Intermezzo, generic zolpidem, Edluar, Brand Ambien, generic zolpidem tartrate, Brand Ambien CR, generic zolpidem ER, Zolpimist, Belsomra, estazolam, Brand Lunesta, generic eszopiclone, flurazepam, Brand Halcion, generic triazolam, Brand Restoril, generic temazepam, Brand Silenor, generic doxepin, generic zaleplon, Quvivic	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred* medication, the patient must have a history of failure, contraindication, or intolerance to a trial of at least two preferred* products

- Eszopiclone (Generic Lunesta)
- Zolpidem (Generic Ambien)
- Temazepam 15/30mg capsules (Generic Restoril)

Product Name: Brand Intermezzo, generic zolpidem, Edluar, Brand Ambien, generic zolpidem tartrate, Brand Ambien CR, generic zolpidem ER, Zolpimist, Belsomra, estazolam, Brand Lunesta, generic eszopiclone, flurazepam, Brand Halcion, generic triazolam, Brand Restoril, generic temazepam, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin, generic zaleplon, Quvivic	
Diagnosis	Reject 75: Greater than 1 hypnotic in 30 days
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used to adjust the dose of the drug

OR

2 - The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

3 - The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

4 - The physician attests they are aware of the multiple sedative hypnotics prescribed to the patient and feels treatment with both medications is medically necessary (Document rationale for use)

Product Name: Brand Intermezzo, generic zolpidem, Edluar, Brand Ambien, generic zolpidem tartrate, Brand Ambien CR, generic zolpidem ER, Zolpimist, Belsomra, estazolam, Brand Lunesta, generic eszopiclone, flurazepam, Brand Halcion, generic triazolam, Brand Restoril, generic temazepam, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin, generic zaleplon, Quvivic	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Age Edit

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

2 . Revision History

Date	Notes
6/23/2022	Removed Hetlioz as target, Hetlioz moved to a drug-specific guideline.

Prior Authorization Guideline

GL-99495 Serevent Diskus - Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Serevent Diskus	
Diagnosis	Asthma
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of asthma	

AND

2 - Patient is 4 years of age or older

AND

3 - Patient is also receiving treatment with an inhaled corticosteroid

Product Name: Serevent Diskus	
Diagnosis	Exercise-Induced Bronchospasm
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of exercise-induced bronchospasm (EIB)

AND

2 - Being used for prevention

AND

3 - Patient is 4 years of age or older

Product Name: Serevent Diskus	
Diagnosis	Bronchospasm associated with chronic obstructive pulmonary disease (COPD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of bronchospasm associated with chronic obstructive pulmonary disease (COPD)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99554 SGLT-2 Inhibitors - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Steglatro, Segluromet, Invokamet, Invokamet XR, Synjardy, Synjardy XR, Xigduo XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - History of failure to metformin at a minimum dose of 1500mg daily for 90 days, or contraindication or intolerance to metformin.

AND

3 - History of failure, intolerance, or contraindication to ALL of the following:

- Farxiga
- Jardiance
- Invokana

Prior Authorization Guideline

GL-104885 Short-Acting Opioid Products - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/29/2022

1 . Criteria

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, Brand Tylenol/Codeine. generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Vicodin HP, Norco, Vicodin ES, Lorcet Plus, Lorcet, Lorcet HD, Brand Xodol, generic hydrocodone - ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Ro xicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, oxycodone-ibuprofen, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen -caffeine-dihydrocodeine, Trezix, Dvorah, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	PA REQUIRED for use of MAT and other Opioids (Reject 88)

Guideline Type	DUR

Approval Criteria

1 - Provider attests to notify the prescriber of the MAT therapy and the prescriber of the MAT therapy approves the concurrent opioid therapy.

OR

2 - The days supply does not exceed 14 days for a surgical procedure.

AND

3 - The days supply does not exceed 5 days for all other requests.

AND

4 - There has not been a previous approval in the last 6 months.

Notes	Approval Length: 14 Days for surgical procedure, 5 Days for all other r equests

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, Brand Tylenol/Codeine, Brand Fioricet/codeine, Brand Fiorinal/Codeine, Lortab, Vicodin HP, Norco, Vicodin ES, Lorcet Plus, Lorcet, Lorcet HD, Brand Xodol, Brand Dilaudid, , Brand Roxicodone, Brand Oxaydo, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, Brand Ultracet, generic tramadol-acetaminophen, Qdolo, Nucynta, Fortigan, generic levorphanol, generic acetaminophen - caffeine-dihydrocodeine, Trezix, Dvorah, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone- acetaminophen*	
Diagnosis	Non-Preferred Reviews **
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least FIVE preferred short -acting opioids **.

- hydromorphone (generic Dilaudid)
- meperidine
- morphine sulfate
- oxycodone (generic Roxicodone)
- tramadol (generic Ultram)
- oxycodone w/ acetaminophen (generic Percocet)
- oxycodone-ibuprofen
- acetaminophen w/ codeine
- butalbital-acetaminophen-caffeine w/ codeine (Generic Fioricet)
- butalbital-aspirin-caffeine w/cod (generic Fiorinal)
- hydrocodone-acetaminophen (generic Norco)
- hydrocodone-ibuprofen

Notes	*This section does NOT apply to cough and cold products.

Product Name: generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, generic butalbital-aspirin-caffeine-codeine, generic morphine, generic hydrocodone/acetaminophen, generic hydrocodone-ibuprofen, generic hydromorphone, generic oxycodone, generic oxycodone/acetaminophen, generic tramadol, generic meperidine	
Diagnosis	PA Required for > 2 Short Acting Opioids
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The requested medication is being used to adjust the dose of the

OR

1.2 The requested medication will be used in place of the previously prescribed drug, and not in addition to it

OR

1.3 The requested medication dosage form will be used in place of the previously prescribed medication dosage form, and not in addition to it

OR

1.4 The physician attests they are aware of the multiple short-acting opioids prescribed to the patient and feels treatment with all medications is medically necessary (Document rationale for use)

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for the requested duration, not to exceed 12 months.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen

Diagnosis	Quantity Limit
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - The requested dose cannot be achieved by moving to a higher strength of the product

AND

2 - The requested dose is within FDA (Food and Drug Administration) approved maximum dose per day, where an FDA maximum dose per day exists (See table in background section)

Notes	*This section does NOT apply to cough and cold products.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic

hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Brand Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen	
Diagnosis	Greater than 5 day supply requests for patients 18 years of age and older **
Guideline Type	Quantity Limit
Approval Criteria **1** - ONE of the following conditions or care instances: • Active oncology diagnosis • Hospice care • End-of-life care (other than hospice) • Palliative care • Skilled nursing facility care • Traumatic injury, excluding post-surgical procedures • Chronic conditions for which the provider has received PA approval • Post-surgical procedures	
Notes	Approvals are for 6 months for all of the above with the exception of p ost-surgical procedures which can be approved for a 14 day supply. A dults may obtain additional fills without PA if the refill is requested with in 60 days from the initial fill.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Greater than 5 day supply requests for patients under 18 years of age**
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following conditions or care instances:

- Active oncology diagnosis
- Hospice care
- End-of-life care (other than hospice)
- Palliative care
- Children on opioid wean at time of hospital discharge
- Skilled nursing facility care
- Traumatic injury, excluding post-surgical procedures
- Chronic conditions for which the provider has received PA approval
- Post-surgical procedures

Notes	Approvals are for 6 months for all of the above with the exception of p ost-surgical procedures which can be approved for a 14 day supply. C hildren and adolescents may obtain additional fills without PA for 5 da ys supply unless the submitted PA supports a longer duration for use.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*

Diagnosis	Opioid Naïve (Not having filled an opioid in the past 120 days)*
Guideline Type	Morphine Milligram Equivalents (MME)** MME 50.00 exceeded; PA Required for dosage above 50 MEDD

Approval Criteria

1 - Opioid naïve members may receive greater than 50 morphine milligram equivalent (MME) based on the following:

1.1 If the request is for 50 MME to 90 MME, ONE of the following (NOTE: If the request exceeds 90 MME please skip this section and proceed to the Exceeding the 90 MME Cumulative Threshold Reviews section):

1.1.1 Diagnosis of ONE of the following:

- Cancer
- End of life pain (including hospice care)
- Palliative care
- Sickle cell anemia

OR

1.1.2 Patient is currently exceeding 50 MME and prescriber attests patient has been on a short-acting opioid in the past 120 days

OR

1.1.3 Document ALL of the following:

- The diagnosis associated with the need for pain management with opioid
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment
- Prescriber attests the member requires more than 50 MME per day to adequately control pain

Notes	*This section does NOT apply to cough and cold products. **Approval length for cancer, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for one month.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-

Diagnosis	Cancer/Hospice/End of Life/ Palliative Care/Skilled Nursing Facility/Traumatic Injury Related Pain Exceeding the 90 MME Cumulative Threshold*
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - ONE of the following conditions:

- Active oncology diagnosis
- Hospice
- End-of-life care (other than hospice)
- Palliative care
- Skilled nursing facility care
- Traumatic injury, including burns and excluding post-surgical procedures

Notes	*This section does NOT apply to cough and cold products. ** The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-acetaminophen*	
Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - BOTH of the following:

- Patient has tried and failed non-opioid pain medication (document drug name and date of trial)
- • Opioid medication doses of less than 90 morphine milligram equivalent (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)***

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain related pain up to the current requested MME plus 90 MME. ***If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose.

Product Name: Generic butorphanol, generic carisoprodol-aspirin-codeine, generic codeine, generic acetaminophen w/codeine, generic butalbital-acetaminophen-caffeine w/codeine, Brand Fioricet/codeine, generic butalbital-aspirin-caffeine-codeine, Brand Fiorinal/Codeine, generic morphine, generic hydrocodone/acetaminophen, Lortab, Norco, Brand Xodol, generic hydrocodone-ibuprofen, Brand Dilaudid, generic hydromorphone, generic oxycodone, Brand Roxicodone, Brand Oxaydo, generic oxycodone/acetaminophen, Brand Percocet, Brand Primlev, Brand Prolate, Brand Nalocet, Endocet, generic oxycodone-aspirin, Opana, generic oxymorphone, generic pentazocine w/naloxone, Brand Ultram, Synapryn, generic tramadol, Brand Ultracet, generic tramadol-acetaminophen, Nucynta, generic meperidine, Fortigan, generic levorphanol, generic acetaminophen-caffeine-dihydrocodeine, Trezix, generic belladonna alkaloids-opium, opium, Apadaz, benzhydrocodone-

Diagnosis	Non-cancer/non-hospice/non-end of life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain Exceeding the 90 MME Cumulative Threshold*
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews** (MME 90.00 exceeded; PA REQUIRED; Dosage Above MEDD Limit)

Approval Criteria

1 - Prescriber attests to ALL of the following:

- The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided
- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression

AND

2 - Identify rationale for not tapering and discontinuing opioid (Document rationale)

OR

3 - Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement)***

Notes	*This section does NOT apply to cough and cold products. ** Authorization will be issued for 6 months for non-cancer/non-hospice/non-end-of-life/non-palliative care/non-skilled nursing facility/non-traumatic injury related pain related pain up to the current requested MME plus 90 MME. *** If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 30 -day authorization may be authorized one time for the requested MME dose.

2 . Background

Benefit/Coverage/Program Information

CDC Recommended Opioid Maximum Morphine Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses
Morphine	None
Hydromorphone	None
Hydrocodone	None
Tapentadol	600mg IR products
Oxymorphone	None
Oxycodone	None
Codeine	360mg
Pentazocine	None
Tramadol	400mg IR products
Meperidine	600mg
Butorphanol nasal	None
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day
Acetaminophen	4g/day
Aspirin	2080mg/day
Ibuprofen	3200mg/day
Benzhydrocodone**	None
Levorphanol	None

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

**Morphine Milligram Equivalents is derived from the package insert.

3 . Revision History

Date	Notes
3/28/2022	Added Qdolo as NP target, removed cough&cold drugs as targets.

Signifor

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99643 Signifor

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 One of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Product Name: Signifor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Siliq- Arizona

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99706 Siliq- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 Both of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.5 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Siliq therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Siliq in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Siliq therapy

AND

2 - Patient is not receiving Siliq in combination with one of the following:

- Biologic Disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
5/11/2021	7/1 Implementation

Prior Authorization Guideline

GL-99707 Simponi- Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.3 One of the following:

1.3.1 Patient is receiving concurrent therapy with methotrexate (e.g., Rheumatrex, Trexall)

OR

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 History of failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to BOTH of the following:

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis, Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)

- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis

AND

1.2 One of the following:

1.2.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

1.2.2 History of failure to ONE of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.4 History of failure, contraindication, or intolerance to Humira (adalimumab)

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - All of the following:

2.1 Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of moderately to severely active ulcerative colitis

AND

2.3 Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
5/11/2021	7/1 Implementation

Prior Authorization Guideline

GL-99592 Sivextro

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sivextro	
Diagnosis	Skin and Skin Structure Infections
Approval Length	6 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

OR

1.3 ALL of the following:

1.3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

1.3.2 ONE of the following diagnoses:

1.3.2.1 BOTH of the following:

- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

1.3.2.2 BOTH of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

AND

1.3.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.3.4 History of failure, contraindication, or intolerance to ONE of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

1.4 ALL of the following:

1.4.1 Diagnosis of acute bacterial skin and skin structure infection(including diabetic foot infections)

AND

1.4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

1.4.3 History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

AND

1.4.4 History of failure, contraindication, or intolerance to TWO of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Product Name: Sivextro	
Diagnosis	Off-Label Uses
Approval Length	60 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 The medication is being prescribed by or in consultation with an infectious disease specialist

AND

1.3.2 History of failure, contraindication, or intolerance to linezolid (generic Zyvox), if culture and susceptibility confirm susceptibility.

2 . Revision History

Date	Notes
11/11/2021	Updated off-label approval duration to 60 days.

Prior Authorization Guideline

GL-105854 Skyrizi (risankizumab-rzaa) - AZM

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/11/2022

1 . Criteria

Product Name: Skyrizi	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 BOTH of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 Patient is NOT receiving Skyrizi in combination with ALL of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Skyrizi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Skyrizi in combination with one of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Skyrizi	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy

AND

2 - Patient is not receiving Skyrizi in combination with ALL of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Skyrizi	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active psoriatic arthritis (PsA)

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Enbrel (etanercept)
- Humira (adalimumab)
- Xeljanz oral tablet (tofacitinib)

AND

1.1.4 Patient is NOT receiving Skyrizi in combination with ALL of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

OR

1.2 All of the following:

1.2.1 Patient is currently on Skyrizi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis (PsA)

AND

1.2.3 Patient is NOT receiving Skyrizi in combination with ALL of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Skyrizi	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to Skyrizi therapy

AND

2 - Patient is not receiving Skyrizi in combination with ALL of the following:

- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz/XR (tofacitinib), Olumiant (baricitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

2 . Revision History

Date	Notes
5/23/2022	Added criteria for new PsA indication.

Soliris- AZ

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99727 Soliris- AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of atypical hemolytic uremic syndrome (aHUS) by ruling out BOTH of the following:

- Shiga toxin E. coli-related hemolytic uremic syndrome (STEC-HUS)*
- Thrombotic thrombocytopenia purpura (TTP) (e.g., rule out ADAMTS13 deficiency)

AND

2 - Laboratory results, signs, and/or symptoms attributed to aHUS (e.g., thrombocytopenia, microangiopathic hemolysis, thrombotic microangiopathy, acute renal failure, etc.)

AND

3 - Patient is treatment naïve with Soliris

AND

4 - Soliris is dosed according to the Food and Drug Administration (FDA) labeled dosing for aHUS

AND

5 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Atypical hemolytic uremic syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., reduction of plasma exchanges, reduction of dialysis, increased platelet count, reduction of hemolysis)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for atypical hemolytic uremic syndrome (aHUS)

AND

4 - Prescribed by, or in consultation with, a hematologist or nephrologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation supporting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) that includes BOTH of the following:

- Flow cytometry analysis confirming presence of PNH clones
- Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - Patient is treatment naïve with Soliris

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for PNH

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Documentation demonstrating a positive clinical response from baseline (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in lactate dehydrogenase [LDH], increased reticulocyte count, etc.)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for paroxysmal nocturnal hemoglobinuria (PNH)

AND

4 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) confirming ALL of the following:

1.1 Patient has not failed a previous course of Soliris therapy

AND

1.2 Positive serologic test for anti-acetylcholine receptor (AChR) antibodies

AND

1.3 ONE of the following:

- History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation
- History of positive anticholinesterase test, e.g., edrophonium chloride test
- Patient has demonstrated improvement in myasthenia gravis (MG) signs on oral cholinesterase inhibitors, as assessed by the treating neurologist

AND

1.4 Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

AND

1.5 Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score greater than or equal to 6 at initiation of therapy

AND

2 - BOTH of the following:

2.1 History of failure of at least TWO immunosuppressive agents over the course of at least 12 months [e.g., azathioprine, methotrexate, cyclosporine, mycophenolate, etc.]

AND

2.2 Patient has required TWO or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least the previous 12 months without symptom control

AND

3 - Patient is currently on a stable therapeutic dose (at least 3 to 6 months) of immunosuppressive therapy

AND

4 - Soliris is initiated and titrated according to the United States Food and Drug Administration (FDA) labeled dosing for gMG: up to a maximum of 1200 milligrams every 2 weeks

AND

5 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Generalized myasthenia gravis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by ALL of the following:

- Improvement and/or maintenance of at least a 3 point improvement (reduction in score) in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score from pre-treatment baseline
- Reduction in signs and symptoms of myasthenia gravis
- Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Soliris (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the United States Food and Drug Administration (FDA) labeled dosing for generalized myasthenia gravis (gMG): up to a maximum of 1200 milligrams every 2 weeks

AND

4 - Prescribed by, or in consultation, with a neurologist

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirming ALL of the following:

1.1 Past medical history of ONE of the following:

- Optic neuritis
- Acute myelitis
- Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting
- Acute brainstem syndrome
- Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
- Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

1.2 Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies

AND

1.3 Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

2 - Patient has not failed a previous course of Soliris therapy

AND

3 - History of failure of, contraindication, or intolerance to rituximab (Rituxan, Ruxience, Truxima) therapy

AND

4 - One of the following:

4.1 History of at least two relapses during the previous 12 months prior to initiating Soliris

OR

4.2 History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris

AND

5 - Soliris is initiated and titrated according to the U.S. FDA labeled dosing for NMOSD, up to a maximum of 1200 mg every 2 weeks

AND

6 - Prescribed by, or in consultation with, a neurologist

AND

7 - Patient is NOT receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

Product Name: Soliris	
Diagnosis	Neuromyelitis optica spectrum disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously been treated with Soliris

AND

2 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by BOTH of the following:

2.1 Reduction in the number and/or severity of relapses or signs and symptoms of neuromyelitis optica spectrum disorder (NMOSD)

AND

2.2 Maintenance, reduction, or discontinuation of dose(s) of any baseline immunosuppressive therapy (IST) prior to starting Soliris. (Note: Add on, dose escalation of IST, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on Soliris therapy will be considered as treatment failure)

AND

3 - Soliris is dosed according to the U.S. FDA (Food and Drug Administration) labeled dosing for NMOSD: up to a maximum of 1200 mg every 2 weeks

AND

4 - Prescribed by, or in consultation with, a neurologist

AND

5 - Patient is not receiving Soliris in combination with one of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Anti-IL6 (interleukin 6) therapy [e.g., Actemra (tocilizumab)]

2 . Revision History

Date	Notes
6/8/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107414 Somatuline Depot (lanreotide)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	5/25/2022

1 . Indications

Drug Name: Somatuline Depot (lanreotide)
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. **Carcinoid Syndrome** Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Drug Name: Lanreotide Injection
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and

insulin growth factor-1 (IGF-1) levels to normal.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Off Label Uses: Carcinoid Syndrome [3] Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

2 . Criteria

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting patient does not show evidence of progressive disease while on therapy

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

3 . Revision History

Date	Notes
5/23/2022	New guideline, mirrors ORx with addition of submission of MR req for both initial and reauth in all sections

Prior Authorization Guideline

GL-99644 Somavert

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Somavert	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of acromegaly by ONE of the following:

- Serum GH (growth hormone) level greater than 1 ng/mL (nanograms per milliliter) after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 (Insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 One of the following:

1.2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to one of the following somatostatin analogs:

- Sandostatin (octreotide) or Sandostatin LAR
- Somatuline Depot (lanreotide)

OR

2 - Patient is currently on Somavert therapy for acromegaly

Product Name: Somavert	
Diagnosis	Acromegaly

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Somavert therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Soriatane

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99496 Soriatane

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of severe psoriasis	

AND

2 - Prescribed or recommended by a dermatologist

AND

3 - One of the following:

3.1 Patient is unresponsive to other therapies (e.g., topical corticosteroids, topical vitamin D analogs, tazarotene, methotrexate)

OR

3.2 Other therapies are contraindicated based on the patient's clinical condition

AND

4 - One of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

Product Name: Brand Soriatane, Generic acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Soriatane therapy

AND **2** - Prescribed or recommended by a dermatologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99729 Spinraza- **Arizona- Ultra High Cost Medication**

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

IF member meets ALL the criteria, reviewing pharmacist will send their approval recommendation to a Medical Director for final review.

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Spinraza	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) or claims history of the baseline exam of one of the following exams (based on patient age and motor ability) to establish baseline motor ability:

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test (Non ambulatory)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

AND

6 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

7 - One of the following:

7.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

7.2 One of the following:

7.2.1 Both of the following:

7.2.1.1 Patient recently received gene replacement therapy within the previous 6 months

AND

7.2.1.2 Patient has experienced a declination in clinical status since receipt of gene replacement therapy

OR

7.2.2 Both of the following:

7.2.2.1 Patient has previously received gene replacement therapy

AND

7.2.2.2 Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams for each loading dose

Product Name: Spinraza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) type I, II, or III made by, or in consultation with, a neurologist with expertise in the diagnosis of SMA

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or claims history confirming both of the following:

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following:

- Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)
- Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on use of non-invasive ventilation beyond use for naps and nightime sleep

AND

5 - One of the following:

5.1 Patient has not previously received gene replacement therapy for the treatment of SMA

OR

5.2 Both of the following:

5.2.1 Patient has previously received gene replacement therapy

AND

5.2.2 Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) or claims history with the most recent results (less than 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by one of the following exams:

6.1 Both of the following for Hammersmith Infant Neurological Exam Part 2 (HINE-2) milestones:

6.1.1 One of the following:

- Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick

- Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp

AND

6.1.2 One of the following:

- The patient exhibited improvement or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

6.2 One of the following for Hammersmith Functional Motor Scale Expanded (HFMSE):

- Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.3 One of the following for Upper Limb Module (ULM):

- Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4 One of the following for Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND):

6.4.1 Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline

OR

6.4.2 Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

6.4.3 Both of the following:

- Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy
- Patients clinical status has stabilized after receipt of Spinraza therapy

AND

7 - Prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA

AND

8 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures

AND

9 - Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12 milligrams every 4 months, starting 4 months after the last loading dose

2 . Revision History

Date	Notes
5/25/2021	7/1 Implementation

Prior Authorization Guideline

GL-99569 Spiriva Respimat

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Spiriva Respimat	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for Spiriva Respimat should be denied. The plan's preferred product is Spiriva Handihaler	

Prior Authorization Guideline

GL-99645 Spravato - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a confirmed diagnosis of major depressive disorder as defined by the DSM-V (Diagnostic and Statistical Manual of Mental Disorders) criteria and is treatment resistant

AND

2 - Patient is 18 years of age or older

AND

3 - Spravato is prescribed by, or in consultation with, a psychiatric provider

AND

4 - ONE of the following:

4.1 Patient does not have an active substance use disorder (SUD)

OR

4.2 BOTH of the following:

- Patient has an active substance use disorder
- Patient is currently receiving treatment

AND

5 - ONE of the following:

5.1 Patient has experienced an inadequate response during the current depressive episode with BOTH of the following therapies:

5.1.1 Two antidepressants from at least two different classes [must include one of each AHCCCS (Arizona Health Care Cost Containment System) preferred agents: SSRI (selective serotonin reuptake inhibitor), SNRI (serotonin-norepinephrine reuptake inhibitor), or bupropion] having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks

AND

5.1.2 At least TWO augmentation therapies below for at least 4 weeks:

- SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
- SSRI or SNRI, and lithium used concomitantly
- SSRI or SNRI, and liothyronine (T3) used concomitantly
- SSRI or SNRI, and mirtazapine
- SSRI and bupropion and buspirone

OR

5.2 Patient has active suicidal ideation and urgent symptom control is necessary

AND

6 - Spravato is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

AND

7 - Spravato is administered under the direct supervision of a healthcare provider

AND

8 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program

AND

9 - Patient must be monitored by a health care provider for at least 2 hours after administration

Product Name: Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	6 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has documented improvement or sustained improvement in depressive symptoms from baseline

AND

2 - Patient use of Spravato is in combination with an oral antidepressant

AND

3 - Patient administers Spravato under the direct supervision of a healthcare provider

AND

4 - Provider is certified in the Spravato REMS (risk evaluation and mitigation strategy) program

AND

5 - Patient must continue to be monitored by a health care provider certified by the Spravato REMS program for at least 2 hours after administration

Product Name: Spravato	
Diagnosis	Requests for Patients less than 6 years of age
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindicated (i.e. other medications or behavioral modification attempted)

AND

2 - The physician attests that the requested medication is medically necessary. (Document rationale for use)

Product Name: Spravato	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5) criteria

AND

2 - Patient is experiencing an acute suicidal ideation or behavior

AND

3 - Patient is receiving newly initiated or optimized oral antidepressant

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-109039 Sprycel (dasatinib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/6/2022

1 . Criteria

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia

AND

2 - One of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name: Sprycel

Diagnosis	Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST) with PDGFRA D842V mutation

Product Name: Sprycel	
Diagnosis	Gastrointestinal stromal tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic chondrosarcoma

Product Name: Sprycel	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Sprycel	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	Lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has an ABL1 (gene) rearrangement

Product Name: Sprycel	
Diagnosis	Lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name: Sprycel	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimen
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Sprycel	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sprycel therapy

2 . Revision History

Date	Notes
7/6/2022	Updated GPIs

Prior Authorization Guideline

GL-99787 Stelara - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

1.1 Submission of medical records (e.g., chart notes, laboratory values, prescription claims history) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.4 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.1.6 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 ONE of the following:

1.1.7.1 Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)

OR

1.1.7.2 BOTH of the following:

- Requested medication is Stelara 90 mg per 1 mL
- Patient's weight is greater than 100 kg (kilograms) (220 pounds)

AND

1.1.8 Prescribed by or in consultation with a dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 ONE of the following

1.1.1.1 BOTH of the following:

- Requested medication is Stelara 45 mg (milligrams) per 0.5 mL (milliliter)
- Diagnosis of active psoriatic arthritis

OR

1.1.1.2 ALL of the following:

- Requested medication is Stelara 90 mg per 1 mL
- Patient's weight is greater than 100 kg (kilograms) (220 pounds)
- Diagnosis of active psoriatic arthritis
- Diagnosis of co-existent moderate to severe plaque psoriasis

AND

1.1.2 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.3 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

1.2 All of the following:

1.2.1 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara (all subcutaneous strengths)	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Stelara 90mg/1 ml	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara 90mg/1 ml	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Both of the following

2.1.1 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

2.1.2 History of failure, contraindication or intolerance to Humira (adalimumab)

OR

2.2 Patient is currently on Stelara therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

3 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Stelara 90mg/1 ml	
Diagnosis	Crohn’s Disease, Ulcerative Colitis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stelara therapy

AND

2 - Patient is NOT receiving Stelara in combination with ONE of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

2 . Revision History

Date	Notes
6/9/2021	7/1 Implementation

Prior Authorization Guideline

GL-99766 Stivarga

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Stivarga	
Diagnosis	Colorectal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of advanced or metastatic colorectal cancer

AND

1.2 History of failure, contraindication, or intolerance to treatment with all of the following:

- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Fluoropyrimidine-based chemotherapy
- Anti-VEGF therapy

AND

1.3 One of the following:

1.3.1 Tumor is RAS mutant-type

OR

1.3.2 Both of the following:

1.3.2.1 Tumor is RAS wild-type

AND

1.3.2.2 History of failure, contraindication, or intolerance to anti-EGFR therapy

Product Name: Stivarga	
Diagnosis	Colorectal cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of One of the following:

- Soft Tissue Sarcoma - extremity/superficial trunk or head/neck that is non-adipocytic with stage IV or recurrent disease with disseminated metastases
- Soft Tissue Sarcoma - retroperitoneal/intra-abdominal that is non-adipocytic, unresectable, or progressive disease
- Pleomorphic rhabdomyosarcoma

OR

1.2 All of the following:

1.2.1 Diagnosis of gastrointestinal stromal tumor (GIST)

AND

1.2.2 Disease is one of the following:

- Progressive
- Locally advanced
- Unresectable
- Metastatic

AND

1.2.3 History of failure, contraindication, or intolerance to one of the following:

- Imatinib mesylate (Gleevec)

- Sutent (sunitinib malate)

Product Name: Stivarga	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	Hepatobiliary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of one of the following:

- Gallbladder cancer
- Extrahepatic cholangiocarcinoma
- Intrahepatic cholangiocarcinoma

AND

1.1.2 Disease is one of the following:

- Unresectable

- Metastatic

OR

1.2 All of the following:

1.2.1 Diagnosis of hepatocellular carcinoma

AND

1.2.2 History of failure, contraindication or intolerance to Nexavar (sorafenib tosylate)

Product Name: Stivarga	
Diagnosis	Hepatobiliary Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Osteosarcoma
- Dedifferentiated chondrosarcoma

- High grade undifferentiated pleomorphic sarcoma (UPS)

AND

2 - Disease is one of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second-line therapy

Product Name: Stivarga	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent glioblastoma

Product Name: Stivarga

Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name: Stivarga	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Stivarga	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stivarga therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99646 Strensiq

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Strensiq	
Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - All of the following:	

1.1 Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on all of the following:

1.1.1 One of the following:

- Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)
- Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

- Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age-adjusted normal range
- Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

OR

1.1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing*

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following:

- Patient is prescribed Strensiq 80 mg/0.8 mL vial
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering

Product Name: Strensiq

Diagnosis	perinatal/infantile or juvenile-onset hypophosphatasia (HPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

AND

1.2 Prescribed by one of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

1.3 One of the following:

1.3.1 Both of the following:

- Diagnosis of perinatal/infantile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

OR

1.3.2 Both of the following:

- Diagnosis of juvenile-onset hypophosphatasia
- Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

AND

1.4 One of the following:

1.4.1 Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

1.4.2 Both of the following

- Patient is prescribed Strensiq 80 mg/0.8 mL vials
- Patient's weight is greater than or equal to 40 kg

AND

1.5 Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-105262 Sublingual Immunotherapy (SLIT)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: All products	
Diagnosis	Patients 21 years of age and older
Approval Length	N/A - All requests for patients 21 years of age and older should be DENIED as benefit exclusion
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for patients 21 years of age and older are not covered	
Notes	Approval Length: N/A - All requests for patients 21 years of age and older should be denied as a benefit exclusion.

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to Timothy grass or cross-reactive grass pollens (eg, Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)
- in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Grastek	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]
- in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

AND

3 - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Oralair	
Diagnosis	Grass pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oralair therapy

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to short ragweed pollen
- in vitro testing for pollen-specific IgE antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Ragwitek	
Diagnosis	Short ragweed pollen-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis.

AND

2 - Diagnosis confirmed by one of the following:

- Positive skin test to licensed house dust mite allergen extracts
- in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites

AND

3 - History of failure, contraindication, or intolerance to two of the following:

- oral antihistamine [e.g. cetirizine (Zyrtec)]
- intranasal antihistamine [e.g. azelastine (Astelin)]
- intranasal corticosteroid [e.g. fluticasone (Flonase)]
- leukotriene inhibitor [e.g. montelukast (Singulair)]

AND

4 - Patient does not have unstable and/or uncontrolled asthma

AND

5 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name: Odactra	
Diagnosis	House dust mite (HDM)-induced allergic rhinitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Odactra therapy

2 . Revision History

Date	Notes
3/28/2022	Added box to deny as benefit exclusion for patients 21 years and old er

Prior Authorization Guideline

GL-99647 Sublocade - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sublocade	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has severe Opioid Use Disorder (OUD) as defined by the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) OUD Diagnostic Tool and has a demonstrated history of non-adherence to oral medications

AND

2 - Patient is currently maintained on 8mg to 24mg per day dose of oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection

AND

3 - Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine

AND

4 - Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

5 - Prescriber meets DATA 2000 (Drug Addiction Treatment Act of 2000) requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X)

AND

6 - Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

7 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: 300mg (milligrams) subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100mg or 300mg monthly

Product Name: Sublocade

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician documentation that the patient has experienced a positive clinical response to buprenorphine extended-release therapy, as defined by the provider

AND

2 - Patient has not, nor will receive supplemental, oral, sublingual, or transmucosal buprenorphine

AND

3 - Patient is receiving psychosocial interventions as part of a comprehensive medication assisted treatment (MAT) program

AND

4 - Prescriber meets DATA 2000 (Drug Addiction Treatment Act of 2000) requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X)

AND

5 - Prescriber checks the Arizona State Board of Pharmacy Controlled Substance Prescription Monitoring Program (CSPMP) database prior to each monthly injection

AND

6 - Sublocade dosing is in accordance with the U. S. Food and Drug Administration approved labeling: maintenance dose of 100mg (milligrams) or 300mg monthly

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99509 Suboxone -- Arizona

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zubsolv, Bunavail *	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a Diagnostic and Statistical Manual, Fifth Edition, Text Revision, (DSM-V-TR) diagnosis of opioid use disorder

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products **

- brand Suboxone Film
- buprenorphine (generic Subutex)
- buprenorphine HCl/naloxone Tab (Generic Suboxone Tab)
- naloxone
- naltrexone
- Narcan (naloxone)
- Sublocade (buprenorphine)
- Vivitrol (naltrexone microspheres)

Notes	*Up to 24 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the initial period

Product Name: Zubsolv, Bunavail *	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been prescribed a buprenorphine product for the purpose of opioid use disorder maintenance therapy

AND

2 - The patient must have a reason or special circumstance that they cannot use the preferred products**

AND

3 - Patient must have tried Suboxone film or buprenorphine-naloxone ODT tablets. tablets.

Notes	* Up to 16 mg per day of Suboxone, or equivalent dosing of an alternative medication, will be authorized for the reauthorization period **Please reference current PDL: https://www.uhcprovider.com/en/health-plans-by-state/arizona-health-plans/az-comm-plan-home/az-cp-pharmacy.html https://www.azahcccs.gov/Resources/Downloads/PharmacyUpdates/AHCCCS_FFS_DRUG_LIST_20210101.pdf

Product Name: Brand suboxone, generic buprenorphine hcl-naloxone, buprenorphine/naloxone sublingual tablet, Zubsolv, Bunavail *	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician has provided rationale for needing to exceed the buprenorphine daily limit

AND

2 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

Notes	* This criteria applies to requests exceeding 24 mg of buprenorphine or equivalent

Product Name: Brand suboxone, generic buprenorphine hcl-naloxone, buprenorphine/naloxone sublingual tablet, Zubsolv, Bunavail *	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician has provided rationale for needing to exceed the buprenorphine daily limit

AND

2 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation	
Notes	*This criteria applies to requests exceeding 16 mg of buprenorphine or equivalent

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99648 Sucraid

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sucraid	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital sucrase-isomaltase deficiency (CSID) as confirmed by one of the following:

1.1 Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides

OR

1.2 All of the following:

- Stool pH less than 6
- Negative lactose breath test
- Increase in breath hydrogen greater than 10 ppm (parts per million) when challenged with sucrose after fasting

AND

2 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

3 - Will be used with a sucrose-free, low starch diet

Product Name: Sucraid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

2 - Will be used with a sucrose-free, low starch diet

AND

3 - Provider attests that the patient has achieved a clinically meaningful response while on Sucraid therapy, defined as at least a 50 percent reduction in all of the following:

- Symptoms of abdominal pain, cramps, bloating, gas, vomiting
- Number of stools per day
- Watery, loose stool consistency
- Number of symptomatic days

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99524 Sunosi

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

OR

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

AND

2 - Physician attestation to the following:

- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance to BOTH of the following:

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist

- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

AND

1.2.2 ONE or more of the following sign/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - History of failure, contraindication, or intolerance to armodafinil

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g. continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP])

2 . Revision History

Date	Notes
5/27/2021	7/1 Implementation

Prior Authorization Guideline

GL-99767 Sutent

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to Gleevec (imatinib)

Product Name: Sutent	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Diagnosis of Stage IV disease

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name: Sutent	
Diagnosis	Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of islet cell tumor / progressive pancreatic neuroendocrine tumors (pNET)

AND

2 - Disease is ONE of the following:

- Unresectable, locally advanced
- Metastatic

Product Name: Sutent	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor / hemangiopericytoma

Product Name: Sutent

Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 Disease is refractory to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary thyroid carcinoma

AND

1.2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Sutent	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name: Sutent	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name: Sutent	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

Product Name: Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Renal Cell Carcinoma (RCC), Islet Cell Tumor / Progressive Pancreatic Neuroendocrine Tumors

	(pNET), Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Sutent therapy	

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Sutent will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Sutent	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Sutent therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Symdeko

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99649 Symdeko

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory result documenting ONE of the following:

2.1 The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

OR

2.2 The patient has at least ONE mutation in the CFTR gene that is responsive to Symdeko (See Table in Background Section)

AND

3 - The patient is greater than or equal to 6 years of age

AND

4 - Prescribed by or in consultation with a specialist affiliated with a CF care center

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Symdeko therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations

- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Background

Benefit/Coverage/Program Information

Table 1 CFTR Gene Mutations

A1067T	D1270N	F1052V	R1070W	S945L	3272-26A→G
A455E	D579G	F1074L	R117C	S977F	3849+10kbC→T
D110E	E193K	K1060T	R347H		711+3A→G
D110H	E56K	L206W	R352Q		2789+5G→A
D1152H	E831X	P67L	R74W		

3 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99499 Symlin

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Symlin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have ONE of the following diagnoses:

- Type 1 diabetes
- Type 2 diabetes

AND **2** - Concurrent use of insulin therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99650 Synagis

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Synagis*	
Diagnosis	Prematurity
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is an infant born before 29 weeks, 0 days gestation

AND

1.2 Patient is less than 12 months of age at the start of RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

• Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Chronic Lung Disease (CLD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following for patients age 0 to less than 12 months:

1.1.1 The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

AND

1.1.2 Patient has developed chronic lung disease (CLD) of prematurity

AND

1.1.3 There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

OR

1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:

1.2.1 The patient was born at less than 32 weeks, 0 days gestation

AND

1.2.2 The patient required at least 28 days of oxygen after birth

AND

1.2.3 The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV "season"***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

• Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present] • Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present) • Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital Heart Disease (CHD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following for patients age 0 to less than 12 months:

1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:

- Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Moderate to severe pulmonary hypertension

- Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist

OR

1.1.2 The patient is undergoing cardiac transplantation during the RSV “season”

OR

1.2 BOTH of the following:

1.2.1 The patient is greater than or equal to 12 months to less than 24 months of age:

AND

1.2.2 ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Congenital abnormalities of the airway or neuromuscular disease
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is age 0 to less than 12 months

AND

1.2 Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)

• Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab • Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children • Synagis prophylaxis for prevention of nosocomial disease • Treatment of symptomatic RSV disease	
Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Immunocompromised children less than 24 months of age
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 24 months of age

AND

1.2 The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as p

	art of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name: Synagis*	
Diagnosis	Cystic fibrosis (CF)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following for patients age 0 to less than 12 months:

1.1.1 Patient has cystic fibrosis

AND

1.1.2 Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

OR

1.2 BOTH of the following:

1.2.1 Patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable
- Weight for length less than the 10th percentile on a pediatric growth chart

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Monthly dose of Synagis does not exceed 5 doses per single RSV “season”***

AND

5 - The patient does not meet ONE of the following situations

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease
- Treatment of symptomatic RSV disease

Notes	*NOTE: Approval for up to 5 doses per single RSV “season” ** Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) • http://uhc-cs-10.uhc.com/sites/cspm/CSSP/Pages/Synagis.aspx ***NOTE: Infants in a neonatal intensive care

	unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthly doses may be needed.

2 . Background

Benefit/Coverage/Program Information
Additional Information In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration. [10] • Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida. • On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants. • Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV "season" offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10%. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.

3 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99768 Synribo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Synribo	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

1.1 Diagnosis of advanced phase chronic myelogenous leukemia with progression to accelerated phase

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of chronic or accelerated phase chronic myelogenous leukemia

AND

1.2.2 ONE of the following:

1.2.2.1 Patient has a history of failure, contraindication, or intolerance to TWO or more tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib), Iclusig (ponatinib)]

OR

1.2.2.2 Patient has relapsed or refractory disease after hematopoietic stem cell transplant

Product Name: Synribo	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Synribo therapy

Product Name: Synribo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Synribo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Synribo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Synribo therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99534 Systane, Refresh, Gonak, Genteal, Tears Naturale

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: brand Systane, brand Refresh, brand Gonak, brand Genteal, Tears Naturale	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure, contraindication, or intolerance to ALL of the following:

- Generic equivalents for drops, ointments and gel formulations for Systane, Refresh, Gonak, Genteal, Tears Naturale, and Generic equivalent to the requested brand product

- sodium chloride ophthalmic ointment

2 . Revision History

Date	Notes
5/20/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99792 Tabrecta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors

Product Name: Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tabrecta therapy

Product Name: Tabrecta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tabrecta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tabrecta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tabrecta therapy	

2 . Revision History

Date	Notes
6/11/2021	7/1 Implementation

Prior Authorization Guideline

GL-99769 Tafinlar

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tafinlar	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.3.2 Used in combination with Mekinist (trametinib)

AND

2 - Cancer is positive for BRAF V600 mutation

Product Name: Tafinlar	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name: Tafinlar	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has metastatic brain lesions

AND

2 - Tafinlar is active against primary tumor (melanoma)

AND

3 - Used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name: Tafinlar	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - ONE of the following:

- Used in combination with Mekinist (trametinib)
- Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated

Product Name: Tafinlar	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name: Tafinlar	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.1.2 Cancer is positive for BRAF V600E mutation

AND

1.1.3 Used in combination with Mekinist (trametinib)

AND

1.1.4 ONE of the following:

1.1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.1.4.2 Prescribed as adjuvant therapy following resection

OR

1.2 ALL of the following:

1.2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.2.4 Disease is refractory to radioactive iodine treatment

AND

1.2.5 Cancer is positive for BRAF V600 mutation

Product Name: Tafinlar	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name: Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Tafinlar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tafinlar therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99794 Tagrisso

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Central Nervous System (CNS) Cancer

AND

2 - Primary disease (tumor) is responsive to Tagrisso therapy [e.g., epidermal growth factor receptor (EGFR) T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive non-small cell lung cancer (NSCLC)]

Product Name: Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Product Name: Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced

- Metastatic

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is sensitizing epidermal growth factor receptor (EGFR) mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive)

AND

3.1.2 Used as a first-line therapy

OR

3.2 BOTH of the following:

3.2.1 Disease is sensitizing epidermal growth factor receptor (EGFR) mutation positive (e.g., EGFR T790M mutation, exon 19 deletions, or exon 21 L858R mutation-positive)

AND

3.2.2 Subsequent therapy for disease that has progressed while on Tagrisso therapy

OR

3.3 BOTH of the following:

3.3.1 Disease is epidermal growth factor receptor (EGFR) T790M mutation-positive

AND

3.3.2 History of failure, contraindication, or intolerance to prior EGFR tyrosine kinase inhibitor (TKI) therapy [e.g., Tarceva (erlotinib), Gilotrif (afatinib), Iressa (gefitinib)]

Product Name: Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tagrisso therapy

Product Name: Tagrisso	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tagrisso will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tagrisso	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

2 . Revision History

Date	Notes
6/12/2021	Updated GPI

Prior Authorization Guideline

GL-104868 Takhzyro

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/17/2022

1 . Criteria

Product Name: Takhzyro	
Approval Length	8 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and one of the following:

- Confirmed presence of a FXII, angiopoietin-1 or plasminogen gene mutation
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

AND

2 - BOTH of the following:

2.1 For prophylaxis against HAE attacks

AND

2.2 Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda)

AND

3 - BOTH of the following:

3.1 Prescriber attests that patient has experienced attacks of a severity and-or frequency such that they would clinically benefit from prophylactic therapy with Takhzyro

AND

3.2 Documentation of baseline HAE attack rate is greater than or equal to one attack per 4 weeks

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

5 - ONE of the following:

5.1 History of failure, contraindication, or intolerance to Haegarda

OR

5.2 Patient is currently on Takhzyro therapy

Product Name: Takhzyro	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response, defined as a clinically significant reduction in the rate and-or number of hereditary angioedema (HAE) attacks, while on Takhzyro therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ruconest, Firazyr, Kalbitor) as determined by claims information, while on Takhzyro therapy

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND **4** - BOTH of the following: **4.1** For prophylaxis against hereditary angioedema (HAE) attacks **AND** **4.2** Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda **AND** **5** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting the number of acute HAE attacks in the previous 6 months while on Takhzyro therapy*	
Notes	*Authorization: • Patient experienced no (zero) acute HAE attacks in t he previous 6 months: Takhzyro 300mg given every 4 weeks for 12 m onths (**Patients experiencing unexpected breakthrough HAE attacks once switched to every 4 week dosing will require additional review to allow for 2 weeks dosing.**) • Patient experienced one or more acute HAE attacks in the previous 6 months: Takhzyro 300mg given every 2 weeks for 6 months

2 . Revision History

Date	Notes
3/16/2022	Added new GPI. Added submission of records to initial and reauth cri teria

Prior Authorization Guideline

GL-101395 Talicia and Mycobutin

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	1/4/2022

1 . Criteria

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Mycobacterium Avium Complex Prophylaxis	

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Member has failed azithromycin or clarithromycin or is intolerant to the medication due to significant adverse effects or both are contraindicated

AND

4 - If request is for brand Mycobutin and the member is allergic to the generic formulation, the prescriber must submit the FDA MedWatch form

AND

5 - The requested dosage does not exceed 450 mg per day

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

Product Name: Mycobutin	
Diagnosis	Mycobacterium Avium Complex Prophylaxis
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - For doses that exceed 450mg, the use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- • United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- MicroMedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

Product Name: Mycobutin	
Diagnosis	Helicobacter pylori Infection (off-label)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - Prescribed in combination with amoxicillin and a proton pump inhibitor

AND

3 - If request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin)

Product Name: Talicia	
Diagnosis	Helicobacter pylori Infection
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of H. pylori infection

AND

2 - The medication is prescribed by or in consultation with a gastroenterologist or infectious disease specialist

AND

3 - One of the following:

3.1 Member has tried 3 first-line treatment regimens listed in the table in background section (One of which must be Rifabutin triple therapy)

OR

3.2 Both of the following:

3.2.1 Culture and sensitivity report indicate resistance or lack of susceptibility of H. pylori to all first-line treatment regimens except Rifabutin triple therapy

AND

3.2.2 Member must have tried and failed Rifabutin triple therapy

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberculosis infection

AND

2 - Prescribed by or in consultation with an HIV or infectious disease specialist

AND

3 - Current treatment with protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the treatment of HIV infection

AND

4 - If the request is for brand Mycobutin, inability to use generic rifabutin (e.g., contraindications to excipients in rifabutin).

Product Name: Mycobutin	
Diagnosis	Tuberculosis (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member is responding positively to therapy

2 . Background

Benefit/Coverage/Program Information

Dosing Table

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Azithromycin	**MAC:** 1,200 mg PO once weekly or 600 mg PO twice weekly	500 mg/day
Clarithromycin	**MAC:** 500 mg PO BID	1.5 g/day
clarithromycin triple regimen	***H. pylori* infection:** 14 days: PPI (standard or double dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg or metronidazole 500 mg TID (if penicillin allergy)	See dosing regimen
bismuth quadruple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; bismuth subcitrate (120-300 mg) or subsalicylate (300 mg) QID; tetracycline 500 mg QID; metronidazole 250 mg QID or 500 mg TID-QID	See dosing regimen
concomitant regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg; Metronidazole or tinidazole 500 mg	See dosing regimen
sequential regimen	***H. pylori* infection:** 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, clarithromycin 500 mg + metronidazole/tinidazole	See dosing regimen
hybrid regimen	***H. pylori* infection:** 7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 7 days of BID PPI, amoxicillin +	See dosing regimen

		clarithromycin 500 mg + metronidazole/tinidazole		
	levofloxacin triple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; levofloxacin 500 mg QD; amoxicillin 1,000 mg BID	See dosing regimen	
	levofloxacin sequential regimen	***H. pylori* infection:**	See dosing regimen	
		5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, amoxicillin + metronidazole/tinidazole + QD levofloxacin 500 mg		
	rifabutin triple	***H. pylori* infection:** 10 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID + rifabutin 300 mg QD	See dosing regimen	

3 . Revision History

Date	Notes
1/4/2022	Corrected Talicia criteria

Prior Authorization Guideline

GL-99799 Taltz - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.1.2 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.1.3 BOTH of the following:

1.1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):*

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)

- Otezla (apremilast)

AND

1.1.5 History of failure, contraindication, or intolerance to ALL of the following nonpreferred biologic products (document drug, date, and duration of trial): *

- Cimzia

AND

1.1.6 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukin umab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.7 Prescribed by or in consultation with a dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active psoriatic arthritis

AND

1.1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date, and duration of trial)*

AND

1.1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.1.4 History of failure, contraindication, or intolerance to THREE of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Orencia
- Cimzia

- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active psoriatic arthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active ankylosing spondylitis

AND

1.1.2 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.4 History of failure, contraindication, or intolerance to BOTH of the following non-preferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active ankylosing spondylitis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Taltz	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.1.2 History of failure, contraindication, or intolerance to BOTH of the following preferred biologic products (document drug, date, and duration of trial):*

- Humira (adalimumab)
- Enbrel (etanercept)

AND

1.1.3 History of failure, contraindication, or intolerance to BOTH of the following nonpreferred biologic products (document drug, date, and duration of trial):*

- Cimzia
- Simponi

AND

1.1.4 History of failure to TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)*

AND

1.1.5 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.1.6 Prescribed by or in consultation with a rheumatologist

OR

1.2 ALL of the following:

1.2.1 Patient is currently on Taltz therapy as documented by claims history or medical records (document date, and duration of therapy)

AND

1.2.2 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2.3 Patient is not receiving Taltz in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

1.2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trials

Product Name: Taltz	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is not receiving Taltz in combination with ONE of the following:

- Biologic disease-modifying anti-rheumatic drugs (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
6/25/2021	Updated Program

Prior Authorization Guideline

GL-104876 Talzenna (talazoparib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/17/2022

1 . Criteria

Product Name: Talzenna	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of deleterious or suspected deleterious germline BRCA (breast cancer)-mutations as detected by the Food and Drug Administration (FDA)-approved companion diagnostic for Talzenna

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - ONE of the following:

5.1 Patient has a contraindication, or history of intolerance to Lynparza

OR

5.2 Provider attests that the patient is not an appropriate candidate for Lynparza

OR

5.3 Patient is currently on Talzenna therapy

Product Name: Talzenna	
Diagnosis	Breast Cancer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Talzenna therapy

Product Name: Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Talzenna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Talzenna therapy

2 . Revision History

Date	Notes

3/17/2022	Added new GPIs. Added Submission of Records req to BC initial auth.

Tarceva

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99779 Tarceva

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pancreatic cancer	

AND

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Used in combination with Gemzar (gemcitabine)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR)exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g. in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of kidney cancer
- Disease is stage IV or relapsed

AND

2 - Disease is of non-clear cell histology

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from Non-Small Cell Lung Cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., in-frame exon 20 insertions, exon 18 G719 mutation, exon 21 L861Q mutation)

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvar cancer

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tarceva will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tarceva therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99771 Targretin

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cutaneous T-cell lymphoma (CTCL)	

AND

2 - History of failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g.

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not had disease progression while on therapy

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Targretin will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Targretin caps, generic bexarotene caps, Targretin gel	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Targretin therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-104975 Tarpeyo (budesonide)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m2

AND

5 - One of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: [2]

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

2 . References

1. Tarpeyo Prescribing Information. Calliditas Therapeutics AB. Stockholm, Sweden. December 2021.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021;100(4S):S1-S276.

3 . Revision History

Date	Notes
3/22/2022	New Program mirrors ORx with Submission of Records added to initial and reauth

Prior Authorization Guideline

GL-99772 Tasigna

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myeloid leukemia	

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib (Gleevec) as attested by physician

OR

2.2 Patient is currently on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive gastrointestinal stromal tumor (GIST)

AND

2 - History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name: Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and ABL1 (gene) rearrangement

AND

2 - Neoplasm is in blast or chronic phase

Product Name: Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tasigna therapy

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tasigna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tasigna therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99785 Tavalisse - ARIZONA

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic immune thrombocytopenia (ITP)	

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 History of failure, contraindication, or intolerance to ONE of the following:

- Corticosteroids
- Immunoglobulins

AND

2.1.2 History of failure, contraindication, or intolerance to both of the preferred alternatives*

- Nplate (romiplostim)
- Promacta Tablet (eltrombopag)

OR

2.2 Patient is currently on Tavalisse therapy

Product Name: Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tavalisse therapy

2 . Revision History

Date	Notes
6/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99512 Tazverik

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has a diagnosis of epithelioid sarcoma

AND

2 - Disease is one of the following:

- Metastatic
- Locally advanced

AND

3 - Disease is not eligible for complete resection

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tazverik therapy

Product Name: Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tazverik will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tazverik therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99652 Tegsedi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following:	

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name: Tegsedi

Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has previously received treatment with Tegsedi

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient continues to have a neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

5 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-106301 Temodar (temozolomide)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/19/2022

1 . Criteria

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of central nervous system tumors:

- Intracranial and Spinal Ependymoma (excluding Subependymoma)

- Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglioma
- Medulloblastoma
- Anaplastic Gliomas
- Glioblastoma
- Limited or extensive brain metastases
- Primary CNS (central nervous system) lymphoma

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Cutaneous Melanoma or Uveal Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of melanoma:

- Metastatic cutaneous melanoma
- Metastatic uveal melanoma

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Cutaneous Melanoma or Uveal Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of neuroendocrine tumors:

- Bronchopulmonary/thymic disease
- Poorly controlled carcinoid syndrome in lung or thymus
- Pancreas
- Pheochromocytoma/paraganglioma
- Poorly differentiated (High Grade)/ large or small cell

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of primary cutaneous lymphomas:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)
- Primary cutaneous anaplastic large cell lymphoma

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ONE of the following:

- Diagnosis of angiosarcoma
- Diagnosis of unresectable or progressive retroperitoneal/intra-abdominal soft tissue sarcoma
- Diagnosis of rhabdomyosarcoma
- Undifferentiated pleomorphic sarcoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of soft tissue sarcoma of the extremity/superficial trunk, head/neck

AND

1.2.2 ONE of the following:

- Disease is stage IV
- Disease has disseminated metastases

OR

1.3 BOTH of the following:

- Diagnosis of solitary fibrous tumor/hemangiopericytoma
- Used in combination with Avastin (bevacizumab)

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ewing’s sarcoma family of tumors
- Mesenchymal chondrosarcoma

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is progressive following primary treatment
- Used as second-line therapy for metastatic disease

AND

3 - Used in combination with Campostar (irinotecan)

AND

4 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic uterine sarcoma

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - ONE of the following:

2.1 Relapse within 6 months following complete or partial response or stable disease with initial treatment

OR

2.2 Primary progressive disease

AND

3 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Temodar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

AND

2 - For Brand Temodar requests ONLY: Trial and failure to generic temozolomide (verified via paid pharmacy claims or submission of medical records/chart notes)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
4/19/2022	Added step through generic for Brand Temodar only. Removed refer ence to drug name in reauth sections.

Prior Authorization Guideline

GL-99549 Test Strips

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Non-preferred Test Strip Products	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - History of failure, contraindication, or intolerance to BOTH of the following:

- True Metrix
- Accu-Chek

OR

2 - Patient is on an insulin pump

OR

3 - Patient is visually impaired

Product Name: Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 For Insulin Dependent or Pregnant patients, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

1.2 For Non-Insulin Dependent Patients, ONE the following:

1.2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR

1.2.2 The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time

OR

1.2.3 The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time

OR

1.2.4 The patient requires additional testing due to fluctuations in blood glucose due to physical activity or exercise

OR

1.2.5 Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by OptumRx reviewing pharmacist and/or medical director)

2 . Revision History

Date	Notes
7/1/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107461 Testosterone - AZM

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Tlando	
Diagnosis	Hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 TWO pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab, taken at separate times (Document lab value and date for both levels)

OR

1.2 BOTH of the following:

1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.2.2 ONE pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (less than 5 ng/dL or less than 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

OR

1.3 Patient has a history of ONE of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

2 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope

- Saizen

AND

3 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

4 - Patient was male at birth

AND

5 - Diagnosis of hypogonadism

AND

6 - ONE of the following:

- Significant reduction in weight (less than 90 percent ideal body weight) (e.g., AIDS wasting syndrome)
- Osteopenia
- Osteoporosis
- Decreased bone density
- Decreased libido
- Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

AND

7 - If the request is for generic Androgel, patient must have tried and failed Brand Androgel (verified via paid pharmacy claims or submission of medical records)

AND

8 - If the request is for JATENZO or TLANDO, patient must have tried and failed Brand

Androgel or Androderm (Applies to Jatenzo and Tlando only) (verified via paid pharmacy claims or submission of medical records)

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Tlando	
Diagnosis	Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is using hormones to change physical characteristics

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

3 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

4 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

AND

5 - If the request is for generic Androgel, patient must have tried and failed Brand Androgel (verified via paid pharmacy claims or submission of medical records)

AND

6 - If the request is for JATENZO or TLANDO, patient must have tried and failed Brand Androgel or Androderm (Applies to Jatenzo and Tlando only) (verified via paid pharmacy claims or submission of medical records)

Product Name: Brand Androgel pump, generic testosterone 1.62% pump (generic Androgel pump), Brand Androgel gel, generic testosterone gel (generic Androgel), testosterone enanthate, Androderm, testosterone topical 30mg/act solution, testosterone cypionate, Brand Testim, generic testosterone 50mg/5gm TD gel (generic Testim), Brand Vogelxo, generic testosterone TD gel (generic Vogelxo), Jatenzo, Tlando	
Diagnosis	Gender Dysphoria, hypogonadism
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

1.1 Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

OR

1.2 Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

1.3 BOTH of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 ONE of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

2 - Patient is NOT taking ONE of the following growth hormones, unless diagnosed with panhypopituitarism:

- Genotropin
- Humatrope
- Norditropin FlexPro
- Nutropin AQ
- Omnitrope
- Saizen

AND

3 - Patient is NOT taking with an Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

2 . Revision History

Date	Notes
5/24/2022	Added Jatenzo and Tlando as NP targets. Added submission of reco rds to criteria.

Prior Authorization Guideline

GL-104976 Tezspire (tezepelumab-ekko)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	4/1/2022

1 . Criteria

Product Name: Tezspire	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of severe asthma

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following: [2,3]

- Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months
- Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [2,3]

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]) [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Tezspire	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by one of the following:

- A reduction in asthma exacerbations
- Improvement in forced expiratory volume in 1 second (FEV1) from baseline

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [4]

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

2 . Endnotes

A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, after initiation of treatment, patients should be re-evaluated in 3 to 6 months. [4]
B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention guideline recommend patients with severe asthma should be treated with maximal optimized high dose ICS-LABA therapy. [4]

3 . Revision History

Date	Notes
3/22/2022	New Program mirrors ORx with Submission of Records added to initial and reauth

Prior Authorization Guideline

GL-99780 Thalomid

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple myeloma	

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

2.1 Used for acute treatment

OR

2.2 Used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, recurrent aphthous stomatitis or ulcer

Product Name: Thalomid	
Diagnosis	Aphthous Stomatitis or Ulcer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyoderma gangrenosum

AND

2 - Used as third line treatment

Product Name: Thalomid	
Diagnosis	Pyoderma Gangrenosum
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous manifestations of systemic lupus erythematosus (SLE)

Product Name: Thalomid	
Diagnosis	Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman's Disease (CD)

AND

2 - NOT used as first line therapy

Product Name: Thalomid	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary myelofibrosis

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Serum erythropoietin levels less than 500 mU/mL

AND

2.1.2 History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

OR

2.2 Serum erythropoietin levels greater than or equal to 500 mU/mL

Product Name: Thalomid	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that member has evidence of symptom improvement or reduction in spleen-liver volume while on Thalomid

Product Name: Thalomid	
Diagnosis	Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Acquired Immunodeficiency Syndrome (AIDS)- Related Kaposi Sarcoma

AND

2 - Patient is currently being treated with antiretroviral therapy (ART)

AND

3 - Not used as first line therapy

Product Name: Thalomid	
Diagnosis	AIDS- Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Thalomid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Thalomid therapy	

2 . Revision History

Date	Notes
6/3/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99691 Tibsovo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH1 mutation-positive

AND

3 - ONE of the following:

- Disease is relapsed or refractory
- Patient is greater than or equal to 75 years old
- Patient has comorbidities that preclude the use of intensive induction chemotherapy

Product Name: Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tibsovo therapy

Product Name: Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tibsovo will be approved for uses supported by The National Comprehensive Cancer

Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tibsovo therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99653 Tobramycin Inhalation - ARIZONA

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Bethkis, Kitabis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Lung infection with positive culture demonstrating Pseudomonas aeruginosa infection

AND

3 - History of failure, intolerance, or contraindication to BOTH of the following

- Brand Bethkis
- Kitabis

Product Name: Brand TOBI Nebulizer Solution, generic tobramycin solution for inhalation, TOBI Podhaler	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99574 Topical NSAIDs

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Flector Patch, generic diclofenac epolamine 1.3% patch	
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute pain due to minor strains, sprains, or contusions

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI (gastrointestinal) bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Product Name: Pennsaid 2%, diclofenac sodium soln 1.5%	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of pain due to osteoarthritis of the knee(s)

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)
- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis

- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

AND

3 - Patient has a history of failure, intolerance, or contraindication to diclofenac topical gel 1% (Rx formulation), or Voltaren OTC (over the counter)

Product Name: generic diclofenac topical gel 1% (Rx formulation), Voltaren OTC	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of pain due to osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists

AND

2 - ONE of the following:

2.1 The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs (NSAIDs) (An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy)

- Diclofenac DR (Generic Voltaren)
- Diclofenac ER (Generic Voltaren ER)
- Etodolac (Generic Lodine)
- Etodolac ER (Generic Lodine ER)
- Fenoprofen (Generic Nalfon)
- Flurbiprofen (Generic Ansaid)
- Ibuprofen
- Indomethacin (Generic Indocin)
- Ketorolac (Generic Toradol)
- Mefenamic (Generic Ponstel)
- Meloxicam (Generic Mobic)
- Nabumetone (Generic Relafen)
- Nabumetone DS (Generic Relafen DS)
- Naproxen (Generic Anaprox)

- Naproxen DR (Generic Anaprox DR)
- Naproxen EC (Generic Anaprox EC)
- Oxaprozin (Generic Daypro)
- Piroxicam (Generic Feldene)
- Sulindac (Generic Clinoril)

OR

2.2 The patient has one of the following risk factors for NSAID-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori gastritis
- Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g. warfarin, heparin)
- Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Prior Authorization Guideline

GL-99570 Toujeo Solostar, Toujeo Max Solostar, Semglee, Basaglar

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Toujeo Solostar, Toujeo Max Solostar, Semglee, Basaglar	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for Toujeo Solostar, Toujeo Max Solostar, Semglee, Basaglar should be denied. The plan's preferred products are.

- Lantus
- Lantus Solostar
- Levemir

- Levemir FlexPen
- Humulin R U 500 (PA Required)

Prior Authorization Guideline

GL-99500 Trelegy Ellipta - ARIZONA

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Trelegy Ellipta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and-or emphysema

AND

2 - History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of both of the following used in combination:

- Stiolto Respimat (tiotropium-olodaterol)
- Flovent HFA (fluticasone propionate)

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99730 Tremfya - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.3 BOTH of the following:

1.3.1 History of failure to ONE of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.3.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.4 History of failure, contraindication, or intolerance to ALL of the following preferred biologic products (document drug, date, and duration of trial)*:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

AND

1.5 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.6 Prescribed by or in consultation with a dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

2.3 Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with one of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

AND

1.3 History of failure, contraindication, or intolerance to THREE of the following preferred biologic products (document drug, date, and duration of trial):

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)
- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

1.5 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

2.4 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is not receiving Tremfya in combination with ONE of the following:

- Biologic disease modifying antirheumatic drug (DMARD) [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99513 Tretinoin Capsules - ARIZONA

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute promyelocytic leukemia

Product Name: Tretinoin capsules	
Diagnosis	Acute Promyelocytic Leukemia (APL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tretinoin capsules will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tretinoin capsules	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tretinoin capsules

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99591 Tretinoin Topical

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Retin-A cream and gel*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is 26 years of age or less

OR

1.2 Both of the following:

- Patient is greater than 26 years of age
- Diagnosis of acne vulgaris

AND

2 - The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following:

- benzoyl peroxide
- topical clindamycin
- topical erythromycin

Notes	*Only Brand Covered

2 . Revision History

Date	Notes
10/29/2021	Changed effective date to 12/1/21

Prior Authorization Guideline

GL-103832 Trikafta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/18/2022

1 . Criteria

Product Name: Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis (CF)	

AND

2 - Submission of laboratory results documenting that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data

AND

3 - The patient is 6 years of age or older

AND

4 - Prescribed by, or in consultation with, a specialist affiliated with a CF care center

Product Name: Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the patient has achieved a clinically meaningful response while on Trikafta therapy to ONE of the following:

- Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
- Body mass index (BMI)
- Pulmonary exacerbations
- Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

AND

2 - Prescribed by, or in consultation with, a specialist affiliated with a cystic fibrosis (CF) care center

2 . Revision History

Date	Notes
2/17/2022	Updated age and mutation requirements to reflect labeling update

Prior Authorization Guideline

GL-99544 Triptans - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Amerge, generic sumatriptan nasal spray, brand Imitrex tablets, Brand Imitrex injection, generic sumatriptan 6mg PFS, generic almotriptan, brand Maxalt, brand Maxalt MLT, Onzetra Xsail, brand Relpax, generic eletriptan, brand Treximet, generic sumatriptan naproxen, Zembrace, brand Zomig, brand Zomig ZMT, brand Frova, generic frovatriptan, Tosymra	
Diagnosis	Non-preferred products
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of migraine headaches with or without aura	

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least three preferred products (document drugs, duration, and date of trials)*

- brand Imitex Nasal Spray
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt)
- sumatriptan (Generic Imitrex)
- zolmitriptan (Generic Zomig)

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Migraine Headaches with or without Aura
Approval Length	12 month(s)
Guideline Type	Quantity Limits

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See "Quantity Limits" table in background section for quantity limits * * Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be included in denial to provider

Product Name: Brand Imitrex (inj, cartridge, auto-injector and PFS), generic sumatriptan (inj, cartridge, auto-injector and PFS)*	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of cluster headaches

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits

Product Name: Brand Amerge, generic naratriptan, Brand Frova, generic frovatriptan, Brand Imitrex tablets and nasal spray, generic sumatriptan tablets and nasal spray, generic almotriptan, Brand Maxalt and Maxalt MLT, generic rizatriptan and rizatriptan MLT, Onzetra Xsail, Brand Relpax, generic eletriptan, Brand Treximet, generic sumatriptan-naproxen, Zembrace Sym Touch, Brand Zomig and Zomig ZMT, generic zolmitriptan and zolmitriptan ZMT, brand Zomig nasal, generic zolmitriptan nasal spray, Tosymra *	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain management specialist

AND

3 - Patient is currently receiving prophylactic therapy with at least ONE of the following:

3.1 Amitriptyline (Elavil)

OR

3.2 One of the following beta-blockers:

- atenolol
- metoprolol
- nadolol**
- propranolol
- timolol**

OR

3.3 Divalproex sodium (Depakote/Depakote ER)

OR

3.4 OnabotulinumtoxinA (Botox) ***

OR

3.5 Topiramate (Topamax)

OR

3.6 Venlafaxine (Effexor/Effexor XR)

OR

3.7 Calcitonin gene-related peptide (CGRP) receptor antagonists [e.g., Aimovig (erenumab), Emgality (galcanezumab)]

AND

4 - One of the following:

4.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

4.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA (Food and Drug Administration) for the diagnosis indicated

AND

5 - Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	* See “Quantity Limits” table in background section for quantity limits * * Nadolol and timolol are non-preferred and should not be included in denial to provider *** OnabotulinumtoxinA (Botox) is a medical benefit, should not be included in denial to provider

Product Name: Brand Zomig nasal spray, generic zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient has a history of failure, contraindication, or intolerance to a trial of Imitrex Nasal Spray

AND

2 - If the request is for generic zolmitriptan nasal spray, patient must have tried and failed Brand Zomig Spray

2 . Background

Benefit/Coverage/Program Information

Quantity Limits

Quantity Limits

Drug Name	Strength	Quantity Limit
Brand Amerge generic naratriptan	1mg, 2.5mg	9 tabs/month
Brand Frova Generic frovatriptan	2.5mg	9 tabs/month
Brand Imitrex tablets generic sumatriptan tablets	25mg, 50mg, 100mg	9 tabs/month
Brand Maxalt Generic rizatriptan	5mg, 10mg	9 tabs/month
Brand Maxalt MLT Generic rizatriptan ODT	5mg, 10mg	9 tabs/month
Generic almotriptan	6.25mg, 12.5mg	6 tabs/month
Relpax Generic eletriptan	20mg, 40mg	6 tabs/month
Brand Zomig Generic zolmitriptan	2.5mg, 5mg	6 tabs/month

Brand Zomig ZMT Generic zolmitriptan ODT	2.5mg, 5mg	6 tabs/month
Brand Imitrex Nasal Spray Generic sumatriptan nasal spray	5mg, 20mg	6 spray devices/month
Zomig Nasal Spray	2.5mg, 5mg	6 spray devices/month
Treximet Generic sumatriptan/naproxen	85mg/500 mg, 10mg/60mg	9 tabs/month
Onzetra Xsail	11mg	1 box (8 units)/month
Zembrace SymTouch	3mg	1 box (4 units)/month
Brand Imitrex Generic Sumatriptan Autoinjector/Cartridge Refills	4mg/0.5mL 6mg/0.5mL	8 autoinjectors or cartridge refills/month (4 boxes/month)
Brand Imitrex Generic Sumatriptan Vials	6mg/0.5mL	10 vials/month (2 boxes/month)
Generic Sumatriptan Pre-filled Syringe	6mg/0.5mL	8 prefilled syringes (4 boxes/month)
Tosymra nasal spray	10mg	6 units per month

Prior Authorization Guideline

GL-99774 Tukysa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of breast cancer	

AND

2 - Disease is ONE of the following:

- Advanced unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting [e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)]

AND

5 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Product Name: Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Product Name: Tukysa

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tukysa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Tukysa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tukysa therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99692 Turalio

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis (PVNS)

Product Name: Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Turalio therapy

Product Name: Turalio	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Turalio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Turalio	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Turalio therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-107465 Twyneo (tretinoin-benzoyl peroxide 0.1-3% cream)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Twyneo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting both of the following:

1.1 Both of the following:

- Patient is 9 years of age or older

- Diagnosis of acne vulgaris

AND

1.2 The patient must have a history of therapeutic failure, contraindication, or intolerance to ALL of the following (verified via paid pharmacy claims or submission of medical records):

- benzoyl peroxide
- topical clindamycin
- topical erythromycin
- topical tretinoin (Brand Retin-A)

2 . Revision History

Date	Notes
5/24/2022	New program

Prior Authorization Guideline

GL-99775 Tykerb

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of recurrent or stage IV hormone receptor positive, human epidermal growth factor receptor 2-positive (HER2+) breast cancer

AND

1.1.2 Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of advanced or stage IV human epidermal growth factor receptor 2-positive (HER2+) breast cancer

AND

1.2.2 Used in combination with ONE of the following:

- Herceptin (trastuzumab)
- Xeloda (capecitabine)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

AND

1.1.2 Tykerb is active against primary (breast) tumor

AND

1.1.3 Used in combination with Xeloda (capecitabine)

OR

1.2 ALL of the following:

1.2.1 Diagnosis of recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

1.2.2 Patient has received previous radiation therapy

AND

1.2.3 Patient has received ONE of the following:

- Gross total or subtotal resection
- Localized recurrence
- Evidence of metastasis (brain, spine, or cerebral spinal fluid)

AND

1.2.4 Used in combination with Temodar (temozolomide)

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Chordoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epidermal growth factor receptor (EGFR) -positive, recurrent chordoma

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced or metastatic colon cancer (Human epidermal growth factor receptor 2 (HER2)-amplified and RAS wild type)

AND

2 - Patient has not previously been treated with a Human epidermal growth factor receptor 2 (HER2) inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

AND

4 - Used in combination with trastuzumab

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced or metastatic rectal cancer (Human epidermal growth factor receptor 2 (HER2)-amplified and RAS wild type)

AND

2 - Patient has not previously been treated with a Human epidermal growth factor receptor 2 (HER2) inhibitor [e.g., Kanjinti (trastuzumab), Perjeta (pertuzumab), Nerlynx (neratinib)]

AND

3 - Patient has previously been treated with ONE of the following regimens:

- Oxaliplatin-based therapy without irinotecan
- Irinotecan-based therapy without oxaliplatin
- FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- A fluoropyrimidine without irinotecan or oxaliplatin

AND

4 - Used in combination with trastuzumab

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tykerb will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tykerb therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99789 Tymlos - Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Tymlos	
Diagnosis	Postmenopausal patients with osteoporosis at high risk for fracture
Approval Length	24 Months**
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of postmenopausal osteoporosis	

AND

2 - ONE of the following:

2.1 Bone Mineral Density (BMD) T-score less than or equal to -3.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

OR

2.2 BOTH of the following:

2.2.1 BMD T-score between -2.5 and -3.5 (BMD T-score greater than -3.5 and less than or equal to -2.5) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.2.2 ONE of the following:

2.2.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.2.2.2 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial)

- bisphosphonate (e.g. ALENDRONATE, IBANDRONATE)
- selective estrogen receptor modulator (SERM) (e.g RALOXIFENE)
- Prolia (DENOSUMAB)
- Forteo.(TERIPARATIDE)

OR

2.3 ALL of the following:

2.3.1 BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [NOTE: Provider must submit patient specific BMD T-score]

AND

2.3.2 ONE of the following:

2.3.2.1 History of ONE of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

2.3.2.2 ONE of the following Fracture Risk Assessment Tool (FRAX) 10-year fracture probabilities:

- Major osteoporotic fracture at 20 percent or more
- Hip fracture at 3 percent or more

AND

2.3.3 History of failure, contraindication, or intolerance to ALL of the following (Document drug, date, and duration of trial)

- bisphosphonate (e.g. ALENDRONATE, IBANDRONATE)
- selective estrogen receptor modulator (SERM) (e.g RALOXIFENE)
- Prolia (DENOSUMAB)
- Forteo.(TERIPARATIDE)

AND **3** - Treatment duration has not exceeded a total of 24 months* of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime **AND** **4** - Prescriber attests to the following: The information provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided	
Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial **Duration of coverage will be limited to 24 months of cumulative parathyroid hormone analog therapy (e.g., Forteo, Tymlos) in the patient's lifetime

2 . Revision History

Date	Notes
7/1/2021	Update Guideline

Prior Authorization Guideline

GL-99501 Uloric

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Uloric, generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - History of failure, contraindication or intolerance to allopurinol (generic Zyloprim)	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99693 Valchlor

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of ONE of the following:

- Chronic or smoldering T-cell leukemia-lymphoma
- Primary cutaneous marginal zone or follicle center B-cell lymphoma
- Lymphomatoid papulosis (LyP) with extensive lesions
- Mycosis fungoides (MF)-Sezary syndrome (SS)

Product Name: Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Valchlor will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99527 Vancomycin - AZ

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	10 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]

AND

2 - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vancomycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]
Approval Length	12 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of Clostridioides difficile infection [previously known as Clostridium difficile-associated diarrhea] after prior treatment with oral vancomycin

Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vancomycin capsules are preferred.

Product Name: Brand Firvanq oral solution, Brand Vancocin, generic vancomycin capsules, vancomycin oral solution	
Diagnosis	Staphylococcus aureus
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterocolitis due to Staphylococcus aureus

AND **2** - If the request is for vancomycin oral solution, the prescriber provides a reason or special circumstance the patient cannot use Firvanq and vancomycin capsules*	
Notes	NOTE: *Vancomycin oral solution is non-preferred. Firvanq and vanco mycin capsules are preferred.

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Prior Authorization Guideline

GL-99655 Vecamyl

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderately severe to severe essential hypertension	

OR **2** - Diagnosis of uncomplicated malignant hypertension

Product Name: Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of a positive clinical response to Vecamyl therapy	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99596 Velphoro (sucroferric oxyhydroxide), Auryxia (ferric citrate)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Velphoro, Auryxia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

- Diagnosis of hyperphosphatemia
- Diagnosis of End Stage Renal Disease

AND **2** - Adherence to and trial and failure to Sevelamer and Fosrenol at maxiumum dosages (MUST be verified via paid pharmacy claims or submission of medical records) • Sevelamer Carbonate at the maximum dosage – 800mg/15 per day • Sevelamer Powder Packets at maximum dosage – 2.4gm packet 4 per day • Fosrenol Chewable Tablets and/or Powder Packets at the maximum dosage 4500 mg per day in divided doses	
Notes	1. Approval will not be granted for requests based on potential side effects, i.e., constipation 2. Approval will not be granted for submitted prior authorizations based on pill burden. Velphoro and Sevelamer are both taken 3 times a day.

2 . Revision History

Date	Notes
11/23/2021	Added 'verified via paid pharmacy claims or submission of medical records' to t/f req

Veltassa

Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99553 Veltassa

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Lokelma, Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-life threatening hyperkalemia	

AND

2 - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs]) have been discontinued or reduced to the lowest effective dose

AND

3 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

4 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Product Name: Lokelma, Veltassa	
Diagnosis	Non-Life Threatening Hyperkalemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Lokelma or Veltassa therapy

AND

2 - Patient continues to require treatment for hyperkalemia

AND

3 - Where clinically appropriate, medications known to cause hyperkalemia (e.g. angiotensin-

converting enzyme inhibitor, angiotensin II receptor blocker, aldosterone antagonist, non-steroidal anti-inflammatory drugs [NSAIDs])) have been discontinued or reduced to the lowest effective dose

Prior Authorization Guideline

GL-99731 Vemlidy

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vemlidy	
Diagnosis	Treatment-Naïve Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Patient has a contraindication to entecavir therapy	

Product Name: Vemlidy

Diagnosis	Treatment-Experienced Chronic Hepatitis B Infection
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 BOTH of the following:

1.1.1 Patient is currently on Viread therapy

AND

1.1.2 ONE of the following:

- Patient has a creatinine clearance less than 60 mL per minute
- Patient has a diagnosis of osteoporosis

OR

1.2 Patient is currently on Vemlidy therapy

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Prior Authorization Guideline

GL-99703 Venclexta

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Product Name: Venclexta	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Not used as first line therapy

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Newly-diagnosed acute myeloid leukemia (AML)

AND

1.2 Venclexta therapy to be given in combination with ONE of the following:

- Azacitidine
- Decitabine

- Low-dose cytarabine

AND

1.3 ONE of the following:

- Patient is greater than or equal to 60 years old
- Patient has significant comorbidities that preclude the use of intensive induction chemotherapy

OR

2 - ALL of the following:

2.1 Diagnosis of relapsed/refractory acute myeloid leukemia (AML)

AND

2.2 Relapse is greater than or equal to 12 months from most recent disease remission

AND

2.3 Venclexta therapy to be given in combination with the patient's previous initial successful induction regimen (e.g., azacitidine, decitabine, low-dose cytarabine, etc.)

Product Name: Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Mantle Cell Lymphoma, Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Product Name: Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Venclexta will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Venclexta therapy

2 . Revision History

Date	Notes
4/13/2021	7/1 Implementation

Prior Authorization Guideline

GL-99557 Ventolin, Proventil, generic albuterol

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Ventolin, Proventil, generic albuterol	
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for Ventolin, Proventil, and generic albuterol should be denied. The plan's preferred product is Proair.	
Notes	ProAir is the only preferred albuterol. Patients on other albuterol formu lations are to be transitioned to ProAir.

2 . Revision History

Date	Notes
6/29/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107454 Verkazia (cyclosporine ophthalmic emulsion 0.1%)

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Verkazia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting all of the following:

1.1 Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of

clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia)

AND

1.2 Trial and failure, contraindication, or intolerance to one of the following (verified via pharmacy paid claims or submission of medical records):

- Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

1.3 Trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone) ((verified via pharmacy paid claims or submission of medical records)

AND

2 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

Product Name: Verkazia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)

2 . Revision History

Date	Notes
5/24/2022	New program

Prior Authorization Guideline

GL-99702 Verzenio

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 Used in combination with Faslodex (fulvestrant)

OR

4.2 ALL of the following:

- Used as monotherapy
- Patient has disease progression following endocrine therapy
- Patient has already received at least one prior chemotherapy regimen

OR

4.3 Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)]

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Verzenio therapy

Product Name: Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verzenio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Verzenio therapy

2 . Revision History

Date	Notes
4/13/2021	7/1 Implementation

Prior Authorization Guideline

GL-108523 Vijoice (alpelisib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	7/1/2022

1 . Criteria

Product Name: Vijoice	
Approval Length	6 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)	

AND

2 - Submission of documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Submission of documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

AND

5 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of documentation of positive clinical response to therapy (e.g., radiological response defined as a ≥ 20% reduction from baseline in the sum of target lesion volume)

AND

2 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

2 . Revision History

Date	Notes
6/22/2022	New program

Prior Authorization Guideline

GL-99535 Vitamin B-12

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin B-12	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin B-12 deficiency.	

2 . Revision History

Date	Notes
5/20/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99532 Vitamin C

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin C	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin C deficiency	

2 . Revision History

Date	Notes
5/19/2021	7/1 Implementation

Prior Authorization Guideline

GL-99533 Vitamin D

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vitamin D	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Provider has submitted lab work documenting a Vitamin D deficiency	

2 . Revision History

Date	Notes
5/19/2021	7/1 Implementation

Prior Authorization Guideline

GL-99694 Vitrakvi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Vitrakvi	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Presence of a solid tumor

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic
- Unresectable

AND

5 - ONE of the following:

- Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)
- Disease has no satisfactory alternative treatments

Product Name: Vitrakvi	
Diagnosis	Solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Product Name: Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Vitrakvi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.	

Product Name: Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Vitrakvi therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99776 Vizimpro

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vizimpro	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is advanced or metastatic

AND

3 - Disease is positive for ONE of the following EGFR (epidermal growth factor receptor) mutations:

- Exon 19 deletion
- Exon 21 L858R substitution

Product Name: Vizimpro	
Diagnosis	Non-small cell lung cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vizimpro therapy

Product Name: Vizimpro	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vizimpro will be approved for uses supported by The National Comprehensive Cancer

Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Vizimpro	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Vizimpro therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-107466 Vonjo (pacritinib)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following:

1.1 Diagnosis of ONE of the following:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

1.2 Disease is intermediate or high risk

AND

1.3 Pre-treatment platelet count below 50 x 10^9 L

AND

2 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Product Name: Vonjo	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)

Product Name: Vonjo	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - This drug will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
5/24/2022	New Program

Votrient

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99701 Votrient

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of renal cell carcinoma (RCC)	

AND

2 - ONE of the following:

- Disease is relapsed
- Stage IV disease

Product Name: Votrient	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of ONE of the following:

- Angiosarcoma
- Alveolar soft part sarcoma
- Pleomorphic rhabdomyosarcoma
- Retroperitoneal/Intra-abdominal disease that is unresectable or progressive
- Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases
- Solitary fibrous tumor/hemangiopericytoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

1.2.2 History of failure, contraindication, or intolerance to ALL of the following:

- Gleevec (imatinib)
- Sutent (sunitinib)
- Stivarga (regorafenib)

Product Name: Votrient	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Hürthle cell carcinoma
- Papillary carcinoma

AND

1.1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.1.4 ONE of the following:

- Disease is refractory to radioactive iodine treatment
- Distant metastatic disease not amenable to radioactive iodine treatment

OR

1.2 ALL of the following:

1.2.1 Diagnosis of medullary carcinoma

AND

1.2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

1.2.3 History of failure, contraindication, or intolerance to ONE of the following:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name: Votrient	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - One of the following:

- Disease is recurrent
- Disease is metastatic

AND

3 - Disease has progressed following previous cytotoxic chemotherapy (e.g., doxorubicin, docetaxel/gemcitabine, etc.)

Product Name: Votrient	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

- Disease is persistent
- Disease is recurrent

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Votrient	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Votrient therapy

2 . Revision History

Date	Notes
4/13/2021	7/1 Implementation

Prior Authorization Guideline

GL-107444 Voxzogo (vosoritide)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	6/1/2022

1 . Criteria

Product Name: Voxzogo	
Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 5 years of age or older	

AND

2 - Patient has open epiphyses

AND

3 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of achondroplasia as confirmed by one of the following: [2, 3]

3.1 Both of the following:

3.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

3.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

3.2 Molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

4 - Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo	
Diagnosis	Achondroplasia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to have open epiphyses

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy as evidenced by one of the following:

- Improvement in annualized growth velocity (AGV) compared to baseline
- Improvement in height Z-score compared to baseline

AND

3 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo	
Diagnosis	Idiopathic Short Stature (ISS)

Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for coverage for diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved	
Notes	Approval Length: N/A - Requests for Idiopathic Short Stature (ISS) sh ould not be approved. Deny as a benefit exclusion.

2 . Revision History

Date	Notes
5/24/2022	New Program

Prior Authorization Guideline

GL-99867 Vyndaqel and Vyndamax

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)	

AND

2 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting ONE of the following:

2.1 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 Submission of medical records (e.g., chart notes, lab work, imaging) documenting ALL of the following

2.3.1 Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of monoclonal protein identified in serum, urine immunofixation (IFE), serum free light chain (sFLC) assay

AND

3 - Prescribed by, or in consultation, with a cardiologist

AND

4 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

AND

5 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting BOTH of the following:

5.1 ONE of the following:

5.1.1 Patient has New York Heart Association (NYHA) Functional Class I or II heart failure

OR

5.1.2 BOTH of the following:

5.1.2.1 Patient has New York Heart Association (NYHA) Functional Class III heart failure

AND

5.1.2.2 Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in six minutes or less

AND

5.2 Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 picograms/milliliter

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

OR

6.2 If the patient is receiving Vyndaqel/Vyndamax in combination with Onpattro (patisiran) or Tegsedi (inotersen), the physician attests that he/she will coordinate care with other specialist(s) involved in the patient's amyloidosis treatment plan to determine optimal long term monotherapy** treatment regimen

Notes	NOTE: *May require prior authorization and notification ** Referring to monotherapy with Vyndaqel/Vyndamax, Onpattro, or Tegsedi

Product Name: Vyndaqel, Vyndamax	
Diagnosis	Transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting that the patient has experienced a positive clinical response to Vyndaqel or Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Submission of medical records (e.g., chart notes) documenting that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Paid claims or submission of medical records (e.g., chart notes) verifying patient is not receiving Vyndaqel or Vyndamax in combination with either of the following:

- Onpattro (patisiran)
- Tegsedi (inotersen)

2 . Revision History

Date	Notes
12/9/2021	Added submission of records/paid claims where applicable.

Prior Authorization Guideline

GL-104873 Vyvgart (efgartigimod alfa-fcab)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	3/17/2022

1 . Criteria

Product Name: Vyvgart	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes, lab work, imaging) documenting diagnosis of generalized myasthenia gravis (gMG)	

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - Prior to administration, patient must be on a stable dose of at least ONE of the following therapies for the treatment of gMG:

- acetylcholinesterase (AChE) inhibitors (e.g., pyridostigmine)
- steroids (e.g., prednisone)
- non-steroidal immunosuppressive therapies (NSISTs) [e.g., azathioprine, cyclosporine, cyclophosphamide)

AND

4 - One of the following:

4.1 Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks

OR

4.2 In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Vyvgart	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab work, imaging) documenting positive clinical response to therapy

AND

2 - One of the following:

2.1 Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks

OR

2.2 In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks

2 . Endnotes

A. In the ADAPT study all patients received cycle 1, then the time between each treatment cycle was individualized based on the duration of the patient's clinically meaningful response (with a maximum of 3 treatment cycles allowed in 26 week).

3 . Revision History

Date	Notes
3/31/2022	New guideline, mirrors ORx with addition of submission of MR req for both initial and reauth

Prior Authorization Guideline

GL-99732 Wakix

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to the following: Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - One of the following:

3.1 Patient has a history of failure, contraindication, or intolerance to all of the following:

3.1.1 One of the following:

- An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine)
- A methylphenidate-based stimulant

AND

3.1.2 Armodafinil (Nuvigil)

AND

3.1.3 Sunosi (solriamfetol)

OR

3.2 Patient has a history of or potential for a substance abuse disorder

AND

4 - Prescribed by one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Wakix	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99695 Xalkori

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name: Xalkori	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive
- Tumor is positive for mesenchymal-epithelial transition (MET) amplification
- Tumor is positive for MET exon 14 skipping mutation

Product Name: Xalkori	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS1-positive

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

Product Name: Xalkori

Diagnosis	Inflammatory Myofibroblastic Tumor (IMT), Non-Small Cell Lung Cancer (NSCLC), Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xalkori therapy

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xalkori will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xalkori therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99733 Xeljanz, Xeljanz XR - AZ

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to all of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)*

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)*

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to three of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Otezla (apremilast)

- Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

1.5 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

1.2 History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- Corticosteroids (e.g., prednisone, methylprednisone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Aminosalicylates (e.g., mesalamine, sulfasalazine)

AND

1.3 If the request is for Xeljanz XR, the patient has a history of failure, contraindication, or intolerance to Xeljanz (tofacitinib)

AND

1.4 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - All of the following:

2.1 Patient is currently on the requested therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

AND

2.2 Diagnosis of moderately to severely active UC

AND

2.3 Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Xeljanz, Xeljanz XR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Xeljanz	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

3 - Prescribed by, or in consultation with, a rheumatologist

Product Name: Xeljanz	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving the requested medication in combination with one of the following:

- Biologic DMARD (disease-modifying anti-rheumatic drug) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)
- Janus kinase inhibitor [e.g., Olumiant (baricitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

2 . Revision History

Date	Notes
6/3/2021	7/1 Implementation

Prior Authorization Guideline

GL-99657 Xenazine

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chorea in patients with Huntington's disease	

Product Name: Brand Xenazine, generic tetrabenazine

Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia

AND

2 - One of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome

AND

2 - History of failure, contraindication, or intolerance to Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99529 Xenleta

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 History of failure, contraindication, or intolerance to three of the following antibiotics:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name: Xenleta*	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge **OR** **1.2** As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **1.3** The medication is being prescribed by or in consultation with an infectious disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Prior Authorization Guideline

GL-99658 Xermelo

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of carcinoid syndrome diarrhea	

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)

Product Name: Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99659 Xolair

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate or severe asthma	

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80 percent predicted [in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - ONE of the following:

3.1 Baseline (pre-omalizumab treatment) serum total Immunoglobulin E (IgE) level greater than or equal to 30 IU/mL (international units per milliliter) and less than or equal to 1500 IU/mL

OR

3.2 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

4 - Positive skin test or in vitro reactivity to a perennial aeroallergen

AND

5 - Used in combination with ONE of the following:

5.1 One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)-long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate-salmeterol (AirDuo, Advair), budesonide-formoterol (Symbicort)]

OR

5.2 Combination therapy including BOTH of the following:

5.2.1 One high-dose (appropriately adjusted for age) inhaled corticosteroid (ICS) product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

5.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

6 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]

- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

7 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

8 - Prescribed by or in consultation with an allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by ONE of the following:

- reduction in frequency of exacerbations
- decreased utilization of rescue medications
- increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing controller medication

AND

3 - Patient is not receiving Xolair in combination with ONE of the following:

- Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
- Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

AND

4 - Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

AND

5 - Prescribed by or in consultation with allergist-immunologist or pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*

OR

2.2 Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to BOTH of the following taken in combination:

2.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

- Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
- First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*
- H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
- Leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

AND

4 - Prescribed by or in consultation with an allergist-immunologist or dermatologist

Notes	*Patients 65 years of age and older in whom first generation H1-antihistamines are considered high risk medications to be avoided (e.g., Beers criteria, HEDIS) should be directed to try alternatives that are not considered high risk.

Product Name: Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by or in consultation with allergist-immunologist or dermatologist

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99502 Xopenex Respules

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Xopenex inhalation soln, generic levalbuterol inhalation soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - The patient has a history of failure, contraindication, or intolerance to treatment with albuterol inhalation solution	

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99696 Xospata

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Xospata	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

AND

3 - Disease is relapsed or refractory

Product Name: Xospata	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xospata therapy

Product Name: Xospata	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xospata will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Xospata

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xospata therapy	

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99777 Xpovio

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xpovio	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of relapsed or refractory multiple myeloma (RRMM)

AND

2 - Patient has received at least four prior therapies

AND

3 - Disease is refractory to ALL of the following:

- Two proteasome inhibitors (e.g., bortezomib, carfilzomib)
- Two immunomodulatory agents (e.g., lenalidomide, thalidomide)
- • An anti-CD38 monoclonal antibody (e.g., daratumumab)

AND

4 - Xpovio is used in combination with dexamethasone

Product Name: Xpovio	
Diagnosis	Diffuse Large B-cell Lymphoma (DLBCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (including DLBCL arising from follicular lymphoma)

AND

2 - Patient has received at least 2 lines of systemic therapies

Product Name: Xpovio	
Diagnosis	Multiple Myeloma, Diffuse Large B-cell Lymphoma (DLBCL)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xpovio therapy

Product Name: Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xpovio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xpovio therapy

2 . Revision History

Date	Notes

6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99778 Xtandi

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

2.2 Patient has had bilateral orchiectomy

AND

3 - ONE of the following:

3.1 If the disease is metastatic, castration-resistant, ONE of the following:

3.1.1 History of failure, contraindication, or intolerance to Zytiga

OR

3.1.2 Continuation of ongoing Xtandi therapy

OR

3.2 If the disease is non-metastatic, castration-resistant, ONE of the following:

3.2.1 History of failure, contraindication, or intolerance to BOTH of the following:

- Erleada (apalutamide)
- Nubeqa (darolutamide)

OR

3.2.2 Continuation of ongoing Xtandi therapy

OR

3.3 If the disease is metastatic, castration-sensitive, ONE of the following:

3.3.1 History of failure, contraindication, or intolerance to both of the following:

- Erleada (apalutamide)
- Zytiga (abiraterone)

OR

3.3.2 Continuation of ongoing Xtandi therapy

Product Name: Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Product Name: Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xtandi will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xtandi therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99660 Xuriden

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of a hereditary orotic aciduria	

Product Name: Xuriden

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xuriden therapy

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Medicaid SP to Medicaid Arizona SP for 7/1

Prior Authorization Guideline

GL-99814 Xyrem, Xywav

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Xyrem, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

AND

3 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Xyrem, Xywav	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Xyrem, Xywav	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - History of failure, contraindication, or intolerance of ALL of the following (MUST be verified via paid pharmacy claims or submission of medical records):

3.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.2 Armodafanil (Nuvigil)

AND

3.3 Sunosi (solriamfetol)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Xyrem, Xywav

Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

2 . Revision History

Date	Notes
11/23/2021	Added 'verified via paid pharmacy claims of submission of medical re cords' to t/f requirements

Yonsa

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99734 Yonsa

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (e.g., N1)

AND

3 - Used in combination with methylprednisolone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - ONE of the following:

5.1 Prescriber provides a reason or special circumstance the patient cannot take Zytiga

OR

5.2 Patient is currently on Yonsa therapy

Product Name: Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Yonsa therapy

Product Name: Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Yonsa will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Yonsa therapy

2 . Revision History

Date	Notes
5/18/2021	7/1 Implementation

Prior Authorization Guideline

GL-99697 Zejula

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of ONE of the following:

- Recurrent or advanced epithelial ovarian cancer
- Recurrent or advanced fallopian tube cancer
- Recurrent or advanced primary peritoneal cancer

AND

1.2 Patient is in a complete or partial response to a platinum-based chemotherapy

AND

1.3 Request is for maintenance therapy

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Treatment)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Both of the following:

1.1.1 Diagnosis of advanced, persistent, or recurrent ovarian, fallopian tube, or primary peritoneal cancer

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

1.1.2.1.1 Patient has been treated with three or more prior chemotherapy regimens

AND

1.1.2.1.2 Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:

1.1.2.1.2.1 Presence of deleterious or suspected deleterious BRCA (breast cancer) mutation

OR

1.1.2.1.2.2 BOTH of the following:

- Genomic instability
- Cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin)

OR

1.1.2.2 BOTH of the following:

- Disease is platinum-sensitive
- Used in combination with bevacizumab

Product Name: Zejula	
Diagnosis	Ovarian Cancer (Maintenance, Treatment)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zejula therapy

Product Name: Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zejula will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zejula therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99698 Zelboraf

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zelboraf	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Unresectable melanoma

- Metastatic melanoma

AND

2 - Patient is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has metastatic brain lesions

AND

2 - Zelboraf is active against primary tumor (melanoma)

AND

3 - Used in combination with Cotellic (cobimetinib)

Product Name: Zelboraf	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

Product Name: Zelboraf	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Non-Small Cell Lung Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

Product Name: Zelboraf	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester Disease

AND

2 - Cancer is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - BOTH of the following:

4.1 Used in combination with irinotecan

AND

4.2 Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Zelboraf	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rectal cancer

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - ONE of the following:

- Unresectable or advanced disease
- Metastatic disease

AND

4 - BOTH of the following:

4.1 Used in combination with irinotecan

AND

4.2 Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name: Zelboraf	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Hurthle cell carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Metastatic disease
- Persistent disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine

AND

5 - Cancer is positive for BRAF V600 mutation

Product Name: Zelboraf	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name: Zelboraf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zelboraf will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Zelboraf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zelboraf therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-103270 Zeposia (ozanimod)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	2/4/2022

1 . Criteria

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS)	

AND

2 - Patient has a history of failure, contraindication, or intolerance to a trial of at least TWO of the preferred alternatives * (May require PA) (Verified via pharmacy paid claims or submission of medical records)

- Interferon Beta-1B (Extavia)
- Fingolimod (Gilenya)
- Brand Copaxone 20mg
- Brand Glatopa 40mg
- Interferon Beta-1A (Refib, Avonex)

Notes	*Note: Preferred alternatives may require PA

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 Weeks [B, 3, 4]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)*:

- 6-mercaptopurine (Purinethol)
- Aminosalicylates (e.g., mesalamine [Asacol, Pentasa, Rowasa], osalazine [Dipentum], Sulfasalazine [Azulfidine, Sulfazine])
- Azathioprine (Imuran)
- Corticosteroids (e.g., prednisone, methylprednisolone)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:

- Humira (adalimumab)
- Simponi (golimumab)
- Stelara (ustekinumab)

OR

3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient is NOT receiving Zeposia in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

• Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]	
Notes	*Note: Claims history may be used in conjunction as documentation of drug, date, and duration of trial

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is NOT receiving Zeposia in combination with ANY of the following:

- Biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab)]
- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
- Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

2 . Revision History

Date	Notes
2/3/2022	New drug-specific guideline for Zeposia, with new criteria added for UC indication

Prior Authorization Guideline

GL-99786 Zolgensma (onasemnogene abeparvovec-xioi)

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zolgensma	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - The mutation or deletion of genes in chromosome 5q resulting in one of the following: [1-8, A]

1.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

1.2 Compound heterozygous mutation of SMN1 gene (e.g., deletion of Survival of Motor Neuron 1 [SMN1] exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2 - One of the following:

2.1 Both of the following: [1-5]

2.1.1 Diagnosis of diagnosis of SMA Type 0, I or Type II spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the treatment of SMA

AND

2.1.2 Patient is less than or equal to 2 years of age

OR

2.2 Both of the following:

2.2.1 Diagnosis of SMA based on the results of SMA newborn screening

AND

2.2.2 Patient has 3 copies or less of Survival of Motor Neuron 2 (SMN 2)

AND

3 - Patient is not dependent on either of the following:

- Invasive ventilation or tracheostomy
- Use of invasive ventilation beyond use of naps and nighttime sleep

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting patient's anti-AAV9 antibody titers are less than or equal to 1:50 [1]

AND

5 - Patient is not to receive concomitant SMN modifying therapy (e.g. Spinraza)

AND

6 - Prescribed by a neurologist with expertise in the diagnosis of SMA

AND

7 - Patient has never received Zolgensma treatment in their lifetime

2 . Endnotes

A. This is the definition that the clinical trials used. Also consistent with clinical guidelines. [2-8]
B. There were 3 key clinical trials for Zolgensma (START, STR1VE, SPR1NT). START and STR1VE only enrolled patients with SMA Type 1 and SPR1NT enrolled pre-symptomatic SMA patients. [2-5]
C. Exclusion criteria found in clinical trials. [2-5]
D. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Spinraza and Zolgensma) is superior to any single treatment alone. RESPOND is a phase 4 trial that will assess the efficacy and safety of Spinraza in patients with suboptimal clinical response to Zolgensma. It is planned to begin enrollment in 2021. [9-10]

3 . References

1. Zolgensma Prescribing Information. AveXis Inc. Bannockburn, IL. May 2019.

2. Mendell J.R., Al-Zaidy S, Shell R, etc. Single-Dose Gene Replacement Therapy for Spinal Muscular Atrophy. New Eng J of Med. 2017; 377:1713-22.
3. Al-Zaidy S, Pickard AS, Kotha K, et al. Health outcomes in spinal muscular atrophy type 1 following AVXS-101 gene replacement therapy. Pediatr Pulmonol. 2019;54(2):179-185.
4. Day JW, Chiriboga CA, Crawford TO, et al. AVXS-101 gene-replacement therapy for spinal muscular atrophy type 1: phase 3 study (STR1VE) update. Poster presented at: The 71st Annual American Academy of Neurology Meeting, Philadelphia PA, May 4-10, 2019.
5. Strauss KA, Swoboda KJ, Farrar MA, et al. AVXS-101 gene-replacement therapy in presymptomatic spinal muscular atrophy: SPR1NT study update. Poster presented at the 71st Annual American Academy of Neurology Meeting; May 4-10; 2019; Philadelphia, PA.
6. Markowitz JA, Sing P, Darras BT. Spinal muscular atrophy: a clinical and research update. Pediatr Neurol. 2012;46(1):1-12.
7. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007;22(8):1027-1049.
8. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. J Neuromuscul Dis. 2018;28(2):103-115.
9. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2020. https://doi.org/10.1016/j.ejpn.2020.07.001.
10. Biogen. Biogen plans to initiate phase 4 study evaluating benefit of Spinraza® (nusinersen) in patients treated with Zolgensma® (onasemnogene abeparvovec). https://investors.biogen.com/news-releases/news-release-details/biogen-plans-initiate-phase-4-study-evaluating-benefit-spinrazar. July 21, 2020. Accessed October 6, 2020.

4 . Revision History

Date	Notes
6/28/2021	7/1 Implementation

Prior Authorization Guideline

GL-99699 Zolinza

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zolinza	
Diagnosis	T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cutaneous T-cell lymphoma	

Product Name: Zolinza	
Diagnosis	T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zolinza therapy

Product Name: Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zolinza therapy

2 . Revision History

Date	Notes
4/8/2021	7/1 Implementation

Prior Authorization Guideline

GL-99503 Zontivity

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zontivity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- History of myocardial infarction (MI)
- Peripheral arterial disease (PAD)

AND

2 - Patient does not have a history of ONE of the following:

- Stroke
- Transient ischemic attack (TIA)
- Intracranial hemorrhage (ICH)

AND

3 - Patient does not have active pathological bleeding

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99504 Zortress - ARIZONA

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zortress	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Kidney transplant rejection prophylaxis in patients at low-moderate immunologic risk

OR

2 - Liver transplant rejection prophylaxis

2 . Revision History

Date	Notes
3/11/2021	Bulk Copy C&S Arizona Standard to Medicaid Arizona Standard for 7 /1 go live

Prior Authorization Guideline

GL-99672 Zydelig-Arizona

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zydelig will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Zydelig therapy	

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Prior Authorization Guideline

GL-99781 Zykadia

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Zykadia	
Diagnosis	Non- Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - ONE of the following:

- Disease is metastatic
- Disease is recurrent

AND

3 - ONE of the following:

- Tumor is anaplastic lymphoma kinase (ALK)-positive
- Tumor is ROS-1 positive

Product Name: Zykadia	
Diagnosis	Non- Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name: Zykadia	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name: Zykadia	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name: Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zykadia will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zykadia therapy

2 . Revision History

Date	Notes
6/2/2021	Arizona Medicaid 7.1 Implementation

Zytiga

Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Prior Authorization Guideline

GL-99800 Zytiga

Formulary Medicaid - Arizona SP (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021

1 . Criteria

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of prostate cancer	

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (e.g., N1)

AND

3 - Used in combination with prednisone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - If the request is for brand Zytiga, must meet both of the following:

5.1 Patient has tried and failed generic Zytiga

AND

5.2 The prescriber provides reason or special circumstance why the patient cannot take generic Zytiga

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zytiga therapy

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Zytiga will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Product Name: Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zytiga therapy

2 . Revision History

Date	Notes
6/28/2021	Updated criteria added ABIRATERONE ACETATE TAB 500 MG

Prior Authorization Guideline

GL-99578 Zyvox

Formulary Medicaid - Arizona (AZM, AZMREF, AZMDDD)

Formulary Note

Guideline Note:

Effective Date:	12/9/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Labeled Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 BOTH of the following:

1.3.1 ONE of the following diagnoses:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Skin and skin structure infections (complicated and uncomplicated)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Zyvox

OR

1.4 Invasive infection caused by or likely to be caused by vancomycin-resistant Enterococcus faecium (VRE)

Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals will be issued for 14 days.

Product Name: Brand Zyvox*, generic linezolid*	
Diagnosis	Off label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge **OR** **2** - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication **OR** **3** - The medication is being prescribed by or in consultation with an Infectious Disease specialist	
Notes	*Approval Duration: Based on provider recommended treatment durations, not to exceed 6 months.

2 . Revision History

Date	Notes
7/21/2021	Update guideline

Celecoxib (Celebrex) Guideline

Effective Date: 6/15/2021
Date(s) of Review and Revision:

APPLICABLE AGENT(S):
1. Celecoxib (Celebrex) capsules

CRITERIA FOR INITIAL AUTHORIZATION:
1.Has the member been on following drug therapy in previous 90 days? ***Yes*** (Approved) ***No***
(Step 2)
-Member is concurrently on anticoagulants/antiplatelet agents (e.g., warfarin, Xarelto, Pradaxa, Plavix, Eliquis)
-Member is currently receiving antiulcer agents (i.e. proton-pump inhibitors (PPIs) (e.g., pantoprazole, omeprazole, lansoprazole), histamine H2 receptor antagonists (H2RAs) (e.g., ranitidine, famotidine))
-Member has chronic use of oral corticosteroids (i. e. prednisone)
-Member is receiving methotrexate
-Member has a history of peptic ulcer disease (PUD) or history of gastrointestinal (GI) bleed
2. Is the member equal to or greater than 65 years old? ***Yes*** (Approved) ***No*** (step 3)
3.Has the member tried and failed or is intolerant to **ONE** formulary Nonsteroidal Anti-inflammatory Drugs (NSAIDs) (e.g., ibuprofen, diclofenac sodium, naproxen, etodolac, nabumetone)? ***Yes*** (Approved) ***No*** (Step 4)
4.Is the member using for acute pain, including acute post-op pain? ***Yes*** (Approved) ***No (Denied)***

CRITERIA FOR RENEWAL:
1. Is the member experiencing positive response to therapy? ***Yes*** (Approved) ***No*** (Denied)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 12 months
Renewal Approval Duration: 12 months

Cabotegravir and Rilpivirine (Cabenuva) Guideline

Effective Date: 9/1/2022
Date(s) of Review and Revision: 8/10/22

APPLICABLE AGENT(S):
Cabotegravir and Rilpivirine (Cabenuva)

CRITERIA FOR INITIAL AUTHORIZATION:

Member must meet all of the following criteria:

Member is currently receiving a stable antiretroviral regimen for 3 months or greater
Member has been adherent to current regimen for 3 months or greater
Submission of medical records showing member has maintained virologic suppression (HIV-1 RNA less than 50 copies per mL) on current antiretroviral regimen for at least 3 months prior to initiation of Cabenuva.
Member has no history of treatment failure within the past 6 months
Member has no known or suspected resistance to either cabotegravir or rilpivirine

CRITERIA FOR RENEWAL:

Member has been adherent to regimen AND has not experienced virologic failure while on the requested drug, defined as two consecutive plasma HIV-1 RNA levels greater than or equal to 200 copies per mL.

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 12 months
Renewal Approval Duration: 12 months

Voretigene Neparvovec (Luxturna)

Effective Date: 9/1/2022
Date(s) of Review and Revision: 9/1/2022

APPLICABLE AGENT(S):

Luxturna – Medical Review

CRITERIA FOR INITIAL AUTHORIZATION:

One dose per eye may be approved if ALL the following criteria are met:

- Age 1 year or older
- Diagnosis of retinal dystrophy confirmed via genetic testing:
  - RPE65 mutation in both alleles
- Prescribed by ophthalmologist or retinal surgeon with experience providing subretinal injections.
- Viable retinal cells determined by ONE of the following:
  - spectral domain optical coherence tomography confirming retinal thickness greater than 100 microns within posterior pole.
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - Any remaining visual field within 30° of fixation as measured by III4e isopter or equivalent
- Member has not had intraocular surgery within the previous six months
- Member has not previously received Luxturna through BUHP or another Payer

IF member meets ALL the above criteria, reviewing pharmacist will send their approval recommendation to a Medical Director for final review.

CRITERIA FOR RENEWAL:

N/A. Members will only be approved for 1 injection per eye per lifetime

LENGTH OF AUTHORIZATION:

Initial approval duration: 3 months for 1 dose per eye
Renewal approval duration: N/A

Hyaluronic acid agents Step Therapy Guideline

Effective Date: 9/1/2022
Date(s) of Review and Revision: 8/10/2022

APPLICABLE AGENT(S):

	Preferred	Non-Preferred
Medicaid	Euflexxa	Durolane, Gel-One, Genvisc 850, Hyalgan, Hymovs, Monovis, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, Visco-3

CRITERIA FOR STEP THERAPY AUTHORIZATION:

1. Has the patient previously been treated for the same knee with any hyaluronic acid/viscosupplementation product? YES (step 2) NO (step 6)
2. Has it been at least 6 months since the last treatment with this agent? YES (step 3) NO (Denied)
3. Does medical record documentation support that the patient experienced a significant improvement in knee pain and functional capacity from the last series of injections? YES (step 4) NO (Denied)
4. Does the medical record documentation support that the patient experienced improved pain and functional capacity for at least 6 months? (including no intraarticular corticosteroids administered for at least 6 months) YES (step 5) NO (Denied)
5. Does the member have an order for Euflexxa?
   YES: approve treatment with Euflexxa. Approval time frame is 3 months from the receipt date or the date of service, if known, whichever is longer.
   NO: outreach to switch to formulary alternative. If not interested to switch- deny request.
6. Is the member at least 18 years of age with a diagnosis of osteoarthritis confirmed by radiology? YES (step 7) NO (Denied)
7. Is there medical record documentation that the member has previously trialed non-pharmacologic therapy (exercise, physical therapy, weight loss, braces, local heat and cold application) for a minimum of 6 weeks? YES (step 8) NO (Denied)
8. Is there medical record documentation that the member has trialed and failed to adequately respond to simple analgesics (acetaminophen, topical capsaicin, oral or topical NSAIDs) for a minimum of 6 weeks? YES (step 9) NO (Denied)
9. Has the member received at least one prior intra-articular corticosteroid injection or has a contraindication to corticosteroids? YES (Approve) NO (Denied)

CRITERIA FOR RENEWAL:

Has it been at least 6 months since the last treatment with this agent? YES (step 2) NO (Denied)
Does medical record documentation support that the patient experienced a significant improvement in knee pain and functional capacity from the last series of injections? YES (step 3) NO (Denied)
Does the medical record documentation support that the patient experienced improved pain and functional capacity for at least 6 months? (no intraarticular corticosteroids administered for at least 6 months) YES (Approve) NO (Denied)

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 3 months
Renewal Approval Duration: 1 year

Continuous Glucose Monitor Guidelines for AHCCCS

Effective Date: 9/1/2022
Date(s) of Review and Revision: 8/10/2022

APPLICABLE AGENT(S):
Preferred agents:
Dexcom G6 CGM
FreeStyle Libre
FreeStyle Libre 2

CRITERIA FOR INITIAL AUTHORIZATION:

Member meets all of the following criteria:

-The member has a diagnosis of diabetes
-The member's treating practitioner has concluded that the member or caregiver has had sufficient training using the glucose monitoring device prescribed
-Within six months prior to ordering the Continuous Glucose Monitor, the treating practitioner has an appointment with the member to evaluate their diabetes control and determine criteria above is met
-Age is appropriate for preferred prescribed Continuous Glucose Monitor

Dexcom G6 CGM: 2 years old to less than 4 years old
FreeStyle Libre: 18 years or older
FreeStyle Libre 2: 4 years and older

-One of the following must be met:
Currently on an insulin pump
OR requires 3 or more daily insulin injections and the insulin treatment regimen requires frequent adjustment on the basis of the blood glucose results
OR the member monitors blood glucose 4 or more times per day with frequent adjustment on the basis of the blood glucose results
OR the member is currently pregnant
OR the member has history of hypoglycemic unawareness
OR the member is on U-500 insulin or utilizing twice daily mixed insulins (short and intermediate or long fixed insulins)

CRITERIA FOR RENEWAL:

Continues to meet documentation of medical necessity above

INSERT QUANTITY LIMITS

Diabetes Continuous Glucose Monitor

Readers:

FreeStyle Libre, FreeStyle Libre 2 and Dexcom G6 limited to one reader per year

Sensors:

FreeStyle Libre and FreeStyle Libre 2: Two (2) sensors per 28 days

Dexcom G6: Three (3) sensors per 30 days

Transmitters:

Dexcom G6: 1 transmitter per 90 days

Criteria to receive greater than one reader monitoring system per year:

Current reader is inaccurate, or not functioning properly

Current reader has been damaged, or was lost or stolen

Criteria to receive greater than 3 Dexcom G6 sensors per 30 days or more than 2 FreeStyle Libre sensors per 28 days

Current sensor is inaccurate, or not functioning properly

Sensor has been damaged, or was lost or stolen

LENGTH OF AUTHORIZATION:

Initial Approval Duration: 12 months

Renewal Approval Duration: 12 months

Diabetic blood glucose monitoring supply quantity limit guideline

Effective Date: 9/1/2022
Date(s) of Review and Revision: 7/15/2022

APPLICABLE AGENT(S):
Blood glucose monitors
Blood glucose test strips

CRITERIA FOR INITIAL AUTHORIZATION:

The member has diabetes.
The member's treating practitioner has concluded that the member or caregiver has had sufficient training using the glucose monitoring device prescribed

CRITERIA FOR RENEWAL:

High Utilization diabetic test strips
Review and new documentation in the medical record of member regularly using quantities of supplies must be present at least annually

INSERT QUANTITY LIMITS

Diabetes Glucometer Quantity Limits
Limited to 1 glucometer per 12 months
Criteria to receive greater than one glucometer per year:
Current glucometer is unsafe or inaccurate, or not functioning properly
Current glucometer has been damaged, or was lost or stolen

Diabetes Test Strip Usual Utilization Quantity Limits
Up to 100 test strips every 3 months are covered
Members with diabetes not currently being treated with insulin or insulin containing products or GLP-1's
Up to 150 test strips every 3 months are covered
Members on non-insulin secretagogues
Members on GLP-1 receptor agonists
Up to 300 test strips every 3 months are covered
Members with diabetes currently being treated with insulin or insulin containing products
Newly diagnosed diabetes within the first 6 months after diagnosis
Members utilizing U-500 insulin

Diabetes Test Strip High Utilization

Members utilizing more than 300 test strips every 3 months criteria:

-Members with diabetes who are currently being treated with insulin injections routinely testing more than 4 times per day or more
-Gestational diabetes or Pregnancy
-Members at high risk of hypoglycemia or with history of severe hypoglycemic events
-Children with diabetes that are less than 18 years of age
-Currently utilizing an insulin pump

Requirements:
The treating physician has seen the member and evaluated their diabetes control within 6 months prior to ordering quantities of test strips that exceed the usual utilization above and has documented in the member's medical record the reason the additional materials are necessary
If refills of quantities of supplies exceed the utilization guidelines, there must be documentation in the member's medical record that the member is in fact testing at the prescribed high utilization frequency. Physician documentation in the medical record or a copy of the member's blood sugar testing log is appropriate. If the member is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every year
Maximum of 900 test strips every 3 months covered
Consider continuous glucose monitoring (CGM) for members who are on intensive insulin therapy (3 to 4 injections per day or on insulin pump).

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LENGTH OF AUTHORIZATION:

Initial Approval Duration: 6 months
Renewal Approval Duration: 1 year

Difelikefalin (Korsuva) PA Criteria

Effective Date: 9/1/2022
Date(s) of Review and Revision: 8/2022

APPLICABLE AGENT(S):
Difelikefalin (Korsuva)

CRITERIA FOR INITIAL AUTHORIZATION:

All of the following criteria must be met:

For FDA approved indication of chronic kidney disease associated pruritus, moderate to severe, in adults undergoing hemodialysis
Member is ≥ 18 years old
Documentation the moderate to severe pruritis is impacting qualify of life (sleep disturbances, fatigue, or depression)
Patient is not receiving peritoneal dialysis

CRITERIA FOR RENEWAL:

Documentation of significant reduction in itch intensity or improvement in itch-related quality of life and not experiencing serious adverse effects.

INSERT QUANTITY LIMITS

Not to exceed 0.5 mcg/kg per HD session

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 3 months
Renewal Approval Duration: 12 months

Enfurvitide (Fuzeon) Guideline

Effective Date: 6/15/2021
Date(s) of Review and Revision:

APPLICABLE AGENT(S):
o Fuzeon (Enfuvirtide)

CRITERIA FOR INITIAL AUTHORIZATION:
Does the member have a diagnosis of HIV-1 infection? ***Yes*** (Step 2) ***No*** (Denied**, step 5)
Has the member tried and failed or experienced intolerance to at least two of anti-HIV therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, OR protease inhibitor) after 3 or more months of therapy? ***Yes*** (Step 3) ***No*** (Denied)
Will the member use Fuzeon in combination with other antiretroviral agents? ***Yes*** (Step 4) ***No*** (Denied)
Is this medication prescribed by or in consultation with an infectious disease or HIV specialist? ***Yes*** (Approved) ***No*** (Denied)
Please provider member's diagnosis: _____

CRITERIA FOR RENEWAL:
Has the member had experienced positive response to treatment? ***Yes*** (Step 2) ***No*** (Denied, ask step 2)
If the provider is requesting a dose increase, does the new dose exceed recommended 180 mg per day? ***Yes*** (Denied) ***No*** (Approved)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 6 Months
Renewal Approval Duration: 12 Months

Ezetimibe (Zetia) Guideline

Effective Date: 06/15/2021
Date(s) of Review and Revision:

APPLICABLE AGENT(S):
o Ezetimibe (Zetia) tablets

CRITERIA FOR INITIAL AUTHORIZATION:
Is this medication prescribed for FDA approved or compendial supported diagnosis? ***Yes*** (Question 2) ***No*** (Denied**, ask Question 3)
If the request is prescribed for the diagnosis of primary hypercholesterolemia or mixed dyslipidemia, then has the patient tried and failed or experienced intolerance to statin therapy? ***Yes*** (Approved) ***No*** (Denied)
Please provider member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member had experienced positive response to treatment? ***Yes*** (Approved) ***No*** (Denied)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 12 months
Renewal Approval Duration: 12 months

Maraviroc (Selzentry) Guideline

Effective Date: 6/15/2021
Date(s) of Review and Revision: 7/25/2022

APPLICABLE AGENT(S):
o Maraviroc (Selzentry) tablets

CRITERIA FOR INITIAL AUTHORIZATION:
1.Has the member been clinically diagnosed with CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay? ***Yes*** (Step 2) ***No*** (Denied**, ask Step 5)
2. Does the member weigh at least 2 kg, regardless of age? ***Yes*** (Step 3) ***No*** (Denied, ask step 3)
3. Is the member currently taking or will be prescribed an optimized background antiretroviral therapy regimen? ***Yes*** (Step 4) ***No*** (Denied, ask step 4)
4.Is the medication prescribed by, or in conjunction with an HIV specialist? ***Yes*** (Approved) ***No*** (Denied)
5.Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member experienced a positive clinical response to Selzentry therapy? ***Yes*** (Approved) ***No*** (Denied)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 12 Months
Renewal Approval Duration: 12 Months

Umeclidinium-Vilanterol Aerosol Powder (Anoro Ellipta)

Effective Date: 6/15/2021
Date(s) of Review and Revision: 7/25/2022

APPLICABLE AGENT(S):
o Umeclidinium-Vilanterol Aerosol Powder (Anoro Ellipta)

CRITERIA FOR INITIAL AUTHORIZATION:
Does the member have a documented diagnosis of COPD? ***Yes*** (Approved) ***No*** (Denied**, ask question 2)
Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member seen improvement or positive response in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ***Yes*** (Approved) ***No*** (Denied)

LENGTH OF AUTHORIZATION:
Initial Approval Duration: 12 Months
Renewal Approval Duration: 12 Months