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AHCCCS Prior Authorization Guidelines

Banner – University Family Care is committed to ensuring appropriate access to high quality and cost effective medications for all members.

The following prior authorization guidelines and criteria are intended for use by the Banner – University Family Care Utilization Management team. These guidelines support the AHCCCS Preferred Drug List and other formulary decisions. In the instance that these guidelines conflict with AHCCCS Policy or Preferred Drug List, then the AHCCCS Policy or Preferred Drug List take precedence.

Prior authorization requests will be adjudicated using drug or therapeutic class-specific criteria where available. If not available, the General Prior Authorization Guideline will be used. As clinical information becomes available regarding patient safey or efficacy, the Utilization Management team will account for this information in the prior authorization determination.

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The above criteria apply to the listed diagnoses only. Should you require the medication for an alternate diagnosis not included in these criteria, the pharmacist reserves the right to review the prior authorization and request additional information as necessary to determine approval or denial status.

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Guideline Name: General Prior Authorization Guideline

Effective Date: 06/15/2021
Date(s) of Review and Revision:

GUIDELINE SCOPE:

- This guideline is to be followed for prior authorization determinations, unless prior authorization criteria or guidelines that are specific to the drug therapy or drug class are in place. If a more specific guideline or criteria are available, those guidelines will be used for determinations.
- In the instance that this guideline conflicts with AHCCCS coverage guidelines, then the AHCCCS coverage guideline will take precedence.

CRITERIA FOR INITIAL AUTHORIZATION:

- Prior authorization requests for medications requiring prior authorization and do not have specific prior authorization criteria will be reviewed based on the following:
  - Appropriate diagnosis or indication for the requested medication
  - Appropriate dose, route, frequency of administration of medication based on patient specific criteria such as age, height, weight, BSA, renal function, liver function, indication, or other appropriate factor(s)
- If the prior authorization request is made for a non-formulary medication and there is a formulary drug within the therapeutic class, the following additional criteria will be applied:
  - Member has previously tried up to three formulary drugs with evidence of lack of efficacy or intolerance
  - Member's prescribing clinician provides evidence of medical necessity of the non-formulary drug over the drug
- Off-label Use of Medications
  - Off-label use of medications may be approved when all of the below criteria are met:
    - Prescribing clinical is treating a chronic, disabling or life-threatening condition
    - Sufficient clinical literature exists to support the safety and efficacy of the medication in patients with similar conditions
    - The member has tried medications with FDA-approved indications, for a sufficient period of time, and the drug was not efficacious or was not tolerated by the patient

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to treatment

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 months or less based on duration or course of therapy**
- **Renewal Approval Duration: 12 months**

REFERENCES

1. AHCCCS Medical Policy Manual Pharmacy Policy 310-V Prescription Medication / Pharmacy Services.

The above criteria apply to the listed diagnoses only. Should you require the medication for an alternate diagnosis not included in these criteria, the pharmacist reserves the right to review the prior authorization and request additional information as necessary to determine approval or denial status.

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Guideline Name: Quantity Limit

Effective Date: 05/01/2021
Date(s) of Review and Revision:

CRITERIA FOR INITIAL AUTHORIZATION:

- If the requested quantity does not exceed the FDA maximum dosing, one of the following must be met:
  - Member must try and fail the formulary quantity limit of the requested dosing, **OR**
  - Member must try and fail alternative strengths of the medication, covered on the AHCCCS Preferred Drug List (PDL), that allow for dose optimization, **OR**
  - Prescriber must attest and provide clinical rationale that the formulary quantity limit and optimized dosing options would be ineffective in treating the member's condition.
- If the requested quantity does exceed the FDA maximum dosing:
  - Member must try and fail the formulary quantity limit of the requested dosing, **AND**
  - Prescriber must submit documentation showing the requested dosing is supported for the member's condition in a clinical trial, scientific journal, drug compendia, evidence-base clinical practice guideline, etc, **AND**
  - Prescriber provides clinical rational indicating why the requested dosing is medically necessary in treating the member's condition.

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to threapy and continues to benefit from the medication, AND
- If the requested quantity does exceed the FDA maximum dosing, both of the following:
  - Prescriber submits documentation showing the requested dosing is supported for the member's condition in a clinical trial, scientific journal, drug compendia, or evidence-base clinical practice guideline, **AND**
  - Prescriber provides clinical rational indicating why the requested dosing continues to be medically necessary in treating the member's condition.

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

1. Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug List

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Guideline Name: ADHD Medication in Children <6 years of age

Effective Date: 05/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Adderall and Adderall XR
- Focalin XR
- Ritalin LA 10MG Capsule
- Daytrana
- Methylphenidate (Tablets & Chewables)
- Concerta
- Guanfacine Tablets (IR & ER)
- Atomoxetine
- Ritalin LA Tablets
- Amphetamine-Dextroamphetamine
- Dexmethylphenidate Tablets
- Aptensio XR
- Methylin Solution
- Methylphenidate CD & ER Capsules
- Vyvanse (Capsules & Chewables)
- Clonidine Tablets (IR & ER)
- Clonidine Patch

CRITERIA FOR INITIAL AUTHORIZATION:

- **Preferred Agents:**
  - Member has diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD), **AND**
  - Psychosocial issues and non-medical interventions are being addressed by a clinical team, **AND**
  - Documentation submitted of psychosocial evaluation occurring prior to request for ADHD medications, **AND**
  - Documentation submitted of non-medication alternatives that have been attempted before request for ADHD medications, **AND**
  - Provider must adhere to AHCCCS Psychiatric and Psychotherapeutic Best Practices for Children: Birth through Five years of age, **AND**
  - If initial medication prescription, must be for methylphenidate containing medication.

- **Non-Preferred Agents:**
  - Member must meet above criteria for preferred agents, **AND**
  - Trial of 3 or more preferred formulary agents within same class (if applicable), **OR**
  - Documentation of why preferred agents are unable to be used.

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to treatment.

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 months**
- **Renewal Approval Duration: 12 months**

The above criteria apply to the listed diagnoses only. Should you require the medication for an alternate diagnosis not included in these criteria, the pharmacist reserves the right to review the prior authorization and request additional information as necessary to determine approval or denial status.

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REFERENCES

2. Wolraich ML, Hagan JF, Allan C, et al. AAP SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVE DISORDER. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528
3. Pliska SR, Greenhill LL, Crismon ML, et al. The Texas children's medication algorithm project: revision of the algorithm for pharmacotherapy of attention-deficit/hyperactivity disorder. J Am Academy Child Adolescent Psychology. 2006; 45(6): 642-657.
4. Bolea-Alamanac B, Nutt DJ, Adamou M, et al. Evidence-based guidelines for the pharmacological management of attention deficit hyperactivity disorder: Update on recommendations from the British Association for Psychopharmacology. Journal of Psychopharmacology. 2014; 1-25.
5. National Guideline Centre (UK). Attention deficit hyperactivity disorder: diagnosis and management. London: National Institute for Health and Care Excellence (UK); 2018 Mar. (NICE Guideline, No. 87.)

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Guideline Name: Androgens-Anabolic

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Testosterone Cypionate Solution (Depo-Testosterone)
- Testosterone Enanthate Solution (Testosterone Enanthate, Xyosted)
- Testosterone Gel (Androgel)
- Testosterone Patch (Androderm)

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?

- The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history
- The patient has **ONE** of the following laboratory values confirming low testosterone levels:
- At least **TWO** morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state
- A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

If yes, continue to #2.
If no, continue to #5.

2. Is the request for Xyosted **AND** the patient meets the following criteria?

- The patient is 18 years of age or older
- The requested medication is being used for testosterone replacement therapy

If yes, **approve Xyosted for 12 months by GPID for all strengths as follows:**

- **50mg/0.5mL: #2mL per 28 days.**
- **75mg/0.5mL: #2mL per 28 days.**
- **100mg/0.5mL: #2mL per 28 days.**

If no, continue to #3.

3. Is the request for Jatenzo **AND** has the following criterion been met?

- The patient is 18 years of age or older

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If no, continue to #4

4. Is the request for other testosterone products?

- **Aveed (750mg/3mL): No quantity limit.**
- **AndroGel (testosterone) 1% (25mg and 50mg gel packet): #300 grams per 30 days.**
- **AndroGel (testosterone) 1.62% [1.25g gel packet, 2.5g gel packet, and 20.25mg/1.25g multi-dose pump]: #150 grams per 30 days.**
- **Androderm 2mg/24hr and 4mg/24hr patches: #30 patches per 30 days.**
- **Axiron (testosterone) 30mg/1.5mL solution pump: #180mL per 30 days.**
- **Testosterone Cypionate 100mg/mL and 200mg/mL: No quantity limit.**
- **Testosterone Enanthate 200mg/mL 5mL vial: #5mL per 28 days.**
- **Fortesta (testosterone) 10mg (2%): #120 grams per 30 days.**
- **Natesto (testosterone) 5.5mg/0.122g gel pump: #21.96 grams per 30 days.**
- **Striant 30mg buccal tablets: #60 systems (tablets) per 30 days.**
- **Testim (testosterone) 1% (50mg gel tube): #300 grams per 30 days.**
- **Vogelxo (testosterone) 1% [12.5mg/1.25g gel pump and 50mg (1%) gel]: #300 grams per 30 days.**

If no, do not approve.

5. Is the request for testosterone enanthate 200mg/mL vial for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder?
   - If yes, **approve Testosterone Enanthate 200mg/mL 5mL vial**

If no, continue to #6.

6. Is the request for testosterone enanthate 200mg/mL vial for a female patient with a diagnosis of metastatic breast cancer?
   - If yes, **approve Testosterone Enanthate (200mg/mL 5mL vial)**

If no, do not approve

CRITERIA FOR RENEWAL

- You have primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
- Your physician indicates that your symptoms have improved compared to baseline and you tolerated treatment

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 Months**
- **Renewal Approval Duration: 12 Months**

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REFERENCES

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- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2018.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2018.
- Aveed [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Solutions, Inc.; January 2018.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. July 2018.
- Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; March 2019.
- Natesto [Prescribing Information]. Englewood, CO: Aytu Biosciences, Inc.; September 2017.
- Striant [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals, Inc.; November 2016.
- Testim [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals, Inc.; April 2018.
- Testosterone 10mg (2%) [Prescribing Information]. Chestnut Ridge, NY: Par Pharmaceutical; August 2017.
- Testosterone Cypionate [Prescribing Information]. Parsippany, NJ: Actavis Pharma, Inc.; November 2018.
- Testosterone Enanthate [Prescribing Information]. Parsippany, NJ: Actavis Pharma, Inc.; December 2017.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; October 2017.
- Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; November 2019.

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Guideline Name: Anticonvulsant Misc.

Effective Date: 6/15/2021
Date(s) of Review and Revision:

AGENTS:

- Gabapentin (Gralise)
- Gabapentin Enacarbil Extended Release tablets (Horizant)
- Lacosamide Solution (Vimpat)
- Lacosamide Tablets (Vimpat)

CRITERIA FOR INITIAL AUTHORIZATION

Gralise-

- Diagnosis of post-herpetic neuralgia (PHN).
- Must be 18 years old or older.
- Member had trial and failure of (up to 90 days) or intolerance to both of the following:
  a. Gabapentin (generic Neurontin) up to 1,800mg per day OR Lyrica (pregabalin) up to 150-600mg per day (Prior authorization required) for at least 90 days.
  b. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, desipramine)

Note:

- Gralise should be titrated up to a therapeutic dose of 1800 mg taken orally once a day.
- Avoid TCA in patients with heart disease, epilepsy or glaucoma and should be used cautiously in older patients.

Horizant-

- Documented diagnosis of moderate-to-severe primary restless leg syndrome (RLS) and all of the following is met:
  a. Must be 18 years old or older.
  b. Must have had a documented trial and failure of or intolerance to both of the following:
    i. Gabapentin (up to 1,800 mg per day of 90 days trial) OR Lyrica* (pregabalin) (up to 150-600mg per day of 90 days trial) *Prior authorization required
    ii. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, desipramine)

- Diagnosis of post-herpetic neuralgia (PHN) and meets all of the following:
  a. Must be 18 years old or older.
  b. Must have had a documented trial and failure of or intolerance to both of the following:
    i. Gabapentin (up to 1,800 mg per day of 90 days trial) OR Lyrica* (pregabalin) (up to 150-600mg per day of 90 days trial) *Prior authorization required
    ii. Tricyclic antidepressants (e.g., amitriptyline, nortriptyline, desipramine

Note:

- Horizant is indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome (RLS) in adults and the management of postherpetic neuralgia (PHN) in adults. It is not interchangeable with other gabapentin products including Gralise. Available as a 300mg and 600mg tablet.

Vimpat-

- The member is ≥ 4 years old.
- Diagnosis of partial-onset seizures or primary generalized tonic-clonic seizures
- The member has first tried and failed, or has a contraindication or intolerance to TWO different formulary anticonvulsants

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Dosage-

i. Adults (17 years and older) initial adjunct therapy = 50mg BID.
ii. Adults (17 years and older) initial monotherapy = 100mg BID.
iii. Max dose = 400mg/day
iv. Renal (severe)/Hepatic impairment (mild to moderate) = 300 mg/day.
v. Children ≥4 to 17 years: a. 11 to

CRITERIA FOR RENEWAL

Gralise-

- Documentation member is receiving a positive clinical response to Gralise based upon reevaluation in the past 12 months.

Horizant-

- For RLS, a decrease in International Restless Legs Syndrome (IRLS) Rating Scale score from baseline OR positive clinical response based on clinical reevaluation in past 12 months.
- For PHN, documentation member is receiving a positive clinical response to Horizant based upon reevaluation in the past 12 months.

Vimpat-

- Consistent/compliant fill history. Chart notes documenting a positive response to therapy noted as a reduction in seizure frequency and/or severity

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

Gralise-

- Gralise should not be used in patients with CrCl less than 30 or patients on hemodialysis

Horizant-

N/A

Vimpat-

- Use is not recommended in patients with severe hepatic impairment.

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 Months**
- **Renewal Approval Duration: 12 Months**

Quantity Limits:

Gralise-

- Up to #90 per 30 days

Horizant-

- RLS – #30 per 30 days.
- PHN – Up to #60 per 30 days

REFERENCES

Gabapentin-

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4. Dubinsky RM, Kabbani H, et al. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology Sept 2004 vol. 63 no. 6;959- 965.
5. Johnson RW, Rice A, et al. Postherpetic Neuralgia. N Engl J Med. 2014;371:1526-33.
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Horizant-
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2. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2017. Available at: http://eanswers.factsandcomparisons.com.ezproxy.lib.utexas.edu/. 03/2019..
3. Horizant prescribing information. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised 10/2016.
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6. Johnson RW, Rice A, et al. Postherpetic Neuralgia. N Engl J Med 2014;371:1526-33.
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8. Bell, Amanda, Fashner, Julia. Herpes Zoster and Postherpetic neuralgia: Prevention and Management. Am Fam Physician. 2011 Jun 15; 83(12):1432-1437. https://www.aafp.org/afp/2011/0615/p1432.html#sec-5. Accessed on 03/2019.

Vimpat-
1. VIMPAT medication guide Revised: 06/2019.
2. Micromedex

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Guideline Name: Anti-Dementia Agents

Effective Date: 02/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Donepezil (Tablets and ODT)
- Galantamine (Tablets, Solution, and ER Capsules)
- Rivastigmine (Patch, Tablets and Solution)
- Memantine (Tablets and Solution)

CRITERIA FOR INITIAL AUTHORIZATION:

- Preferred Agents:
  - Donepezil
    - Member is ≥18 years old
    - Member has a diagnosis of one of the following:
      - Mild, moderate or severe Alzheimer's dementia with or without vascular dementia
        - If vascular dementia present, include brain imaging confirming cerebrovascular disease
      - Dementia with Lewy Bodies
      - Parkinson's Disease dementia
    - Submission of baseline (within past 90 days) cognitive assessment (i.e. Standardized Mini Mental Status Exam, SLUMS, MoCA)
    - Diagnosis has been established by or in consultation with a neurologist or psychiatrist or geriatrician
  - Galantamine
    - Member is ≥18 years old
    - Member has a diagnosis of one of the following:
      - Mild to moderate Alzheimer's dementia with or without vascular dementia
        - If vascular dementia present, include brain imaging confirming cerebrovascular disease
      - Dementia with Lewy Bodies (if rivastigmine or donepezil was not tolerated)
        - Documentation is provided of trial and failure of donepezil and rivastigmine
      - Parkinson's Disease dementia
    - Submission of baseline (within past 90 days) cognitive assessment (i.e. Standardized Mini Mental Status Exam, SLUMS, MoCA)
    - Diagnosis has been established by or in consultation with a neurologist or psychiatrist or geriatrician
  - Rivastigmine
    - Member is ≥18 years old
    - Member has a diagnosis of one of the following:
      - Mild to moderate Alzheimer's dementia with or without vascular dementia

        - If vascular dementia present, include brain imaging confirming cerebrovascular disease
      - Dementia with Lewy Bodies
      - Parkinson's Disease dementia
    - Submission of baseline (within past 90 days) cognitive assessment (i.e. Standardized Mini Mental Status Exam, SLUMS, MoCA)
    - Diagnosis has been established by or in consultation with a neurologist or psychiatrist or geriatrician
- Memantine
  - Member is ≥18 years old
  - Member has a diagnosis of one of the following:
    - Moderate or severe Alzheimer's dementia with or without vascular dementia
      - If vascular dementia present, include brain imaging confirming cerebrovascular disease
    - Diagnosis of Parkinson's Disease dementia if cholinesterase inhibitors are not tolerated or contraindicated
  - Submission of baseline (within 90 days) cognitive assessment (i.e. Standardized Mini Mental Status Exam, SLUMS, MoCA)
  - Diagnosis established by or in consultation with a neurologist or psychiatrist or geriatrician

- Non-Preferred Agents:
  - Member must meet above criteria for preferred agents, and
  - Trial of all preferred agents

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to treatment

EXCLUSION CRITERIA:

- Not for use for non-listed dementias, such as frontotemporal dementia due to a lack of evidence and guideline support.

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

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7. National Guideline Centre (UK). Dementia: assessment, management and support for people living with dementia and their carers. London: National Institute for Health and Care Excellence (UK); 2018 Jun. (NICE Guideline, No. 97.)
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Summergrad P, Woods SM, Berger J, Cross CD, Brandt HA, Margolis PM, Shemo JP, Blinder BJ, Duncan DL, Barnovitz MA, Carino AJ, Freyberg ZZ, Gray SH, Tonnu T, Kunkle R, Albert AB, Craig TJ, Regier DA, Fochtmann LJ. American Psychiatric Association practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Second edition. Am J Psychiatry. 2007 Dec;164(12 Suppl):5-56.

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Guideline Name: Non-Preferred Antidepressants

Effective Date: 02/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- See AHCCCS Drug List for formulary agents

NON-FORMULARY AGENTS:
- Trintellix
- Viibryd

CRITERIA FOR INITIAL AUTHORIZATION:
- Non-Formulary Agents:
  - Member is ≥18 years old
  - Member has a diagnosis of moderate to severe Major Depressive Disorder
  - Documentation of adequate trial and failure of 3 or more formulary antidepressants from 2 or more subclasses
    - Failure of a preferred agent must meet the following criteria:
      - Adequate dose - maximally tolerated dose, at or above half the FDA maximum dose
      - Adequate duration - a duration of 4-6 weeks at an adequate dose (defined above)
    - Failure is not defined by intolerance to a medication
    - Failure due to intolerance will be applied, when all drugs in a subclass have been trialed
      - Claims evidence of trials of all subclass options must be submitted/observed if provider is claiming failure is due to intolerance

CRITERIA FOR RENEWAL:
- Prescriber attests the member has had a positive clinical response to treatment

EXCLUSION CRITERIA:
N/A

LENGTH OF AUTHORIZATION
- **Initial Approval Duration: 6 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

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5. Depression Guideline Development Panel. Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. American Psychological Association. Feb 2019.
6. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163:1905–1917.
7. Cipriani A, Furukawa TA, Salanti G, et al. Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis. Lancet. 2018 Apr 7;391(10128):1357-1366.

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Guideline Name: Cystic Fibrosis

Effective Date: 06/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- Bethkis
- Kitabis PAK

NON-PREFERRED AGENTS:
- Tobramycin INH (Tobi Podhaler)
- Cayston

CRITERIA FOR INITIAL AUTHORIZATION:
- Preferred Agents (Bethkis, Kitabis PAK)
  - Member must meet all of the following criteria:
    - Diagnosis of cystic fibrosis
    - Sputum culture is positive for Pseudomonas aeruginosa
    - Member is 6 years of age or older
- Pulmozyme
  - Member must meet all of the following criteria
    - Diagnosis of cystic fibrosis
    - Member is 5 years of age or older
    - Usage in conjunction with standard therapies for cystic fibrosis (eg, airway clearance techniques)
- Non-Preferred Agents (Tobramycin Solution for inhalation (TOBI Podhaler), Cayston)
  - For Tobramycin INH (TOBI Podhaler), member has tried and failed or has a contraindication to Bethkis or Kitabis.
  - For Cayston:
    - Diagnosis of cystic fibrosis
    - Sputum culture positive for Pseudomonas aeruginosa
    - Member is 7 years of age or older
    - Respiratory function: FEV1 is between 25% and 75% of predicted
    - No evidence of Burkholderia cepacian in respiratory tract
    - Member meets one of the following criteria
      - Failur of or intolerance to preferred agents
      - Culture shows resistance to tobramycin
      - Susceptibility results indication that Cayston (aztreonam) is the only inhaled antibiotic to which Pseudomonas aeruginosa is sensitive

CRITERIA FOR RENEWAL:
- Prescriber attests the member has had a positive clinical response to treatment
- Evidence of improving or stable lung function (FEV1, decrease number of pulmonary exacerbations)

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EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 6/15/2021
2. Cayston (aztreonam for inhalation solution). Physician Prescribing Information [Internet] Gilead Sciences Inc. 2019 Nov Accessed at: https://www.cayston.com/. [created 1986; accessed 2020 Nov 16]
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4. Bethkis (tobramycin inhalation solution). Physician Prescribing Information [Internet] Chiesi USA, Inc. 2017 Jul Accessed at: https://bethkis.com/. [created 1980; accessed 2020 Nov 16]

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Guideline Name: Hepatitic C Virus

AHCCCS Prior Authorization Requirements for Direct Acting Antiviral Medication Treatment

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Guideline Name: Oncology – Antineoplastic Agents

Effective Date: 06/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- See AHCCCS Preferred Drug List for up-to-date preferred drug listing

CRITERIA FOR INITIAL AUTHORIZATION:
- Member is under the care of an Oncologist or Hematologist
- Medication is prescribed for a Food and Drug Administration (FDA) approved indication or for a "medically accepted indication" as noted in one of the following compendia:
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium or National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines, category 1, 2a, or 2b.
  - Drug Facts and Comparisons
  - American Hospital Formulary Service Drug Information
  - Micromedex DrugDex Information SYstem
  - UpToDate
- The does prescribed is within the FDA approved range of for the indication and patient-specific factors, including but not limited to:
  - Height
  - Weight
  - Body surface area
  - Renal function
  - Liver function
  - Drug – drug, disease, other other interaction
- Criteria for Non-Formulary Antineoplastic agents must meet one of the following criteria:
  - Trials of formulary agents, when used for an adequate duration were not effective or were poorly tolerated
  - Formulary alternatives are contraindicated based on patient-specific factors
  - There ar no formulary medications that match the patient's indication
  - Member has a genetic mutation that is resistant to formulary medication
  - All formulary alternatives are not supported by an approved Compendia.
- Medical records, laboratory information, test results and other clinical data support the diagnosis and treatment plan must be submitted with the request
- Member does not have a contraindication to the medication
- The medication is not being used for experimental or investigational purposes as part of a clinical trial

CRITERIA FOR RENEWAL:
- Attestation of clinically significant improvement or stabilization of disease state

EXCLUSION CRITERIA:
- N/A

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LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 3 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

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Guideline Name: Opioids

Effective Date: 06/15/2021
Date(s) of Review and Revision:

GENERAL GUIDANCE:

- Members who are prescribed preferred drugs and meet one of the following criteria are exempted from certain provisions within this policy:
  - Active cancer
  - Member within a skilled nursing facility
  - Member managed by palliative care program
  - End-of-life care
- Exept as otherwise stated, opioids should only be used in members 18 years of age or older, and all fills are limited to 5-day supplies
- All short acting opioids are limited to a 5-day supply for initial fill
- All long acting opioids require prior authorization
- Opioids should be prescribed at the lowest effective dose
- Signed treatment plans must be submitted for prior authorizations that includes at least one of the following elements
  - Non-pharmacologic therapy plan
  - Non-opioid pharmacotherapy (ex. NSAIDs, TCAs, and SNRIs)
  - Establishment of realistic goals for pain and function
  - Addresses risk and benefits of opioid therapy
- Medical Director approval is required for all opioid regimens within > = 200 Morphine Milligram Equivalents per day
- For opioid regimens greater than 90 Morphine Milligram Equivalents per day, management or consultation with pain management specialist required

CRITERIA FOR INITIAL AUTHORIZATION:

- Long-Acting Opioid Medications
  - Preferred Drugs
    - Fentanyl patch 72-hour (12 mcg, 25 mcg, 50 mcg, 75 mcg, 100 mcg)
    - Morphine-naltrexone capsule controlled release (Embeda)
    - Morphine sulfate controlled release
    - Oxycodone Hcl tablet 12-hour abuse deterrent (Xtampza ER)
    - Tramadol Hcl tablets ER (Ultram ER)
    - Buprenorphine patch weekly (Butrans) – requires documentation that supports the need for opioids with lower abuse potential than other preferred agents, such as risk of opioid use disorder for the member or others within member's household
  - Non-Preferred drug authorization requires evidence that the drug meets the following criteria
    - Used for chronic pain
    - Member has tried and failed preferred drugs or preferred drugs are not ideal for patient, or patient is pregnant (methadone only)

- Non-Formulary drugs require that the member has had inadequate response or intolerance to all formulary long-acting opioids with a sufficient trial period of at least two weeks.
- Member must meet the following criteria:
  - Opioid is used for the management of chronic pain that is severe and continuous, not for intermittent or immediate use
  - Provider has initated treatment with at least a two-week regimen of immediate-release opioids before initiating long-acting opioids
- Prescriber attests that the following risk assessment has been performed
  - Review of state Prescription Monitoring Program for controlled substances
  - Review of a urine or serum drug screen with confirmation that screening is consistent with prescribed medications
  - Counseling to patient, and offer to counsel household member(s) as appropriate, on the use of naloxone if member has risk factors for opioid overdose, including but not limited to:
    - 50 morphile milligram equivalents per day
    - Concomitant benzodiazepine use
    - Substance use disorder
    - Prior overdose
- If member is a female of reproductive age, counseling on opioid use during pregnancy and neonatal abstinence syndrome

- Short-Acting Opioids
  - Covered Agents
    - Hydromorphone
    - Meperidine
    - Morphine sulfate
    - Oxycodone
    - Tramadol
    - Codeine / acetaminophen
    - Butalbital / acetaminophen / caffeine
    - Hydrocodone / acetaminophen
    - Hydrocodone / ibuprofen
    - Oxycodone / acetaminophen
    - Oxycodone / ibuprofen
  - Member must meet the following criteria:
    - Evidence of medical necessity, if exceeding Morphine Milligram Equivalent or days supply limit
    - Evidence to support continued use of short-acting opioids beyond 30-days when used in combination with long-acting opioid, including description of break-through pain timing and frequency that supports quantities and durations prescribed
  - Non-Formulary drugs require that the member has had inadequate response or intolerance to all formulary short-acting opioids with a sufficient trial period of at least two weeks.
- Members Less Than 18 Years of Age
  - Pain assessment has been completed
  - Member and household members have been screened for opioid use disorder

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- Prescribing clinical has reviewed the Prescription Monitoring Program for controlled substance use
- Member and parent(s)/guardians have been counseled regarding concomitant use of opioid potentiators, including benzodiazepines
- Member has tried and failed, or otherwise cannot tolerate, combination therapy including acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs)
- Opioid will be used in combination with acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs)
- Member has no contraindications to prescribed therapy based on age
- Prescription durage is limited to 12 tablets or less

CRITERIA FOR RENEWAL:

- Sustained improvement in pain levels and functional status
- Urine drug screen performed annually with results consistent with prescribed medications
- Prescribing clinical has reviewed the Prescription Monitoring Program for controlled substance use
- Evidence that the prescribing clinician has counseled the member of naloxone use
- Evidence that if member is using concomitant opioid potentiators, including benzodiazepines, prescribing clinician has counseled the member on the Food and Drug Administration (FDA) Black Box Warning dangers of prescribing opioids and benzodiazepines. Prescribing clinician attests that the lowest effective opioid dose is prescribed.

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration:**
  - **Cancer, End-of-life, Palliative Care: 12 months**
  - **Chronic Pain – 3 months**
  - **Acute Pain – 1 month**
  - **Acute Pain, Members Less than 18 Years of Age – 5 days**
- **Renewal Approval Duration:**
  - **Cancer, Palliative Care: 12 months**
  - **Chronic Pain: 6 months**
  - **Acute Pain: 30 days or less**
  - **Acute Pain, Members Less than 18 Years of Age – 5 days**

REFERENCES

1. Arizona Opioid Prescribing Guidelines. https://www.azcompletehealth.com/content/dam/centene/az-complete-health/pdf/provider/forms/508_az-opioid-prescribing-guidelines.pdf. Accessed 6/15/2021.
2. National Institute for Health and Care Excellence (NICE). Neuropathic pain - pharmacological management. The pharmacological management of neuropathic pain in adults in non-specialist settings. London (UK): National Institute for Health and Care Excellence (NICE). . (Clinical guideline; no. 173). Updated February 2017

3. Xtampza ER (oxycodone hydrochloride) extended-release capsule package insert. Cincinnati OH: Patheon Pharmaceuticals. April 2016
4. Butrans (buprenorphine transdermal system) package insert. Stamford, CT: Purdue Pharma L.P Updated June 2014
5. Nucynta (tapentadol extended-release oral tablets) package insert. Titusville, NJ: Janssen Pharmaceuticals, Inc. Updated December 2016
6. Xartemis XR (acetaminophen; oxycodone) extended-release tablets. Hazelwood MO: Mallinckrodt Brand Pharmaceuticals, Inc. Updated March 2014
7. Belbuca (buprenorphine) buccal film package insert. Endo Pharmaceuticals Inc Updated October 2015
8. Embeda (morphine; naltrexone) package insert. New York, NY: Pfizer, Inc June 2009
9. Dowell D, Haegerich TM, et al. CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016; 65(No.RR-1):1-49. Available at: www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. Accessed March 1, 2019
10. American Pain Society, Clinical Practice Guidelines. Available at http://americanpainsociety.org/education/guidelines/overview. Accessed on March 1, 2019.
11. Abuse-Deterrent Formulations of Opioids: Effectiveness and Value. Final Evidence Report, August 8, 2017. Institute for Clinical and Economic Review (ICER).
12. REMS https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm 9/18/2018 updated - includes all opioid analgesics

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Guideline Name: Opioid Agonists

Effective Date: 05/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- Suboxone film
- Buprenorphine-naloxone ODT tablet
- Sublocade
- Buprenorphine Sublingual Tablet

CRITERIA FOR INITIAL AUTHORIZATION:
- Suboxone Film and Buprenorphine-Naloxone ODT tablets:
  - No prior authorization required.
- Sublocade Extended-Release Injection
  - Member has diagnosis of moderate to severe opioid use disorder, **AND**
  - Maintained on dose of buprenorphine-containing product equivalent to 8-24mg for 7 or more days, **AND**
  - Not receiving supplemental dosing of buprenorphine-containing products, **AND**
  - Prescriber meets DATA 2000 requirements, **AND**
  - Documentation prescriber has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database prior to first injection.
- Buprenorphine Sublingual Tablet
  - Pregnant:
    - Physician has documented on prescription one of the following ICD-10 codes:
      - O09.91 - supervision of high-risk pregnancy, 1st trimester
      - O09.92 - Supervision of high-risk pregnancy, 2nd trimester
      - O09.93 - Supervision of high-risk pregnancy, 3rd trimester
      - O09.91 - Supervision of high-risk pregnancy - use for Postpartum nursing mothers
  - Not Pregnant:
    - Diagnosis of opioid withdrawal OR mild, moderate or severe opioid use disorder, **AND**
    - Documentation prescriber has checked Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database and member is not receiving alternative opioid products, **AND**
    - Prescriber meets DATA 2000 requirements, **AND**
    - Documentation is provided indicating allergy to naloxone, **OR**
    - Clinical rationale is provided indicating why preferred options are not appropriate or cannot be used. ***NOTE: Trial and failure of Suboxone is not adequate for approval; Provider must provide alternate justification for use of buprenorphine alone.***

CRITERIA FOR RENEWAL:
- Sublocade Extended-Release Injection:
  - Prescriber attests the member has had a positive clinical response to treatment, **AND**

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- Member has diagnosis of moderate to severe opioid use disorder, **AND**
- Not receiving supplemental dosing of buprenorphine-containing products, **AND**
- Prescriber continues to meet DATA 2000 requirements, **AND**
- Documentation prescriber has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database prior to each injection.

- Buprenorphine Sublingual Tablet:
  - Pregnant:
    - Prescriber attests the member has had a positive clinical response to treatment, **AND**
    - Physician has documented on prescription one of the following ICD-10 codes:
      - O09.91 - supervision of high-risk pregnancy, 1st trimester
      - O09.92 - Supervision of high-risk pregnancy, 2nd trimester
      - O09.93 - Supervision of high-risk pregnancy, 3rd trimester
      - O09.91 - Supervision of high-risk pregnancy - use for Postpartum nursing mothers
  - Not-Pregnant:
    - Prescriber attests the member has had a positive clinical response to treatment, **AND**
    - Diagnosis of opioid withdrawal OR mild, moderate or severe opioid use disorder
    - Documentation prescriber has checked Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database and member is not receiving alternative opioid products, **AND**
    - Prescriber continues to meet DATA 2000 requirements, **AND**
    - Documentation is provided indicating continued allergy to naloxone, **OR**
    - Clinical rationale is provided indicating why preferred options are still not appropriate or cannot be used. ***NOTE: Trial and failure of Suboxone is not adequate for approval; Provider must provide alternate justification for use of buprenorphine alone.***

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration in Pregnancy: 6 months**
- **Renewal Approval Duration in Pregnancy: 6 months**
- **Initial Approval Duration: 6 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

12. White et al. The ASAM National Practice Guideline for the Treatment of Opioid use disorder: 2020 Focused Update. American Society of Addiction Medicine: 2020.
13. Product Information: SUBUTEX(R) sublingual tablets, buprenorphine sublingual tablets. Indivior Inc. (per FDA), Richmond, VA, 2018.
14. Drug Addiction Treatment Act of 2000
15. The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities or SUPPORT for patients and Communities Act of 2018

16. Product Information: Sublocade, buprenorphine extended-release injection. Indivior Inc. (per FDA), North Chesterfield, VA, 2017.

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Guideline Name: Serotonin (5HT3) Receptor Antagonists

Effective Date: 06/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- N/A

NON-PREFERRED AGENTS
- Granisetron (tablets and solution)
- Dolasetron
- Ondansetron (> 8mg/dose)

CRITERIA FOR INITIAL AUTHORIZATION
- Member must meet all criteria:
  - Receiving radiation therapy or moderate to highly emetogenic chemotherapy
  - Inadequate response to, intolerance to, or contraindication for ondansetron
- For ondansetron > 8mg/dose:
  - Evidence that lower doses do not adequately manage nausea/vomiting

CRITERIA FOR RENEWAL
- Continued exposure to emetogenic treatment

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- **N/A**

LENGTH OF AUTHORIZATION
- **Initial Approval Duration: 12 months or less depending on indication**
- **Renewal Approval Duration: 12 months**

REFERENCES

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 02/2019.
2. Facts&ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016

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Guideline: Tobacco Cessation Products

AHCCCS Tobacco Cessation Products Prior Authorization Criteria

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Guideline Name: Vesicular Monoamine Transporter-2 (VMAT-2) Inhibitors

Effective Date: 05/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- N/A

NON-PREFERRED AGENTS:
- Ingrezza
- Austedo
- Tetrabenazine

CRITERIA FOR INITIAL AUTHORIZATION

INGREZZA OR AUSTEDO (TARDIVE DYSKINESIA):
- Member is ≥18 years old, **AND**
- Member has a diagnosis of moderate to severe Tardive Dyskinesia (TD) defined by an AIMS score meeting one of the following:
  - Score of 2 on three or more items (1-7), or
  - Score of 3 on two or more items (1-7), or
  - Score of 4 on any single item (1-7), **AND**
- Prescriber attests that diagnosis has been established by or in consultation with a neurologist or psychiatrist, **AND**
- Documentation is provided indicating 2 or more of the following alternative treatment methods have been attempted:
  - dose reduction of offending antipsychotic
  - discontinuation of offending antipsychotic
  - switching to second generation antipsychotic, ideally with low dopamine affinity (i.e. quetiapine, clozapine)
  - discontinuation of concurrent anticholinergic medications, **AND**
- Prescriber attests to both of the following:
  - Member is not at significant risk of suicidal behavior (i.e. no active suicidal thoughts or behaviors)
  - Member does not have untreated or poorly treated depression, **AND**
- Prescriber provides documentation of Child-Pugh score (assessed within last 90 days) and dosing is appropriate based on severity of liver disease.

TETRABENAZINE OR AUSTEDO (HUNTINGTON'S CHOREA):
- Member is ≥18 years old, AND
- Diagnosis of Huntington's Disease confirmed in consult with a neurologist and genetic testing
- Unified Huntington's Disease Rating Scale (UHDRS), total maximal chorea score of 8 or greater
- Member had inadequate response, intolerable side effects or contraindication to amantadine
- Documentation that member is not at significant risk for suicidal behavior

- Documentation that member does not have untreated or poorly controlled depression
- Documentation of recent (past 90 days) Child-Pugh score, with requested medication and dose appropriate per FDA prescribing criteria.

CRITERIA FOR RENEWAL

INGREZZA OR AUSTEDO (TARDIVE DYSKINESIA):

- Prescriber attests the member has had a positive clinical response to treatment as evidenced by an updated AIMS exam and score reduction of ≥2 points on items 1-7, **AND**
- Prescriber attests to both of the following:
  - Member continues to not be at significant risk of suicidal behavior (i.e. no active suicidal thoughts or behaviors)
  - Member continues to not have untreated or poorly treated depression, **AND**
- One of the following:
  - Prescriber attests member is not at risk for congenital long QT syndrome or cardiac arrhythmias associated with prolonged QT interval, OR
  - Documentation of EKG provided for members at risk for QT prolongation

TETRABENAZINE OR AUSTEDO (HUNTINGTON'S CHOREA):

- Prescriber attests the member has had a positive clinical response to treatment as evidenced by reduction in UHDRS, total chorea score of ≥3 points

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

- Concurrently prescribed reserpine, MAOIs, or other VMAT-2 inhibtors
- Diagnosis of congenital long QT syndrome or cardiac arrhythmias associated with prolonged QT interval
- Hepatic dysfunction (only if requesting AUSTEDO)
- Active suicidal thoughts or behavior
- Untreated or undertreated depression

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 3 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

Tardive Dyskinesia

1. American Psychiatric Association. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. September 2020.
2. Stacy M, Sajatovic M, Kane JM, et al. Abnormal involuntary movement scale in tardive dyskinesia: Minimal clinically important difference [published correction appears in Mov Disord. 2019 Nov;34(11):1753-1754]. Mov Disord. 2019;34(8):1203-1209. doi:10.1002/mds.27769
3. Ingrezza prescribing information. San Diego, CA. Neurocrine Biosciences, Inc.; Apr 2020.
4. Austedo prescribing information. Parsippany, NJ. Teva Neuroscience, Inc.; Dec 2020.
5. AIMS exam: https://www.dhhs.nh.gov/dcyf/adoption/documents/abnormal-involuntary-movement-scale-exam.pdf

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8. Bhidayasiri R, Jitkritsadakul O, Friedman JH and Fhan S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. Journal of the Neurological Sciences. 2018; 389: 67–75.

Huntington's Chorea

1. Armstrong MJ, Miyasaki JM; American Academy of Neurology. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2012;79(6):597-603.
2. Huntington Study Group. Effect of Deutetrabenazine on Chorea Among Patients With Huntington Disease: A Randomized Clinical Trial. JAMA. 2016;316(1):40–50. doi:10.1001/jama.2016.8655
3. Craufurd D, MacLeod R, Frontali M on behalf of the Working Group on Genetic Counselling and Testing of the European Huntington's Disease Network (EHDN), et al. Diagnostic genetic testing for Huntington's disease. Practical Neurology. 2015;15:80-84.

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Guideline Name: ADALIMUMAB (HUMIRA)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- See AHCCCS Preferred Drug List for up-to-date preferred drug listing

NON-PREFERRED AGENTS:
N/A

CRITERIA FOR INITIAL AUTHORIZATION:

. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate at a dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient had a previous trial of or contraindication to an NSAID

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriasis involving greater than or equal to 5% body surface area (BSA) or psoriatic lesions affecting the hands, feet, face, or genital area

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- The patient had a previous trial of or contraindication to **ONE** conventional therapy, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to **ONE** conventional therapy, such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to **ONE** conventional therapy, such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) **AND** meet the following criterion?

   - **The patient is 12 years of age or older**

9. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criterion?

   - **The patient is 2 years of age or older**

- Our guideline named **ADALIMUMAB (Humira)** requires the following rules be met for approval:

  A. You have ONE of the following diagnoses:
     - Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
     - Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
     - Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
     - Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
     - Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
     - Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
     - Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

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- Moderate to severe hidradenitis suppurativa (skin condition with lumps)
- Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
- You are 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
- You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate at a dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
- You are 2 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
- You have previously tried ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

D. **If you have psoriatic arthritis, approval also requires:**
- You are 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
- You have previously tried ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

E. **If you have ankylosing spondylitis, approval also requires:**
- You are 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
- You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
- You are 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
- You have plaque psoriasis involving greater than or equal to 5% body surface area (BSA) or psoriatic lesions (rashes) affecting your hands, feet, face or genital area
- You have previously tried ONE of the following standard treatments, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (betamethasone, triamcinolone), calcipotriene, acitretin, methotrexate, or cyclosporine

G. **If you have moderate to severe Crohn's disease, approval also requires:**
- You are 6 years of age or older

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- Therapy is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
- You have previously tried ONE of the following standard treatment, unless there is a medical reason why you cannot (contraindication), such as a corticosteroid, azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis, approval also requires:**
- You are 5 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
- You have previously tried ONE standard treatment, unless there is a medical reason why you cannot (contraindication), such as a corticosteroid, azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa, approval also requires:**
- You are 12 years of age or older

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
- You are 2 years of age or older

CRITERIA FOR RENEWAL:

You have **ONE** of the following diagnoses:
- Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
- Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
- Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
- Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
- Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
- Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
- Moderate to severe hidradenitis suppurativa (skin condition with lumps)
- Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

If you have moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis, renewal also requires:

- You continue to benefit from the medication

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION
- **Initial Approval Duration: 6 Months**
- **Renewal Approval Duration: 12 Months**

The above criteria apply to the listed diagnoses only. Should you require the medication for an alternate diagnosis not included in these criteria, the pharmacist reserves the right to review the prior authorization and request additional information as necessary to determine approval or denial status.

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REFERENCES
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2021.

Guideline Name: Apremilast (Otezla)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- See AHCCCS Preferred Drug List for up-to-date preferred drug listing

.

NON-PREFERRED AGENTS:
N/A

CRITERIA FOR INITIAL AUTHORIZATION

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred agents: Cosentyx, Enbrel, Humira, Stelara, Tremfya, Xeljanz (IR or XR)

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriasis involving greater than or equal to 5% of body surface area or psoriatic lesions affecting the hands, feet, face, or genital area
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred agents: Humira, Stelara, Cosentyx, Enbrel, Skyrizi, Tremfya

   If no, continue to #3.

3. Does the patient have a diagnosis of Behçet's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has oral ulcers or a history of recurrent oral ulcers based on clinical symptoms
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE or more conservative treatments (e.g., colchicine, topical corticosteroid, oral corticosteroid, etc.)

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CRITERIA FOR RENEWAL

1. Does the patient have a diagnosis of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), or Behcet's disease **AND** meet the following criterion?
   - The patient continues to benefit from the medication

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 Months**
- **Renewal Approval Duration: 12 Months**

REFERENCES

Otezla [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2020.

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Guideline Name: Celecoxib (Celebrex)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- See AHCCCS Preferred Drug List for up-to-date preferred drug listing

NON-PREFERRED AGENTS:

- **N/A**

CRITERIA FOR INITIAL AUTHORIZATION

- **Celecoxib 50mg, 100mg, or 200mg**: Member must meet the following criteria:
  - Thirty (30) day trial of a formulary oral NSAID in the last 90 days.
- **Celecoxib 400mg**: Member must meet at least one of the following criteria:
  - Member is > 65 years of age
  - Member has a trial and failure of an intolerance to TWO formulary Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. ibuprofen, diclofenac sodium, naproxen, etodolac, nabumetone) Member has been on following drug therapy in previous 90 days:
  - Member is concurrently on anticoagulants/antiplatelet agents (e.g., warfarin, Xarelto, Pradaxa, clopidogrel, 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 use of methotrexate
  - Member has a history of peptic ulcer disease (PUD) or history of gastrointestinal (GI) bleed

CRITERIA FOR RENEWAL

- Member is receiving positive response to therapy.

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

- **N/A**

LENGTH OF AUTHORIZATION

- **Initial Approval Duration:** 12 MONTHS
- **Renewal Approval Duration:** 12 MONTHS

QUANTITY LIMIT

- 50mg, 100mg, 200mg:
- 60 capsules per 30 days
- 400mg: 30 capsules per 30 days

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REFERENCES

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 01/2019
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 03/2017

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Guideline Name: Dronedarone (Multaq)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Dronedarone (Multaq)

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

- Member must meet the following criteria:
  - Member is 18 years of age or older
  - Diagnosis of paroxysmal or persistent atrial fibrillation and
  - Member is currently in normal sinus rhythm, or
  - Member plans to undergo cardioversion to normal sinus rhythm
  - Prescribed by, or in consultation with a cardiologist
- Attestation member does not have any contraindications as outlined per the prescribing information including, but not limited to the following:
  - o Symptomatic heart failure with recent decompensation requiring hospitalization
  - o New York Heart Association (NYHA) Class IV chronic heart failure
- Member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives:
  - o amiodarone
  - o propafenone
  - o flecainide
  - o sotalol

CRITERIA FOR RENEWAL

- Attestation that member has positive response to treatment
- Monitoring of electrocardiogram (ECG) every 3 months to make sure atrial fibrillation (AF) has not become permanent

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 3 Months**
- **Renewal Approval Duration: 6 Months**

REFERENCES

1. Multaq® [package insert]. Sanofi-Aventis U.S. LLC, Bridgewater, NJ; January 2017. http://products.sanofi.us/multaq/multaq.html. Accessed December 11, 2019.
2. 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: Executive Summary. Circulation. 2014; 130:2071-2104.
3. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. European Heart Journal (2016) 37, 2893–2962 doi:10.1093/eurheartj/ehw210.
4. Teme, Tonye, Goldberger, Jeffrey J. Efficacy and tolerability of dronedarone for patients with atrial fibrillation. Cardiology Journal. 2013. 20(5): 486-490.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc., URL: http://www.clinicalpharmacology-ip.com/. Updated periodically. Accessed December 11, 2019.

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6. CORDARONE Amiodarone tablets [Prescribing Information]. Pfizer Wyeth Pharmaceuticals Inc. Philadelphia, PA. March 2015.
7. January CT, Wann S, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Journal of the American College of Cardiology. 2014;64(21). doi.org/10.1016/j.jacc.2014.03.022.
8. Passman, R., Giardina, E.G., (2018), Clinical uses of dronedarone, In B.C. Downey (Ed), UpToDate. Retrieved October 31, 2018 from
9. Kumar, K.K., (2017), Antiarrhythmic drugs to maintain sinus rhythm in patients with atrial fibrillation: Recommendations, In G.M. Saperia (Ed), UpToDate. Retrieved October 31, 2018 from https://www.uptodate.com/contents/antiarrhythmic-drugs-to-maintain-sinus-rhythm-in-patients-with-atrial-fibrillation-recommendation

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Guideline Name: Etanercept (Enbrel)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- See AHCCCS Preferred Drug List for up-to-date preferred drug listing

NON-PREFERRED AGENTS:
N/A

CRITERIA FOR INITIAL AUTHORIZATION
Rheumatoid Arthritis
1. Member must have a diagnosis of moderate to severe active rheumatoid arthritis (RA) as evidenced by one or more of the following:
   - Clinical Disease Activity Index score greater than 10
   - Disease Activity Score of 3.2 or greater
   - Patient Activity Scale of 3.71 or greater
   - Patient Activity Scale-II of 3.71 or greater
   - Routine Assessment of Patient Index Data 3 score greater than 2
   - Simplified Disease Activity Index score greater than 11
2. Member must meet all of the following criteria:
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate at a dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine.

Polyarticular Juvenile Idiopathic Arthritis
1. Member must have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria:
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

Psoriatic Arthritis
1. Member must have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria:
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If no, continue to #4.

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4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriasis involving at least 5% body surface area (BSA) or psoriatic lesions affecting the hands, feet, face, or genital area
   - The patient had a previous trial of or contraindication to **ONE** conventional therapy, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

CRITERIA FOR RENEWAL

You have ONE of the following diagnoses:

- Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
- Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
- Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
- Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)
- You continue to benefit from the medication

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 Months**
- **Renewal Approval Duration: 12 Months**

REFERENCES

Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; March 2020.

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Guideline Name: Ezetemibe (Zetia)

Effective Date: 06/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:
- N/A

NON-PREFERRED AGENTS:
- N/A

CRITERIA FOR INITIAL AUTHORIZATION:
- Member must meet the following criteria:
    - Previous statin therapy with evidence of lack of efficacy or intolerance

CRITERIA FOR RENEWAL:
- Prescriber attests the member has had a positive clinical response to treatment

EXCLUSION CRITERIA:
- N/A

LENGTH OF AUTHORIZATION
- **Initial Approval Duration: 12 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

1. Grundy SM, et al. 2018 ACC/AHA Guideline for the Treatment of Blood cholesterol: A report of the ACC/AHA taskforce on practice guideline.
2. Zetia Prescribing Information. Merck/Schering-Plough Pharmaceuticals, Whitehouse Station. NJ 0889. February 2019.

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Guideline Name: Palivizumab (Synagis)

Effective Date: 10/1/2020
Date(s) of Review and Revision:

PREFERRED AGENTS:
- N/A

CRITERIA FOR INITIAL AUTHORIZATION:
- Member meets one of the following criteria
  - Age of 12 months or less at start of RSV season AND born before 29 weeks 0 days gestation
  - Age of 12 months or less at start of RSV season with Chronic Lung Disease of prematurity (CLD) / Bronchopulmonary Dysplasia AND born at less than 32 weeks 0 days gestation and required >21% oxygen for at least 28 days after birth
  - Age of 12 months or less at start of RSV season with impaired clearance of respiratory secretions from upper air AND one of the following:
    - Congenital pulmonary abnormality
    - Neuromuscular disorder
  - Age of 12 months or less at start of RSV season with hemodynamically significant Congenital Heart Disease AND one of the following:
    - Acyanotic heart disease and receiving medication to control congestive heart failure
    - Moderate to severe pulmonary hypertension
  - Cyanotic heart disease and prescribed in consultation with pediatric cardiologist
  - Age of 23 months or less with Cardiac Transplantation occurring during RSV season
  - Age of 23 months or less at start of RSV season with Severe Immunodeficiency
  - Age of 23 months or less at start of RSV season with Cystic Fibrosis and one of the following:
  - CLD and/or nutritional compromise by the age of 12 months or less
  - Manifestations of severe lung disease during second year of life
  - Age of 23 months or less at start of RSV season with Chronic Lung Disease (CLD)/Bronchopulmonary Dysplasia AND required oxygen, corticosteroids, or diuretics within the past 6 months

CRITERIA FOR RENEWAL:
- **N/A: Member must receive prior authorization each Respiratory Syncitial Virus (RSV) Season**

EXCLUSION CRITERIA:
- N/A

LENGTH OF AUTHORIZATION
- **Initial Approval Duration in Pregnancy: 5 months or 5 courses, beginning November 1st and ending March 31st**
- **Renewal Approval Duration in Pregnancy: 5 months or 5 courses, beginning November 1st and ending March 31st**

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REFERENCES

1. American Academy of Pediatrics (AAP), 2006 Red Book. Report of the Committee on Infectious Diseases. 27th ed. Elk Grove Village, IL: AAP; 2006.
2. American Academy of Pediatrics (AAP), Committee on Infectious Diseases. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics. 2003;112(6 Pt 1):1442-1446.
3. American Academy of Pediatrics. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(2):415-20.

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Guideline Name: Pramlintide (Symlinpen)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Symlinpen 60 (Pramlintide Acetate Solution Pen Injection)

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

- The member has diagnosis of Type 1 or type 2 diabetes mellitus
- Failure to obtain adequate glycemic control despite 3 months (90days) or more of daily mealtime insulin therapy

CRITERIA FOR RENEWAL

- Member had improvement in target goals (e.g., a reduction in hemoglobin A1C, glucose level, weight loss) since starting this therapy (3-6 months) and does not have adverse effects or contraindications

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

- Patients with diagnosis of gastroparesis or taking drugs that alter gastrointestinal motility or drugs that slow intestinal absorption of nutrients (e.g., erythromycin, metoclopramide, cholestyramine, Colestid, Welchol, Donnatal, Lomotil, Precose).

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 Months**
- **Renewal Approval Duration: 12 Months**

REFERENCES

1. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 10/2019
2. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 10/2019
3. American Diabetes Association Standards of Medical Care in Diabetes – 2018. Diabetes Care. Jan 2019;42 (Suppl. 1). Accessed at: https://care.diabetesjournals.org/content/42/Supplement_1. 10/2019.
4. AACE/ACE Comprehensive Type 2 Diabetes Management Algorithm 2019. Endocr Pract. 2019. Accessed at: https://www.aace.com/disease-state-resources/diabetes/clinical-practice-guidelines-treatmentalgorithms/comprehensive. 10/2019.
5. Symlin/SymlinPen [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; February 2019.
6. Nauck MA, Kahle M, Baranov O. Addition of a dipeptidyl peptidase-4 inhibitor, sitagliptin, to ongoing therapy with the glucagon-like peptide-1 receptor agonist liraglutide: A randomized controlled trial in patients with type 2 diabetes. Diabetes Obes Metab. 2017 Feb; 19 (2):200-207. doi: 10.1111/dom.12802. Epub 2016 Nov 9.
7. European society of cardiology guidelines (ESC)/European association for the study of diabetes (EASD)-2019. European Heart Journal. Aug 31, 2019. Accessed at: https://academic.oup.com/eurheartj/advancearticle/doi/10.1093/eurheartj/ehz486/5556890
8. Busch RS, Kane MP. Combination SLGT2 inhibitor and GLP-1 receptor agonist therapy: a complementary approach to the treatment of type 2 diabetes. Postgrad Med. 2017 Sep; 129 (7):686-697. doi: 10.1080/00325481.2017.1342509. Epub 2017 Jun 28
9. DeFronzo RA. Combination therapy with GLP-1 receptor agonist and SGLT2 inhibitor. Diabetes Obes Metab. 2017 Oct; 19(10):1353-1362. doi: 10.1111/dom.12982. Epub 2017 Jun 7

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Guideline Name: Lyrica (Pregabalin)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Lyrica (Pregabalin) tablets and solution

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

- The member must have first tried, failed, or have a documented contraindication to a compliant 60 day trial of the generic product (Pregabalin).
- The member must be clinically diagnosed with one of the following disease states and meet their individual criteria if stated:
- Partial-onset seizures: as adjunctive therapy of partial-onset seizures in patients 18 years of age and older.
  a. Member has tried and failed at least 2 generically available anticonvulsants
- Fibromyalgia
- a. Member has tried and failed duloxetine (generic Cymbalta) at maximum tolerated dose or dose up to 60mg/day for at least 90 days
- Neuropathic pain associated with diabetic peripheral neuropathy
- a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.
- Neuropathic pain associated with spinal cord injury
  a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.
- Postherpetic neuralgia
  a. Member has tried and failed gabapentin (generic Neurontin) at max tolerated dose or dose ≥ 1800mg/day for at least 90 days.

CRITERIA FOR RENEWAL

- Authorization for continued use shall be reviewed at least every 12monthsto confirmthere are no contraindicationsto therapy.

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 Months**
- **Renewal Approval Duration: 12 Months**

QUANTITY LEVEL LIMITS

- For the following strengths: 25mg/50mg75mg/100mg/150mg/200mg, QL is #90 every 30 days
- For the following strengths: 225mg/300mg, QL is #60 every 30 days

REFERENCES

1. Micromedex/DRUGDEXatwww.microdexsolutions.com. Accessed 11/2016
2. Facts& ComparisonseAnswersathttp://online.factsandcomparisons.com. Accessed 11/2016

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Guideline Name: Ranolazine (Ranexa)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Ranolazine (Ranexa)

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

- The member has a documented diagnosis of chronic symptomatic angina, and the initial prescription has been written by a cardiologist. Refills may be written by the primary care provider.
- Within a reasonable therapeutic time period at maximally tolerated doses, the member has tried and failed a beta blocker or calcium channel blocker and a longacting nitrate in combination
- The member has tried and failed generic Ranolazine ER for at least 60 days.
- Thememberdoesnot haveany ofthefollowing:
  - Hepatic cirrhosis.
  - Pre-existing QT prolongation.
  - ConcurrenttherapywithastrongCYP3A4inhibitor such as ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir or saquinavir.
  - ConcurrenttherapywithaCYP3A4inducer such as rifampin, rifabutin, rifapentin, phenobarbitol, phenytoin, carbamazepine or St. John's wort.
  - Acute renal failure, particularly in individuals with a baseline CrCL < 30 mL/min.

CRITERIA FOR RENEWAL

All must be met

- Member's therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the member's condition at that time.
- Member has been adherent with Ranexa fills unless extenuating circumstances exist (hospitalization, medical procedures, etc.).
- Documentation the member is tolerating the medication and there continues to be a medical need.
- Documentation the member has responded to treatment due to a documented decrease in anginal attacks.
-

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration:** 12 Months (500mg twice daily, may be increased to a maximum of 1000mg twice daily, as needed, based on clinical symptoms)
- **Renewal Approval Duration:** 12 Months

REFERENCES

1. Ranexa prescribing information. Foster City, CA. Gilead Sciences, Inc. Rev 1/2016. 2. Amsterdam EA, Wenger NK, et al. 2014 AHA/ACC Guideline for the Management of Patients with Non–STElevation Acute Coronary Syndromes. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Journal of the American College of Cardiology. Vol 64(24) Dec 2014. 3. Micromedex/DRUGDEX at www.microdexsolutions.com. Accessed 7/2017. 4. Facts & Comparisons eAnswers at http://online.factsandcomparisons.com. Accessed 7/2017.

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The above criteria apply to the listed diagnoses only. Should you require the medication for an alternate diagnosis not included in these criteria, the pharmacist reserves the right to review the prior authorization and request additional information as necessary to determine approval or denial status.

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Guideline Name: Banzel (Rufinamide)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Rifinamide Suspension (Banzel)
- Rifinamide Tablets (Banzel)

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

- Diagnosis of Lennox-Gastaut Syndrome (LGS);
- Member does not have Familial Short QT syndrome.
- Member is at least 1 year of age
- Prescribed by or in consultation with a neurologist;
- Failure of two formulary alternatives for LGS (e.g., clonazepam, felbamate, lamotrigine, topiramate) unless all are contraindicated or clinically significant adverse effects are experienced;
- Dose does not exceed 3200 mg per day.
- If request is for Brand Banzel oral suspension, member had a trial and failure of rufinamide oral suspension (generic Banzel), unless contraindicated.

Dosage and administration:

- Children Four Years and Older with Lennox-Gastaut Syndrome: Treatment should be initiated at a daily dose of approximately 10mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10mg/kg increments every other day to a target dose of 45mg/kg/day or 3200mg/day, whichever is less, administered in two equally divided doses. It is not known whether doses lower than the target doses are effective.
- Adults with Lennox-Gastaut Syndrome: Treatment should be initiated at a daily dose of 400- 800mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg/day every 2 days until a maximum daily dose of 3200mg/day, administered in two equally divided doses is reached. It is not known whether doses lower than 3200mg are effective.

CRITERIA FOR RENEWAL

- Currently receiving medication via pharmacy claims history
- Documentation of positive response to therapy;
- If request is for a dose increase, new dose does not exceed 3200 mg per day.

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 Months**
- **Renewal Approval Duration: 12 Months**

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REFERENCES

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2. Banzel Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; June 2015. Available at: https://www.banzel.com/areas/banzel/pdfs/BanzelPI.pdf. Accessed February 05, 2021.

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Guideline Name: Tofacitinib (Xeljanz IR)

Effective Date: 6/15/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

See AHCCCS Preferred Drug List for up-to-date preferred drug listing

NON-PREFERRED AGENTS:

N/A

CRITERIA FOR INITIAL AUTHORIZATION

Rheumatoid Arthritis:

- Prescribed by or in consultation with a rheumatologist.
- Age ≥ 18 years.
- Documentation submitted member has no latent or active tuberculosis infection.
- Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation.
- Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
    - i. Methotrexate
    - ii. Hydroxychloroquine
    - iii. Leflunomide
    - iv. Sulfasalazine

Psoriatic Arthritis:

- Prescribed by or in consultation with a rheumatologist.
- b. Age ≥ 18 years.
- c. Documentation submitted member has no latent or active tuberculosis infection (Humira, Enbrel and Xeljanz only).
- d. Documented diagnosis of moderate to severe psoriatic arthritis (PsA)
- e. Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
    - i. Methotrexate
    - ii. Leflunomide
    - iii. Sulfasalazine

Ulcerative colitis:

- Prescribed by or in consultation with a gastroenterologist.
- Age ≥ 18 years old.
- Documentation submitted member has no latent or active tuberculosis infection.
- Diagnosis of moderately to severely active ulcerative colitis.
- Member has failed two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication submitted.
    - i. An aminosalicylate such as sulfasalazine, mesalamine, balsalazide, Apriso, or Pentasa
    - ii. An oral corticosteroid or controlled ileal release budesonide
    - iii. A thiopurine such as azathioprine
    - iv. Methotrexate up to 25 mg once weekly

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Requests for XELJANZ IR will also require recent labwork for renal function, hepatic function, absolute neutrophil count, absolute lymphocyte count and hemoglobin.

CRITERIA FOR RENEWAL

- Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters. The following diagnoses must demonstrate specifically:

  Ulcerative Colitis must have documentation submitted supporting clinical remission by the initial eight weeks of therapy (Day 57). If clinical remission has not occurred by Day 57 then denial of request must occur.

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

1. Alcohol use is not considered a supported clinical reason for avoidance of methotrexate. 2. Concomitant use with other biologic medications is considered experimental and investigational. 3. The following is a list of acceptable contraindications for the use of methotrexate:
   - Pregnancy
   - Actively breast-feeding
   - Anemia, thrombocytopenia, leukopenia, or bone marrow hypoplasia
   - Immunodeficiency syndrome
   - Hepatitis B or C infection
   - Liver enzymes that are persistently elevated
   - Alcoholism or alcoholic liver disease stated as a diagnosis documented by the provider

Congestive heart failure and the use of TNF inhibitors:

The ACR 2015 Treatment Guidelines for rheumatoid arthritis notes there are no reports of exacerbation of heart failure using non-TNF biologics and the US Food and Drug Administration (FDA) warns against using TNF inhibitors in this population based on worsening of congestive heart failure with TNF inhibitors in the Adverse Event Reporting System database. A TNF inhibitor should only be used if there are no other reasonable options, and then, perhaps, only in compensated heart failure.

Malignancies and the use of TNF inhibitors:

ACR 2015 Treatment Guidelines for rheumatoid arthritis for previously treated or untreated skin cancer (melanoma or non-melanoma) and for previously treated lymphoproliferative disorders state as a recommendation to not use a TNF inhibitor. For previously treated solid organ malignancy the recommendations for treatment are the same as for patients without this condition.

Previous Serious Infections and the use of TNF inhibitors:

Per the ACR 2015 Treatment Guidelines for rheumatoid arthritis there was no consensus for making a recommendations regarding the use of other non-TNF biologics over TNF inhibitors in this setting.

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 6 Months**
- **Renewal Approval Duration: Up to 1 year**

QUANTITY LIMITS

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Ulcerative Colitis; #60 tablets per 30 days
Psoriatic Arthritis: #60 tablets per 30 days
Rheumatoid Arthritis #60 tablets per 30 days

REFERENCES

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2. Singh J, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2015.
3. Lovell DJ, Ruperto N, et al. Adalimumab with or without Methotrexate in Juvenile Rheumatoid Arthritis. N Engl J Med. 359:810- 820 Aug 2018. 146
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6. Ringold S, Weiss P, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Arthritis & Rheumatism. Vol 65(10);Oct 2013,2499-2512.
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8. Crowley JJ, Weinberg JM, et al. Treatment of nail psoriasis: best practice recommendations from the Medical Board of the National psoriasis Foundation. JAMA Dermatol 2015; 151:87.
9. Lichtenstein GR, Loftus EV, et al. ACG Clinical Guidelines: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018 Apr;113(4):481-517.
10. Humira Prescribing information. North Chicago, IL. AbbVie Inc. Rev Dec 2017.
11. Otezla prescribing information. Summit, NJ. Celgene Corporation. Rev Jun 2017.
12. Xeljanz prescribing information. New York, N.Y. Pfizer Inc. Rev May 2018.
13. Enbrel prescribing information. Thousand Oaks, CA. Amgen. Rev Nov 2017

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Guideline Name: Step Therapy: Rozerem

Effective Date: 05/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Rozerem

CRITERIA FOR INITIAL AUTHORIZATION:

- Member has diagnosis of insomnia
- One of the following:
  - Member has tried and failed two of the following:
    - Eszopiclone
    - Temazepam
    - Zolpidem
  - Prescriber attests that the member has an intolerance or contraindication to two of the above medications.
  - Prescriber attests and provides clinical rationale that two of the above medications would be ineffective in treating the member's condition.

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to threapy and continues to benefit from the medication.

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

17. Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug List

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Guideline Name: Step Therapy: Sympathomimetics

Effective Date: 05/01/2021
Date(s) of Review and Revision:

PREFERRED AGENTS:

- Advair (HFA & Diskus)
- Dulera
- Symbicort

CRITERIA FOR INITIAL AUTHORIZATION:

- Member has diagnosis of one of the following:
  - Asthma
  - COPD (Symbicort and Advair Diskus Only)
- One of the following:
  - Member has tried and failed one of the following steroid inhalers:
    - Qvar
    - Pulmicort
    - Flovent
    - Asmanex
  - Prescriber attests that the member has an intolerance or contraindication to one of the above steroid inhalers.
  - Prescriber attests and provides clinical rationale that one of the above steroid inhalers would be ineffective in treating the member's condition.

CRITERIA FOR RENEWAL:

- Prescriber attests the member has had a positive clinical response to therapy and continues to benefit from the medication.

EXCLUSION CRITERIA:

- N/A

LENGTH OF AUTHORIZATION

- **Initial Approval Duration: 12 months**
- **Renewal Approval Duration: 12 months**

REFERENCES

18. Arizona Health Care Cost Containment System (AHCCCS) Preferred Drug List