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Banner University Health Plans
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 Member safety or efficacy, the Utilization Management team will account for this information in the prior authorization determination.

*****NOTE TO PROVIDERS: The outlined 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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Adalimumab (Humira) Guideline

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

APPLICABLE AGENT(S):
- Adalimumab (Humira)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Our guideline named **Adalimumab (Humira)** requires the following rules be met for approval:
    - Member has **AT LEAST** 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)
        - Moderate to severe hidradenitis suppurativa (skin condition with lumps)
        - Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)
    - Hepatitis B HBsAg negative, or concurrent treatment with antiviral therapy
    - No active infection
    - No concurrent treatment with other biological therapy (e.g., anakinra, abatacept, or another tumor necrosis factor inhibitor)
    - No untreated latent or active tuberculosis
2. Member has a diagnosis of ***moderate to severe rheumatoid arthritis (RA)*** and meets **ALL** of the following criteria:
    - Member is ≥ 18 years of age
    - Therapy is prescribed by or given in consultation with a rheumatologist
    - Member had a previous trial of or a 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
    - Moderate to severe active rheumatoid arthritis as indicated by **1 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

3. Member has a diagnosis of ***moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)*** and meets **ALL** of the following criteria:
    - Member is ≥ 2 years of age
    - Therapy is prescribed by or given in consultation with a rheumatologist
    - Treatment needed for disease severity, as indicated by **1 or more** of the following:
        - Four or fewer joints involved (i.e., oligoarticular, low disease activity) and inadequate response to **ALL** of the following:
            - Glucocorticosteroid injection or NSAIDs
            - Methotrexate
        - Five or more joints involved (i.e., polyarticular, moderate to high disease activity) and intolerance or inadequate response to methotrexate
        - Sacroiliitis, and intolerance or inadequate response to methotrexate
        - Uveitis, and inadequate response to **ALL** of the following:
            - Systemic corticosteroids
            - Systemic immunosuppressant (e.g., azathioprine or methotrexate)
            - Topical ophthalmic corticosteroids
4. Member has a diagnosis of ***psoriatic arthritis (PsA)*** and meets **ALL** of the following criteria:
    - Member is ≥ 18 years of age
    - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
    - Active arthritis, as indicated by **1 or more** of the following:
        - Axial disease with inflammatory back pain, and failure or intolerance of NSAIDs
        - Dactylitis
        - Enthesitis that is tender on examination
        - Peripheral disease with one or more tender and swollen joints, and failure of, intolerance to, or contraindication to methotrexate
    - Inadequate response, intolerance, or contraindication to 3 or more months of treatment with NSAIDs
5. Member has a diagnosis of ***ankylosing spondylitis (AS)*** and meets **ALL** of the following criteria:
    - Member is ≥ 18 years of age
    - Therapy is prescribed by or given in consultation with a rheumatologist
    - The Member had a previous trial of or a contraindication to an NSAID
    - Clinical evidence of axial spondyloarthritis, as indicated by **ALL** of the following:
        - Back pain of 3 months or more duration and age of onset of 45 years or younger
        - Diagnostic criteria met, as indicated by **1 or more** of the following:
            - Ankylosing spondylitis, as indicated by **ALL** of the following:
                - Sacroiliitis on imaging

- Spondylarthritis signs and symptoms, as indicated by **1 or more** of the following:
  - Arthritis
  - Dactylitis
  - Elevated C-reactive protein
  - Enthesitis (e.g., inflammation of Achilles tendon insertion)
  - Family history of spondylarthritis
  - HLA-B27
  - Inflammatory bowel disease (Crohn disease, ulcerative colitis)
  - Limited chest expansion
  - Morning stiffness for 1 hour or more
  - Psoriasis
  - Uveitis

- Nonradiographic axial spondyloarthritis, as indicated by **ALL** of the following:
  - HLA-B27
  - Spondyloarthritis signs and symptoms, as indicated by **2 or more** of the following:
    - Arthritis
    - Dactylitis
    - Elevated C-reactive protein
    - Enthesitis (e.g., inflammation of Achilles tendon insertion)
    - Family history of spondylarthritis
    - Inflammatory bowel disease (Crohn disease, ulcerative colitis)
    - Limited chest expansion
    - Morning stiffness for 1 hour or more
    - Psoriasis
    - Uveitis

6. Member has a diagnosis of ***moderate to severe plaque psoriasis (PsO)*** and meets **ALL** of the following criteria:
   - Member is ≥ 18 years of age
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The member has psoriasis involving greater than or equal to 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, face, or genital area
   - The Member had a previous trial of or contraindication to **AT LEAST** one conventional therapy, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
7. Member has a diagnosis of ***moderate to severe Crohn's disease (CD)*** and meets **ALL** of the following criteria:
   - Member is ≥ 6 years of age

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The Member had a previous trial of or contraindication to **AT LEAST** one conventional therapy, such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- Disease activity, as indicated by **1 or more** of the following:
  - Moderate to severe active Crohn disease, as indicated by **1 or more** of the following:
    - Anemia
    - Dehydration
    - Elevated serum C-reactive protein level
    - Fever
    - Intermittent vomiting
    - Perianal or rectal disease on endoscopy
    - Weight loss of greater than 10% of body weight
  - Perianal fistula

8. Member has a diagnosis of ***moderate to severe ulcerative colitis (UC)*** and meets **ALL** of the following criteria:
   - Member is ≥ 5 years of age
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The member had a previous trial of or contraindication to **AT LEAST** one conventional therapy, such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - Moderate to severe active ulcerative colitis, as indicated by **1 or more** of the following:
     - Anemia
     - Bowel movements 4 or more times per day
     - Urgency of defecation
     - Visible blood in stool
9. Member has a diagnosis of ***moderate to severe hidradenitis suppurativa (HS)*** **AND** meets the following criterion:
   - Member is ≥ 12 years of age
   - Inadequate response or intolerance to treatment with oral antibiotic
   - Moderate to severe disease, as indicated by **1 or more** of the following:
     - Multiple interconnected tracts and abscesses in single anatomic area
     - Widely separated and recurrent abscesses with sinus tracts and scarring
10. Member has a diagnosis of ***non-infectious intermediate, posterior and panuveitis*** **AND** meets the following criterion:
    - Member is ≥ 2 years of age
    - Intolerance or inadequate response to **1 or more** of the following:
      - Corticosteroids
      - Methotrexate
      - Systemic immunosuppressants (e.g., azathioprine)

CRITERIA FOR RENEWAL:

1. Provider notes that the member has seen improvement or is stable on therapy AND member has **AT LEAST** 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)

LENGTH OF AUTHORIZATION:

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

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ADHD Medication in Children <6 Years of Age Guideline

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

APPLICABLE AGENT(S):
- See AHCCCS Drug List for most updated list of agents

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member diagnosed with Attention-Deficit Hyperactivity Disorder (ADHD)?
   ☐***Yes*** ☐***No***
2. Does the provider attest that the member has any psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
   a. Please provide the date and name of clinician who performed the psychosocial evaluation: _____
   b. Please provide details on non-medical intervention(s) tried, date and duration of trial(s) and why intervention(s) was unsuccessful: _____
3. Is the initial prescription of medication for a methylphenidate containing product?
   ☐***Yes*** ☐***No***
   a. Please provide clinical rationale for not using methylphenidate or documentation of trial and failure: _____
4. Does the dose of prescription exceed FDA maximum dosing? ☐***Yes*** ☐***No***
   a. Please provide clinical justification and documentation supporting higher than FDA max dose: _____
5. Please indicate the member's diagnosis: _____

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

CRITERIA FOR RENEWAL:
1. Does the provider attest that the member having a positive clinical response to treatment?
   ☐***Yes*** ☐***No***

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

Quantity Limits:
- Refer to AHCCCS PDL for quantity limits

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Androgens – Anabolic Guideline

Effective Date: 6/15/2021
APPLICABLE AGENT(S):

- Testosterone Cypionate Solution (Depo-Testosterone)
- Testosterone Enanthate Solution (Testosterone Enanthate)
- Testosterone Gel (Androgel – brand only)
- Testosterone Patch (generic Androderm)

CRITERIA FOR <u>INITIAL AUTHORIZATION</u>:

1. Does the member have diagnosis of Primary or Secondary Hypogonadism? ☐***<u>Yes</u>*** ☐***<u>No</u>***
2. Does the member meet **<u>AT LEAST</u>** one of the following criteria: ☐***<u>Yes</u>*** ☐***<u>No</u>***
    - The Member 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 Member 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)
3. Does the member have a diagnosis of Female-to-male transsexual (Gender dysphoria)? ☐***<u>Yes</u>*** ☐***<u>No</u>***
4. Is the request for testosterone enanthate 200 mg/mL vial for a male Member with a diagnosis of delayed puberty not secondary to a pathological disorder? ☐***<u>Yes</u>*** ☐***<u>No</u>***
    - If Member meets above criteria, approve **Testosterone Enanthate 200 mg/mL 5 mL vial**
5. Is the request for testosterone enanthate 200 mg/mL vial for a female Member with a diagnosis of metastatic breast cancer? ☐***<u>Yes</u>*** ☐***<u>No</u>***
    - If Member meets above criteria, approve **Testosterone Enanthate 200 mg/mL 5 mL vial**
6. Please indicate the member's diagnosis: _____

CRITERIA FOR <u>RENEWAL</u>:

1. If the member has primary or secondary male hypogonadism (hypotestosteronism or low testosterone), Has the Member's physician indicated that symptoms have improved compared to baseline and Has the member tolerated treatment? ☐***<u>Yes</u>*** ☐***<u>No</u>***
2. If previously approved for different diagnosis than the one listed in question 1, has the member experienced a positive response to the therapy? ☐***<u>Yes</u>*** ☐***<u>No</u>***
3. Please provide diagnosis: _____

LENGTH OF AUTHORIZATION:

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

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Antidementia Agents Guideline

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

APPLICABLE AGENT(S):

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

CRITERIA FOR INITIAL AUTHORIZATION:

1. Is the member equal to or older than 18 years? ☐***Yes*** ☐***No***
2. Does the provider attest that diagnosis is made by or in consultation with a neurologist or psychiatrist or geriatrician? ☐***Yes*** ☐***No***
3. Has a baseline cognitive assessment been conducted in the past 90 days? ☐***Yes*** ☐***No***
    a. Assessment conducted: SLUMS SMMSE MoCA Other (specify): _____
4. Does the member meet criteria for Alzheimer's dementia +/- vascular dementia, Dementia with Lewy Bodies or Parkinson's Disease dementia? ☐***Yes*** ☐***No***
5. Indicate which of the following member is diagnosed with:
    a. Mild Alzheimer's Dementia +/- vascular dementia? ☐***Yes*** ☐***No***
        - If member meets above criteria, approval authorized for **donepezil, galantamine or rivastigmine only**
    b. Moderate Alzheimer's Dementia +/- vascular dementia? ☐***Yes*** ☐***No***
        - If member meets above criteria, approval authorized for **ANY formulary antidementia medication**
    c. Severe Alzheimer's Dementia +/- vascular dementia? ☐***Yes*** ☐***No***
        - If member meets above criteria, approval authorized for **donepezil or memantine only**
    d. Dementia with Lewy Bodies? ☐***Yes*** ☐***No***
        - If member meets above criteria, approve **donepezil or rivastigmine only**
        - If member meets above criteria and request is for galantamine, proceed to question 6
    e. Parkinson's Disease dementia? ☐***Yes*** ☐***No***
        - If member meets above criteria, approve **donepezil, galantamine or rivastigmine only**
        - If member meets above criteria and request is for memantine, proceed to question 7
6. Does the provider attest that rivastigmine and/or donepezil were trialed and not tolerated? ☐***Yes*** ☐***No***
7. Does the provider attest that cholinesterase inhibitors were not tolerated or contraindicated? ☐***Yes*** ☐***No***

8. Does the provider attests that the member is NOT actively taking any highly anticholinergic agents? ☐***Yes*** ☐***No***
9. Please indicate the member's diagnosis: _____

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

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

CRITERIA FOR RENEWAL (for all agents):

1. Does the provider attest that the member having a positive clinical response to treatment? ☐***Yes*** ☐***No***

LENGTH OF AUTHORIZATION:

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

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Antidepressants in Children Under 6 Years of Age and Antidepressant Solutions Guideline

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

APPLICABLE AGENT(S):
- See AHCCCS Drug List for most updated list of agents

CRITERIA FOR INITIAL AUTHORIZATION:

*PA for children <**6 years** of age:*
1. Is child diagnosed, per current DSM criteria, with at least one of the following: ☐***Yes*** ☐***No***
    a. Major Depressive Disorder, Moderate to Severe
    b. Anxiety Disorders (including social anxiety, generalized anxiety disorder, separation anxiety, specific phobia or panic disorder)
    c. Obsessive Compulsive Disorder
2. Has the diagnosis has been established by a child and adolescent behavioral health medical professional? ☐***Yes*** ☐***No***
3. Do you attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
4. Does provided documentation include psychosocial evaluation occurring before request for antidepressant medications, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation: _____
    b. Name of clinician conducting psychosocial assessment: _____
5. Does provided documentation include non-medication alternatives that have been attempted for a minimum of 6 weeks to address symptoms before request for antidepressant medications, which must include all the following components? ☐***Yes*** ☐***No***
    a. Interventions tried: _____
    b. Date and duration of trial: _____
6. Does the submitted include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***
7. Please indicate the member's diagnosis: _____

*Prior Authorization for members **greater than 12 years** of age (antidepressant solutions):*
1. Does the provider attest that the member has difficulty swallowing tablets and/or capsules? ☐***Yes*** ☐***No***

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

CRITERIA FOR RENEWAL (for all agents):
1. Does the provider attest that the member having a positive clinical response to treatment? ☐***Yes*** ☐***No***

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LENGTH OF AUTHORIZATION:

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

QUANTITY LIMITS:

- Refer to AHCCCS PDL for quantity limits

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Antidiabetic Agents – Combination Products Guideline

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

APPLICABLE AGENT(S):
- Invokamet (Canagliflozin-Metformin HCL)
- Xigduo XR (Dapagliflozin-Metformin)
- Synjardy (Empagliflozin-Metformin HCL)
- Glyxambi (Empagliflozin-Linagliptin)
- Trijardy XR (Empagliflozin-Linagliptin-Metformin)
- Jentadueto (Linagliptin-Metformin HCL)
- Kombiglyze XR (Saxagliptin-Metformin HCL)
- Janumet/Janumet XR (Sitagliptin-Metformin HCL/Sitagliptin-Metformin 24-Hour)

CRITERIA FOR INITIAL AUTHORIZATION:

Invokamet, Xigduo XR, Synjardy:
1. Does the member have diagnosis of Type 2 Diabetes Mellitus (DMII) **WITH** established Atherosclerotic Cardiovascular Disease (ASCVD), Heart Failure (HF), **OR** Chronic Kidney Disease (CKD with less than 60 mL/min)? ☐***Yes*** ☐***No***
2. If answer to question 1 is yes then, in addition to the diagnoses listed above, does the member have an eGFR greater than or equal to 45 mL/min? ☐***Yes*** ☐***No***
3. Does the member have a diagnosis of Type 2 Diabetes Mellitus (DMII) **WITHOUT** Cardiovascular Disease? ☐***Yes*** ☐***No***
4. If answer to question 1 or 3 is yes then, in addition to the diagnoses listed above, the Member must meet the following criteria? ☐***Yes*** ☐***No***
    - Failure to obtain adequate glycemic control (A1c less than 7) after at least a 3-month (90 days) trial of metformin and **ONE** additional diabetic agent (e.g., sulfonylureas (SU), insulin sensitizing agents or insulin)
5. Has the patient been adherent to their current diabetic regimen? ☐***Yes*** ☐***No***
6. Please provide member's diagnosis: _____

Glyxambi, Janumet/Janumet XR, Jentadueto, Kombiglyze XR, Trijardy XR:
1. Does the member have baseline A1c or goals of therapy? ☐***Yes*** ☐***No***
2. Does the member have a documented diagnosis of Type 2 Diabetes Mellitus (DMII)? ☐***Yes*** ☐***No***
3. If the answer to question 2 is yes then, in addition to the criteria listed above, does the Member meet the following criteria? ☐***Yes*** ☐***No***
    - Failure to obtain adequate glycemic control (A1c less than 7) after at least a 3-month (90 days) trial of metformin and **ONE** additional diabetic agent (e.g., sulfonylureas (SU), insulin sensitizing agents or insulin)
4. Has the patient been adherent to their current diabetic regimen? ☐***Yes*** ☐***No***
5. Please provide member's diagnosis: _____

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EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

1. Pre-diabetic Members (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) **OR** HbA1c <5.7%)

CRITERIA FOR RENEWAL:

1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

LENGTH OF AUTHORIZATION:

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

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Antidiabetic Agents – Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Guideline

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

APPLICABLE AGENT(S):
- Tradjenta (Linagliptan)
- Onglyza (Saxagliptin HCL)
- Januvia (Sitagliptin Phosphate)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of Type 2 Diabetes Mellitus (DMII)? ☐***Yes*** ☐***No***
2. If answer to question 1 is yes then, in addition to the diagnoses listed above, the Member must meet the following criteria? ☐***Yes*** ☐***No***
   - Failure to obtain adequate glycemic control (A1c less than 7) after at least a 3-month (90 days) trial of metformin and **ONE** additional diabetic agent (e.g., sulfonylureas (SU), insulin sensitizing agents or insulin)
3. Has the patient been adherent to their current diabetic regimen? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

Note: The American Diabetes Association (ADA) 2019 standards of medical care in diabetes do not recommend the use of GLP-1 receptor agonists in combination with DPP-4 inhibitors due to lack of or insufficient data regarding their combined use

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- Pre-diabetic Members (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) **OR** HbA1c <5.7%)

CRITERIA FOR RENEWAL:
1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

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

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Antidiabetic Agents - Humulin R U-500 (concentrated) Guideline

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

APPLICABLE AGENT(S):
- Humulin R U-500 (concentrated) (Insulin Regular (human) pen/solution)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have Diabetes Mellitus (Type 1 or 2)? ☐***Yes*** ☐***No***
2. Has the documentation been submitted to support a requirement of more than 200 units of insulin per day? ☐***Yes*** ☐***No***
3. Please provide member's diagnosis: _____

Note: BD U-500 insulin syringes are the only available syringe that has been approved by the FDA for use with U-500 insulin at this time. They are available only by prescription and cannot be purchased over the counter.

CRITERIA FOR RENEWAL:
1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

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

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Antidiabetic Agents – Incretin Mimetic Agents (GLP-1 Receptor Agonists) Guideline

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

APPLICABLE AGENT(S):
- Trulicity (Dulaglutide Solution Pen-Injection)
- Byetta (Exenatide Solution Pen Injection)
- Bydureon (Exenatide Pen)
- Victoza (Liraglutide Solution Pen Injection)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have diagnosis of Type 2 Diabetes Mellitus (DMII) **WITH** established Atherosclerotic Cardiovascular Disease (ASCVD), Heart Failure (HF), **OR** Chronic Kidney Disease (CKD with less than 60 mL/min)? ☐***Yes*** ☐***No***
2. If answer to question 1 is yes then, in addition to the diagnoses listed above, does the member have an eGFR greater than or equal to 45 mL/min? ☐***Yes*** ☐***No***
3. Does the member have a diagnosis of Type 2 Diabetes Mellitus (DMII) **WITHOUT** Cardiovascular Disease? ☐***Yes*** ☐***No***
4. If answer to question 1 or 3 is yes then, in addition to the diagnoses listed above, the Member must meet the following criteria? ☐***Yes*** ☐***No***
    - Failure to obtain adequate glycemic control (A1c less than 7) after at least a 3-month (90 days) trial of metformin and **ONE** additional diabetic agent (e.g., sulfonylureas (SU), insulin sensitizing agents or insulin)
5. Has the patient been adherent to their current diabetic regimen? ☐***Yes*** ☐***No***
6. Please provide member's diagnosis: _____

Note: The American Diabetes Association (ADA) 2019 standards of medical care in diabetes do not recommend the use of GLP-1 receptor agonists in combination with DPP-4 inhibitors due to lack of or insufficient data regarding their combined use

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- Pre-diabetic Members (e.g., HbA1c ≥ 5.7% and FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L) OR HbA1c <5.7%)
- Byetta, Bydureon, Victoza: Member with personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia Syndrome Type 2 (MEN 2)

CRITERIA FOR RENEWAL:
1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 6 months

- Renewal Approval Duration: 12 Months

Antidiabetic Agents – SGLT2 Inhibitors Guideline

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

APPLICABLE AGENT(S):
- Farxiga (Dapagliflozin Propanediol)
- Invokana (Canagliflozin)
- Jardiance (Empagliflozin)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of Type 2 Diabetes Mellitus (DMII)? ☐***Yes*** ☐***No***
2. If answer to question 1 is yes then, in addition to the diagnoses listed above, does the member meet the following criteria? ☐***Yes*** ☐***No***
   - Failure to obtain adequate glycemic control (A1c less than 7) after at least a 3-month (90 days) trial of metformin and **ONE** additional diabetic agent (e.g., sulfonylureas (SU), insulin sensitizing agents or insulin)
3. Has the patient been adherent to their current diabetic regimen? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
- **Type II Diabetes Mellitus**
  1. Has the member experienced improvement in target goals (a reduction in hemoglobin A1C, glucose level) since starting this therapy (3-6 months) and does not have adverse effects or contraindications? ☐***Yes*** ☐***No***
- **Other compendial supported diagnoses:**
  1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

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

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Antipsychotics – Pediatric Criteria Guideline

Effective Date:
Date(s) of Review and Revision:

FORMULARY AGENTS:

- See AHCCCS Drug List

CRITERIA FOR INITIAL AUTHORIZATION:

NOTE: The following criteria apply to members being prescribed the respective antipsychotic under the age as specified on the AHCCCS drug list by any provider OR under the age of 18 if prescribed by a non-behavioral health provider.

Formulary antipsychotic agents requiring PA for Age <6 years:

1. Is child diagnosed, per current DSM criteria, with at least one of the following: ☐***Yes*** ☐***No***
    a. Bipolar Spectrum Disorder, or
    b. Schizophrenic Spectrum Disorder, or
    c. Tourette's or other tic disorder, or
    d. Autism Spectrum Disorder, and
2. Do you attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
3. Does provided documentation include psychosocial evaluation occurring before request for antipsychotic medications, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation: _____
    b. Name of clinician conducting assessment: _____
4. Does provided documentation include non-medication alternatives that have been attempted to address symptoms before request for antipsychotic medications, which must include all the following components? ☐***Yes*** ☐***No***
    a. Interventions tried: _____
    b. Date and duration of trial: _____
    c. Why interventions were unsuccessful: _____
5. Does the submitted include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***
6. Please indicate the member's diagnosis: _____

Clozapine and Fazaclo:

1. Is child diagnosed, per current DSM criteria, with one of the following: ☐***Yes*** ☐***No***
    a. Schizophrenia, or
    b. Schizoaffective disorder, and
2. Has the diagnosis has been established by or in consultation with a child and adolescent behavioral health medical professional? ☐***Yes*** ☐***No***
3. Does provider submitted documentation include evidence member has tried and failed of 2 or more adequate monotherapy trials of alternate formulary antipsychotics? ☐***Yes*** ☐***No***

4. Do you attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
5. Does provided documentation include psychosocial evaluation occurring before request for antipsychotic medications, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation: _____
    b. Name of clinician conducting assessment: _____
6. Does provided documentation include non-medication alternatives that have been attempted to address symptoms before request for antipsychotic medications, which must include all the following components? ☐***Yes*** ☐***No***
    a. Interventions tried: _____
    b. Date and duration of trial: _____
    c. Why interventions were unsuccessful: _____
7. Does the submitted include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***
8. Please indicate the member's diagnosis: _____

Formulary Long Acting Injectables Antipsychotics requiring PA:

1. Is child diagnosed, per current DSM criteria, with one of the following: ☐***Yes*** ☐***No***
    a. Schizophrenia (All formulary LAIAs)
    b. Schizoaffective disorder (Invega Sustenna, Invega Trinza)
    c. Bipolar I disorder (Abilify Maintena, Risperdal Consta)
2. Is the LAIA requested for an FDA labeled indication (see question 1 for which agents are approved for each indication)? ☐***Yes*** ☐***No***
3. Has the diagnosis has been established by or in consultation with a child and adolescent behavioral health medical professional? ☐***Yes*** ☐***No***
4. Does provided documentation include both of the following components? ☐***Yes*** ☐***No***
    a. Submission of stable dose of oral antipsychotic: _____
    b. Dose of LAIA correlates to oral dose of antipsychotic: _____
5. Does submitted documentation convey a history of medication adherence issues? ☐***Yes*** ☐***No***
6. Do you attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
7. Does provided documentation include psychosocial evaluation occurring before request for antipsychotic medications, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation: _____
    b. Name of clinician conducting assessment: _____
8. Does the submitted include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***
9. Please indicate the member's diagnosis: _____

PA for Orap in age <12 years old:

1. Is child diagnosed, per current DSM criteria, with moderate to severe Tourette's or other tic disorder? ☐***Yes*** ☐***No***

2. Does provider attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
3. Does provided documentation include psychosocial evaluation occurring before request for antipsychotic medications, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation: _____
    b. Name of clinician conducting assessment: _____
4. Does provided documentation include non-medication alternatives that have been attempted to address symptoms before request for antipsychotic medications, which must include all the following components? ☐***Yes*** ☐***No***
    a. Interventions tried: _____
    b. Date and duration of trial: _____
    c. Why interventions were unsuccessful: _____
5. Does the submitted documentation include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***
6. Does provided documentation include evidence of trials of 2 or more preferred antipsychotic agents AND haloperidol medication trials prior to request for pimozide? ☐***Yes*** ☐***No***
7. Please indicate the member's diagnosis: _____

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):

- Members with known hypersensitivity to requested agent.

EXCLUSION CRITERIA - ORAP SPECIFIC:

- Member with congenital long QT syndrome, patients with a history of cardiac arrhythmias, patients taking other drugs which prolong the QT interval of the electrocardiogram or patients with known hypokalemia or hypomagnesemia
- Member is taking citalopram, escitalopram, sertraline, nefazodone, azole antifungal agents, or protease inhibitors.

CRITERIA FOR RENEWAL (for all agents):

1. Does the provider attest that the member having a positive clinical response to treatment? ☐***Yes*** ☐***No***

LENGTH OF AUTHORIZATION:

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

Quantity Limits:

- Refer to AHCCCS PDL for quantity limits

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Antipsychotics and Lithium in Adults Prescribed by a Non-Behavioral Health Provider Guideline

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

APPLICABLE AGENT(S):
- Lithium
- See AHCCCS Drug List for most updated list of antipsychotic agents

CRITERIA FOR INITIAL AUTHORIZATION:
Note: PCPs can prescribe and manage BH conditions including depression, anxiety, ADHD, and OUD.

Formulary Agents:
1. Is the medication a continuation of therapy initially prescribed by a behavioral health medical provider? ☐***Yes*** ☐***No***
2. Is the medication being prescribed for FDA-approved indication? ☐***Yes*** ☐***No***
3. Does the dosage being prescribed comply with FDA guidelines/limits? ☐***Yes*** ☐***No***
4. Is the medication an initial prescription for a long-acting injectable antipsychotic? ☐***Yes*** ☐***No***
5. Does the provider attest that member has history of tolerability to an oral equivalent of the long-acting injectable antipsychotic being prescribed? ☐***Yes*** ☐***No***
6. Does the member have a referral placed or appointment scheduled with a behavior health specialist? ☐***Yes*** ☐***No***
7. Please indicate the member's diagnosis: _____

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

CRITERIA FOR RENEWAL:
1. N/A

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 3 Months

Quantity Limits:
- Refer to AHCCCS PDL for quantity limits

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Apremilast (Otezla) Guideline

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

APPLICABLE AGENT(S):
- Apremilast (Otezla)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Member has a diagnosis of ***psoriatic arthritis (PsA)*** and meets **ALL** of the following criteria:
   - Member is ≥ 18 years of age
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - Initial course, as indicated by **ALL** of the following:
     - Active psoriatic arthritis with one or more tender and swollen joints
     - Failure of or intolerance to **1 or more** of the following:
       - Conventional disease-modifying antirheumatic drugs (DMARDs) (e.g., methotrexate, sulfasalazine)
       - Tumor necrosis factor inhibitor
2. Member has a diagnosis of ***moderate to severe plaque psoriasis (PsO)*** and meets **ALL** of the following criteria:
   - Member is ≥ 18 years of age
   - Therapy is prescribed by or given in consultation with a dermatologist
   - Candidate for systemic therapy or phototherapy
   - Clinical need for systemic treatment, as indicated by **1 or more** of the following:
     - Body surface area involvement of 10% or more
     - Involvement of scalp, face, feet, hands, or genitalia that impacts patient quality of life
3. Member has a diagnosis of ***Behçet's disease*** and meets **ALL** of the following criteria:
   - Member is ≥ 18 years of age
   - Active oral ulcers: 2 or more at time of initiation of therapy
   - Candidate for systemic therapy (ie, topical therapy deemed inappropriate)
   - Failure of or intolerance to one or more non-biologic treatments (eg, systemic glucocorticoids)
   - No active major organ involvement (eg, pulmonary artery aneurysm, thrombophlebitis, gastrointestinal ulcers, meningoencephalitis, uveitis)

CRITERIA FOR RENEWAL:
1. Member has a diagnosis of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), **OR** Behcet's disease **AND** meets the following criterion:
   - Member continues to benefit from the medication

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

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Celecoxib (Celebrex) Guideline

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

APPLICABLE AGENT(S):
- Celecoxib (Celebrex) capsules

CRITERIA FOR INITIAL AUTHORIZATION:
1. Has the member been on following drug therapy in previous 90 days? ☐***Yes*** ☐***No***
    - 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 methotrexate
    - Member has a history of peptic ulcer disease (PUD) or history of gastrointestinal (GI) bleed
2. Is the member equal to or greater than 65 years old? ☐***Yes*** ☐***No***
3. Has the member tried and failed or is intolerant to **ONE** formulary Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (e.g., ibuprofen, diclofenac sodium, naproxen, etodolac, nabumetone)? ☐***Yes*** ☐***No***

CRITERIA FOR RENEWAL:
1. Is the member experiencing positive response to therapy? ☐***Yes*** ☐***No***

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

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Cystic Fibrosis Agents Guideline

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

APPLICABLE AGENT(S):
- Bethkis
- Kitabis PAK
- Pulmozyme

CRITERIA FOR INITIAL AUTHORIZATION:

Bethkis, Kitabis PAK:
1. Is the member equal to or greater than six years old? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of cystic fibrosis? ☐***Yes*** ☐***No***
3. Can the provider confirm that the Sputum culture is positive for Pseudomonas aeruginosa? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

Pulmozyme:
1. Is the member equal to or greater than five years old? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of cystic fibrosis? ☐***Yes*** ☐***No***
3. Is the requested drug being used in conjunction with standard therapies for cystic fibrosis (e.g., airway clearance techniques)? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Can the prescriber attest that the Member has had a positive clinical response such as Evidence of improving or stable lung function (FEV1, decrease number of pulmonary exacerbations) to treatment? ☐***Yes*** ☐***No***

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

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Dronedarone (Multaq) Guideline

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

APPLICABLE AGENT(S):
- Dronedarone (Multaq)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member greater than or equal to 18 years of age? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of paroxysmal **OR** persistent atrial fibrillation? ☐***Yes*** ☐***No***
3. Is the member currently in normal sinus rhythm **OR** plans to undergo cardioversion to normal sinus rhythm? ☐***Yes*** ☐***No***
4. Is the medication prescribed by, or in consultation with a cardiologist? ☐***Yes*** ☐***No***
5. Has the member had inadequate response, intolerable side effect, or contraindication to one of the following formulary alternatives? ☐***Yes*** ☐***No***
    a. amiodarone
    b. propafenone
    c. flecainide
    d. sotalol
6. Please provider member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member had experienced positive response to treatment? ☐***Yes*** ☐***No***

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

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Enfurvitide (Fuzeon) Guideline

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

APPLICABLE AGENT(S):
- Fuzeon (Enfuvirtide)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of HIV-1 infection? ☐***Yes*** ☐***No***
2. Has the member tried and failed or experienced intolerance to at least two of anti-HIV therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, OR protease inhibitor) after 3 or more months of therapy? ☐***Yes*** ☐***No***
3. Will the member use Fuzeon in combination with other antiretroviral agents? ☐***Yes*** ☐***No***
4. Is this medication prescribed by or in consultation with an infectious disease or HIV specialist? ☐***Yes*** ☐***No***
5. Please provider member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member had experienced positive response to treatment? ☐***Yes*** ☐***No***
2. If the provider is requesting a dose increase, does the new dose exceed recommended 180 mg per day? ☐***Yes*** ☐***No***

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

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Esketamine (Spravato) Guideline

Effective Date: 6/22/2020
Date(s) of Review and Revision:

APPLICABLE AGENT(S):
- Esketamine (Spravato) Nasal Spray

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a confirmed diagnosis, per current DSM criteria, of major depressive disorder? ☐***Yes*** ☐***No***
2. Is the member 18 years of age or older? ☐***Yes*** ☐***No***
3. Is Esketamine being prescribed by or in consultation with a psychiatric provider? ☐***Yes*** ☐***No***
4. Does the member have an active substance use disorder (SUD)? ☐***Yes*** ☐***No***
5. Is the member currently receiving treatment for their substance use disorder? ☐***Yes*** ☐***No***
6. Does the member meet one or more of the following criteria? ☐***Yes*** ☐***No***
    a. Member experienced an inadequate response during the current depressive episode with a minimum of two antidepressants from at least two different classes (SSRI, SNRI, bupropion or mirtazapine) having different mechanisms of action for at least 4-6 weeks at the maximally tolerated labeled dose for each agent trialed?
    b. Member has MDD with active suicidal ideation or behavior
7. Is Esketamine being used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)? ☐***Yes*** ☐***No***
8. Is Esketamine being administered under the direct supervision of a healthcare provider? ☐***Yes*** ☐***No***
9. Does the provider attest they are certified in the Spravato REMS program? ☐***Yes*** ☐***No***
10. Does provider attest member is being monitored by a health care provider for at least 2 hours after administration? ☐***Yes*** ☐***No***
11. Please indicate the member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Does the provider attest that the member has documented improvement or sustained improvement in depressive symptoms from baseline? ☐***Yes*** ☐***No***
2. Is Esketamine being used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)? ☐***Yes*** ☐***No***
3. Is Esketamine being administered under the direct supervision of a healthcare provider? ☐***Yes*** ☐***No***
4. Does the provider attest they are certified in the Spravato REMS program? ☐***Yes*** ☐***No***
5. Does provider attest member is being monitored by a health care provider for at least 2 hours after administration? ☐***Yes*** ☐***No***

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LENGTH OF AUTHORIZATION:

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

QUANTITY LIMITS:

- Induction Phase: 24 devices/month
- Maintenance Phase: 12 devices/month

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Etanercept (Enbrel) Guideline

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

APPLICABLE AGENT(S):
- Etanercept (Enbrel)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Rheumatoid Arthritis
    - Member must have a diagnosis of ***moderate to severe active rheumatoid arthritis (RA)*** as evidenced by **AT LEAST** one of the following:
        - Clinical Disease Activity Index Score greater than 10
        - Disease Activity Score of 3.2 or greater
        - Member Activity Scale of 3.71 or greater
        - Member Activity Scale-II of 3.71 or greater
        - Routine Assessment of Member Index Data 3 score greater than 2
        - Simplified Disease Activity Index score greater than 11
    - Member must meet **ALL** of the following criteria:
        - Member is ≥ 18 years of age
        - Therapy is prescribed by or given in consultation with a rheumatologist
        - The Member had a previous trial of or contraindication to **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. Polyarticular Juvenile Idiopathic Arthritis
    - Member must have a diagnosis of ***moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)*** and meet **ALL** of the following criteria:
        - Member is ≥ 2 years of age
        - Therapy is prescribed by or given in consultation with a rheumatologist
        - Joint involvement and treatment scenario includes **1 or more** of the following(38)(45):
            - Four or fewer joints involved (i.e., oligoarticular, low disease activity) and inadequate response to **ALL** of the following:
                - Glucocorticosteroid injection
                - Methotrexate
                - NSAIDs
            - Five or more joints involved (i.e., polyarticular, moderate to high disease activity) and intolerance or inadequate response to methotrexate
3. Psoriatic Arthritis
    - Member must have a diagnosis of ***psoriatic arthritis (PsA)*** and meet **ALL** of the following criteria:
        - Member is ≥ 18 years of age

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- Active arthritis, as indicated by **1 or more** of the following:
  - Axial disease with inflammatory back pain, and failure or intolerance of NSAIDs
  - Dactylitis[D]
  - Enthesitis[E] that is tender on examination
  - Peripheral disease with one or more tender and swollen joints, and failure of, intolerance of, or contraindication to methotrexate
- Inadequate response, intolerance, or contraindication to treatment with NSAIDs

4. Ankylosing Spondylitis
   - Member must have a diagnosis of ***ankylosing spondylitis (AS)*** and meet **ALL** of the following criteria:
     - Member is ≥ 18 years of age
     - Therapy is prescribed by or given in consultation with a rheumatologist
     - The Member has a previous trial of or contraindication to an NSAID
     - Clinical evidence of axial spondyloarthritis, as indicated by **ALL** of the following:
       - Back pain of 3 months or more duration and age of onset of 45 years or younger
       - Diagnostic criteria met, as indicated by **1 or more** of the following:
         - Ankylosing spondylitis, as indicated by **ALL** of the following:
           - Sacroiliitis on imaging
           - Spondylarthritis signs and symptoms, as indicated by **1 or more** of the following:
             - Arthritis
             - Dactylitis
             - Elevated C-reactive protein
             - Enthesitis (e.g., inflammation of Achilles tendon insertion)
             - Family history of spondylarthritis
             - HLA-B27
             - Inflammatory bowel disease (Crohn disease, ulcerative colitis)
             - Limited chest expansion
             - Morning stiffness for 1 hour or more
             - Psoriasis
             - Uveitis
         - Nonradiographic axial spondyloarthritis, as indicated by **ALL** of the following:
           - HLA-B27
           - Spondyloarthritis signs and symptoms, as indicated by **2 or more** of the following:

- Arthritis
- Dactylitis
- Elevated C-reactive protein
- Enthesitis (e.g., inflammation of Achilles tendon insertion)
- Family history of spondylarthritis
- Inflammatory bowel disease (Crohn disease, ulcerative colitis)
- Limited chest expansion
- Morning stiffness for 1 hour or more
- Psoriasis
- Uveitis

5. Plaque Psoriasis
    - Member must have a diagnosis of ***moderate to severe plaque psoriasis (PsO)*** and meet **ALL** of the following criteria:
        - Member is ≥ 4 years of age
        - Therapy is prescribed by or given in consultation with a dermatologist
        - The Member has psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, face, or genital area
        - The Member had a previous trial of or contraindication to **AT LEAST** one conventional therapy, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
6. Additional criteria for all indications:
    - Hepatitis B HBsAg negative, or concurrent treatment with antiviral therapy
    - No active serious infection
    - No concurrent treatment with cyclophosphamide
    - No concurrent treatment with other biological therapy (e.g., anakinra, abatacept, or another tumor necrosis factor inhibitor)
    - No untreated latent or active tuberculosis

CRITERIA FOR RENEWAL:

1. Provider notes that the member has seen improvement or is stable on therapy AND member has **AT LEAST** 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)

LENGTH OF AUTHORIZATION:

- Initial Approval Duration: 6 Months

- Renewal Approval Duration: 12 Months

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Ezetimibe (Zetia) Guideline

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

APPLICABLE AGENT(S):
- Ezetimibe (Zetia) tablets

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is this medication prescribed for FDA approved or compendial supported diagnosis?
   ☐***Yes*** ☐***No***
2. If the request is prescribed for the diagnosis of primary hypercholesterolemia or mixed dyslipidemia, then has the patient tried and failed or experienced intolerance to statin therapy? ☐***Yes*** ☐***No***
3. Please provider member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member had experienced positive response to treatment? ☐***Yes*** ☐***No***

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

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Gabapentin Enacarbil Extended-Release tablets (Horizant) Guideline

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

APPLICABLE AGENT(S):
- Gabapentin Enacarbil Extended-Release tablets (Horizant)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member equal to or older than 18 years? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of post-herpetic neuralgia (PHN)? ☐***Yes*** ☐***No***
3. Does the member have a diagnosis of moderate-to-severe primary restless leg syndrome (RLS)? ☐***Yes*** ☐***No***
4. Has the member tried and failed (up to 90 days) or has experienced intolerance to Gabapentin (generic Neurontin) up to 1,800 mg per day **AND** Pregabalin (Lyrica) up to 150-600 mg per day (Prior Authorization Required) for at least 90 days? ☐***Yes*** ☐***No***
5. Has the member tried and failed (up to 90 days), has experienced intolerance to or has intolerance to ropinirole **AND** pramipexole? ☐***Yes*** ☐***No***
6. Please provide member's diagnosis: _____

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 300 mg and 600 mg tablet

CRITERIA FOR RENEWAL:
1. If the request is for restless leg syndrome (RLS) has the member experienced positive clinical response based on clinical re-evaluation in past 12 months? ☐***Yes*** ☐***No***
2. If the request is for post-herpetic neuralgia (PHN), then has documentation stating that the member is receiving a positive clinical response to Horizant based upon re-evaluation in the past 12 months been provided? ☐***Yes*** ☐***No***

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

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Gabapentin ER oral tablet (Gralise) Guideline

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

APPLICABLE AGENT(S):
- Gabapentin ER oral tablet (Gralise)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member equal to or older than 18 years? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of post-herpetic neuralgia (PHN)? ☐***Yes*** ☐***No***
3. Has the member tried and failed (up to 90 days) or has experienced intolerance to gabapentin (generic Neurontin) up to 1,800 mg per day **OR** pregabalin (Lyrica) up to 150-600 mg per day (Prior Authorization Required) for at least 90 days? ☐***Yes*** ☐***No***
4. Has the member tried and failed (up to 90 days), has experienced intolerance or has a contraindication to Tricyclic Antidepressants (e.g., amitriptyline, nortriptyline, desipramine)? ☐***Yes*** ☐***No***
5. Please provide member's diagnosis: _____

Note:
- ***Gralise should be titrated up to a therapeutic dose of 1,800 mg taken orally once a day***
- ***Avoid Tricyclic Antidepressants in Members with heart disease, epilepsy or glaucoma and should be used cautiously in older Members***

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- Gralise should not be used in Members with CrCl less than 30 mL/min or members on hemodialysis

CRITERIA FOR RENEWAL:
1. Is documentation stating that the member is receiving a positive clinical response to Gralise based upon re-evaluation in the past 12 months provided? ☐***Yes*** ☐***No***

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

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Hepatitis B Agents Guideline

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

APPLICABLE AGENT(S):
- See AHCCCS Drug List for most updated list of agents

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a documented diagnosis of chronic hepatitis B? ☐***Yes*** ☐***No***
2. Has the requested medication been prescribed by, or in consult with an infectious disease physician, a gastroenterologist, a hepatologist, or a transplant physician? ☐***Yes*** ☐***No***
3. Has the member tried and failed, experienced adverse effects or does the provider have alternate justification for not trying Lamivudine? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member seen positive response since starting this therapy and does not have adverse effects or contraindications? ☐***Yes*** ☐***No***

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

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Hepatitis C Agents Guideline

320-N - HEPATITIS C VIRUS (HCV) PRIOR AUTHORIZATION REQUIREMENTS FOR DIRECT ACTING ANTIVIRAL (DAA) MEDICATION TREATMENT

EFFECTIVE DATES: 07/17/14, 01/01/18, 10/01/18, 10/01/21

APPROVAL DATES: 08/01/14, 03/15/15, 10/01/16, 07/06/17, 07/11/18, 07/15/21

I. PURPOSE

This Policy applies to ACC, ALTCS E/PD, DCS/Comprehensive Health Plan (CHP), DES/DDD (DDD), RBHA Contractors; Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), Tribal ALTCS, TRBHA, and all FFS populations, excluding Federal Emergency Services (FES). (For FES, refer to AMPM Chapter 1100). This Policy specifies prior authorization requirements for members for direct acting antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV).

II. DEFINITIONS

Definitions are located on the AHCCCS website at: AHCCCS Contract and Policy Dictionary.

III. POLICY

Prior authorization approval for coverage of Direct Acting Antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV) is required for all members prior to initiating treatment. In order to obtain prior authorization approval, all of the following requirements shall be met:

1. Diagnosis of chronic HCV which has been confirmed by detectable serum HCV RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request that includes the HCV genotype, viral resistance status (when applicable), hepatic status (Child Pugh Score) and HCV viral load.
2. Age of the member is Food and Drug Administration (FDA) approved for the specific HCV DAA product.
3. HCV DAA medications are prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.
4. The prescribing provider assesses the member's ability to adhere to the HCV DAA treatment plan and documents this assessment within the clinical record. For members that would benefit from adherence aids, the treating provider shall refer the member to a treatment adherence program.
5. Member agrees to adhere to the proposed course of treatment, including taking

medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program.

6. The member has been screened for Hepatitis A and B and shall have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

A. TREATMENT MONITORING REQUIREMENTS

1. The prescribing provider is required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.
2. The prescribing provider is required to monitor HCV RNA levels obtained at 12- and 24-weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR).

B. HEPATITIS C RETREATMENT REQUIREMENTS

For members who have HCV and a history of treatment with a DAA, the following criteria shall be met for DAA retreatment approval:

1. The member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.
2. The member's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record.
3. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when:
   a. Required for regimens whereby the FDA requires such testing prior to treatment to ensure clinical appropriateness, and
   b. Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.
4. HCV retreatment with a DAA shall not be approved when:
   a. The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy,
   b. A member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims, or
   c. Is considered an experimental service as specified in A.A.C. R9-22-203.

C. LIMITATIONS

DAA HCV treatment coverage is not provided for the following:

1. Monotherapy of Sofosbuvir (Sovaldi).
2. DAA dosages greater than the FDA approved maximum dosage.

3. Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request.
4. Members who do not agree to adhere to the proposed course of treatment, including participating in a treatment adherence program if applicable.
5. Members whose comorbidities are such that their life expectancy is one year or less.
6. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
7. Greater than one DAA drug regimen used for retreatment.
8. Lost or stolen medication absent of good cause.
9. Fraudulent use of HCV DAA medications.

D. REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS

In order for a prior authorization request for HCV DAA medications to be considered, the following minimum information shall be submitted by the prescribing provider for the member:

1. HCV treatment history and responses.
2. Evidence of Hepatitis A and Hepatitis B vaccinations or laboratory evidence of immunity.
3. Current medication list.
4. Laboratory results for all of the following:
   a. HCV screen,
   b. Genotype and current baseline viral load,
   c. Total bilirubin,
   d. Albumin,
   e. International Normalized Ratio (INR),
   f. Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR),
   g. Liver Function Tests (LFTs), and
   h. Complete Blood Count (CBC).

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Lacosamide (Vimpat) Guideline

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

APPLICABLE AGENT(S):
- Lacosamide Solution (Vimpat)
- Lacosamide Tablets (Vimpat)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member equal to or greater than 4 years of age? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of partial-onset seizures or primary generalized tonic-clonic seizures? ☐***Yes*** ☐***No***
3. Has the member first tried and failed, or has a contraindication or intolerance to **TWO other** formulary anticonvulsants? ☐***Yes*** ☐***No***
4. Please provide member's diagnosis: _____

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- Use is not recommended in Members with severe hepatic impairment

CRITERIA FOR RENEWAL:
1. Have Chart notes documenting a positive response to therapy noted as a reduction in seizure frequency and/or severity been provided? ☐***Yes*** ☐***No***

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

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Linezolid (Zyvox) Guideline

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

APPLICABLE AGENT(S):
- Zyvox (Linezolid) suspension and tablets

CRITERIA FOR INITIAL AUTHORIZATION:

1. Does the member have ONE of the following diagnosis? ☐***Yes*** ☐***No***
    - Community-acquired pneumonia: caused by Streptococcus pneumonia (including multi-drug resistant strains), in addition to cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible strains only)
    - Complicated skin and skin structure infections: e.g., diabetic foot infections, without concomitant osteomyelitis, caused by S. aureus (methicillin-susceptible and resistant strains), Streptococcus pyogenes, or Streptococcus agalactiae
    - Nosocomial pneumonia: caused by S. aureus (methicillin- susceptible and resistant strains), or S. pneumonia (including multi-drug-resistant strains)
    - Uncomplicated skin and skin structure infections: Caused by S. aureus (methicillin-susceptible strains only) or S. pyogenes
    - Vancomycin-resistant enterococcal infections: Vancomycin-resistant Enterococcus faecium infections, including cases with concurrent bacteremia
    - Current Culture and Sensitivity (C&S) in support of FDA indication
2. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. N/A

LENGTH OF AUTHORIZATION:
1. Initial Approval Duration: Authorization will be for duration of therapy not to exceed 6 weeks of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy
2. Renewal Approval Duration: Authorization will be for duration of therapy not to exceed 6 weeks of therapy (including doses given in hospital, emergency room, or urgent care). Additional course of therapy will require new PA submission and clinical notes documenting response and need for additional therapy

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Lithium for Members under 6 Years of Age or under 18 Years of Age when Prescribed by a Non-Behavioral Health Provider Guideline

Effective Date:
Date(s) of Review and Revision:

FORMULARY AGENTS:
- Lithium carbonate capsules
- Lithium carbonate tablets
- Lithium carbonate tablet – controlled release
- Lithium solution

CRITERIA FOR INITIAL AUTHORIZATION:
NOTE: The following criteria apply to members being prescribed lithium under the age of 6 by any provider OR under the age of 18 if prescribed by a non-behavioral health provider.

1. Is the medication a continuation of therapy initially prescribed by a behavioral health medical provider for children aged 6-17 years old? ☐***Yes*** ☐***No***
2. Is child diagnosed, per current DSM criteria, with Bipolar Disorder? ☐***Yes*** ☐***No***
3. Has the diagnosis has been established by or in consultation with a child and adolescent behavioral health medical professional? ☐***Yes*** ☐***No***
4. Does the provider attest that alternate diagnoses have been considered and appropriately ruled out including all the following diagnoses? ☐***Yes*** ☐***No***
    a. ADHD, AND
    b. Oppositional defiant disorder, AND
    c. Conduct disorder, AND
    d. Intermittent explosive disorder, AND
    e. Disruptive mood dysregulation disorder, AND
5. Does provider attest that the member has psychosocial and non-medical interventions being addressed by the clinical team? ☐***Yes*** ☐***No***
6. Does provided documentation include psychosocial evaluation occurring before request for antimanic medication, which must include both of the following? ☐***Yes*** ☐***No***
    a. Date of evaluation, AND
    b. Name of clinician conducting assessment
7. Does provided documentation include non-medication alternatives that have been attempted to address symptoms before request for anti-manic agent, which must include all the following components? ☐***Yes*** ☐***No***
    a. Interventions tried, AND
    b. Date and duration of trial, AND
    c. Why interventions were unsuccessful
8. Does the submitted documentation include information on the expected outcomes and an evaluation of potential adverse events? ☐***Yes*** ☐***No***

9. Please indicate the member's diagnosis: _____

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

CRITERIA FOR RENEWAL (for all agents):
1. Does the provider attest that the member having a positive clinical response to treatment?
   ☐***Yes*** ☐***No***
2. Has provider submitted documentation of labs monitoring lithium level, renal function, and thyroid function? ☐***Yes*** ☐***No***

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

Quantity Limits:
- Refer to AHCCCS PDL for quantity limits

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Maraviroc (Selzentry) Guideline

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

APPLICABLE AGENT(S):
- Maraviroc (Selzentry) tablets

CRITERIA FOR INITIAL AUTHORIZATION:
1. Has the member been clinically diagnosed with CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay? ☐***Yes*** ☐***No***
2. Does the member weigh at least 2 kg, regardless of age? ☐***Yes*** ☐***No***
3. Is the member currently taking or will be prescribed an optimized background antiretroviral therapy regimen? ☐***Yes*** ☐***No***
4. Is the medication prescribed by, or in conjunction with an HIV specialist? ☐***Yes*** ☐***No***
5. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member experienced a positive clinical response to Selzentry therapy? ☐***Yes*** ☐***No***

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

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Oncology – Antineoplastic Agents Guideline

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

APPLICABLE AGENT(S):
- See AHCCCS Drug List

CRITERIA FOR INITIAL AUTHORIZATION:
1. Member is under the care of an Oncologist or Hematologist
2. 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
    - Milliman Care Guidelines
    - American Hospital Formulary Service Drug Information
    - Micromedex DrugDex Information System
    - UpToDate
3. The dose prescribed is within the FDA approved range of for the indication and Member-specific factors, including but not limited to:
    - Height
    - Weight
    - Body surface area
    - Renal function
    - Liver function
    - Drug – drug, disease, other interaction
4. 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 Member-specific factors
    - There are no formulary medications that match the Member's indication
    - Member has a genetic mutation that is resistant to formulary medication
    - All formulary alternatives are not supported by an approved Compendia
5. Medical records, laboratory information, test results and other clinical data support the diagnosis and treatment plan must be submitted with the request
6. Member does not have a contraindication to the medication
7. The medication is not being used for experimental or investigational purposes as part of a clinical trial

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

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 6 months

- Renewal Approval Duration: 12 months

Opioid Agonists Guideline

Effective Date:
Date(s) of Review and Revision:

APPLICABLE AGENT(S) - NOTE (*) indicates PREFERRED medication:

- Suboxone film*
- Buprenorphine-naloxone ODT tablet*
- Sublocade*
- Buprenorphine Sublingual Tablet

CRITERIA FOR INITIAL AUTHORIZATION:

Sublocade Extended-Release Injection

1. Is the Member diagnosed with moderate to severe opioid use disorder? ☐***Yes*** ☐***No***
2. Has the member been maintained on dose of buprenorphine-containing product equivalent to 8-24mg for 7 or more days? ☐***Yes*** ☐***No***
3. Does the provider attest that member is not receiving supplemental dosing of buprenorphine-containing products? ☐***Yes*** ☐***No***
4. Does submitted documentation include evidence that provider has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database for other active opioid prescriptions prior to first injection? ☐***Yes*** ☐***No***
5. Does Prescriber attest that they meet DATA 2000 requirements? ☐***Yes*** ☐***No***
6. Please indicate the member's diagnosis: _____

Buprenorphine Sublingual Tablet

1. Does the member have a diagnosis of opioid withdrawal OR mild, moderate, or severe opioid use disorder? ☐***Yes*** ☐***No***
2. Does submitted documentation include evidence that provider has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database and confirmed member is not receiving alternate opioid products? ☐***Yes*** ☐***No***
3. Does Prescriber attest that they meet DATA 2000 requirements? ☐***Yes*** ☐***No***
4. Does provided clinical documentation indicate member has an allergy to naloxone? ☐***Yes*** ☐***No***
5. Has provider submitted clinical rationale indicating why preferred options (i.e., Suboxone) are not appropriate or cannot be used? ☐***Yes*** ☐***No***

   NOTE: Trial and failure of Suboxone is not adequate for approval; Provider must provide alternate justification for use of buprenorphine alone.
6. Please indicate the member's diagnosis: _____

Note: Buprenorphine prescribed for pregnant members will be approved at point of sale. Provider must document on prescription appropriate ICD-10 code (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).

CRITERIA FOR RENEWAL:

Sublocade Extended-Release Injection

1. Does the provider attest that the member having a positive clinical response to treatment? ☐***Yes*** ☐***No***
2. Is the Member diagnosed with moderate to severe opioid use disorder? ☐***Yes*** ☐***No***
3. Does the provider attest that member is not receiving supplemental dosing of buprenorphine-containing products? ☐***Yes*** ☐***No***
4. Does submitted documentation include evidence that provider has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database for other active opioid prescriptions prior to each subsequent injection? ☐***Yes*** ☐***No***
5. Does Prescriber attest that they meet DATA 2000 requirements? ☐***Yes*** ☐***No***

Buprenorphine Sublingual Tablet

1. Does the provider attest that the member having a positive clinical response to treatment? ☐***Yes*** ☐***No***
2. Does the member have a diagnosis of opioid withdrawal OR mild, moderate, or severe opioid use disorder? ☐***Yes*** ☐***No***
3. Does submitted documentation include evidence that provider has checked the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) Database and confirmed member is not receiving alternate opioid products? ☐***Yes*** ☐***No***
4. Does Prescriber attest that they meet DATA 2000 requirements? ☐***Yes*** ☐***No***

Note: Buprenorphine prescribed for pregnant members will be approved at point of sale. Provider must document on prescription appropriate ICD-10 code (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).

LENGTH OF AUTHORIZATION:

- Initial Approval Duration in Pregnancy: up to 12 months
- Initial Approval Duration: 6 months
- Renewal Approval Duration: 12 months

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Palivizumab (Synagis) Guideline

Effective Date: 09/02/2021
Date(s) of Review and Revision:

APPLICABLE AGENT(S):
- Palivizumab solution (Synagis)

CRITERIA FOR INITIAL AUTHORIZATION:

1. Age of 12 months or less at start of RSV season AND born before 29 weeks 0 days gestation
2. Age of 12 months or less at start of RSV season with **Chronic Lung Disease of prematurity (CLD) / Bronchopulmonary Dysplasia** ICD10 Code: _____ AND born at less than 32 weeks 0 days gestation and required >21% oxygen for at least 28 days after birth
3. 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 ICD10 Code: _____
    - Neuromuscular disorder ICD10 Code: _____
4. 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 ICD10 Code: _____
    - Moderate to severe pulmonary hypertension ICD10 Code: _____
    - Cyanotic heart disease and prescribed in consultation with pediatric cardiologist ICD10 Code: _____
5. Age of 23 months or less with **Cardiac Transplantation** occurring during RSV season
6. Age of 23 months or less at start of RSV season with **Severe Immunodeficiency** ICD10 Code: _____
7. Age of 23 months or less at start of RSV season with **Cystic Fibrosis** and one of the following: ICD10 Code: _____
    - CLD and/or nutritional compromise by the age of 12 months or less ICD10 Code: _____
    - Manifestations of severe lung disease during second year of life ICD10 Code: _____
8. 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 ICD10 Code: _____

LENGTH OF AUTHORIZATION:
Approval Duration:
1. Synagis will be covered for up to 5 doses administered during RSV season (09/02/2021 – 3/31/2022)

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Pramlintide (Symlin / Symlinpen) Guideline

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

APPLICABLE AGENT(S):
- Symlinpen 60 (Pramlintide Acetate Solution Pen Injection)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of Type 1 or Type 2 Diabetes Mellitus? ☐***Yes*** ☐***No***
2. Has the member failed to obtain adequate glycemic control despite 3 months (90 days) or more of daily mealtime insulin therapy? ☐***Yes*** ☐***No***
3. Please provide member's diagnosis: _____

EXCLUSION CRITERIA (INITIAL AND RENEWAL AUTHORIZATIONS):
- Members 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)

CRITERIA FOR RENEWAL:
1. Has the member seen 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? ☐***Yes*** ☐***No***

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

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Pregabalin (Lyrica) Guideline

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

APPLICABLE AGENT(S):
- Lyrica (Pregabalin) tablets and solution

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of partial-onset seizures, Fibromyalgia, Neuropathic Pain Associated with Diabetic Peripheral Neuropathy, Neuropathic Pain Associated with Spinal Cord Injury or Postherpetic Neuralgia? ☐***Yes*** ☐***No***
2. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Authorization for continued use shall be reviewed at least every 12 months to confirm there are no contraindications to therapy

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

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Ramelteon (Rozerem) Guideline

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

APPLICABLE AGENT(S):
- Rozerem tablets

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the member less than six years old? ☐***Yes*** ☐***No***
2. Please provide member's diagnosis: _____
3. Has the member tried and failed, experienced adverse effects or does the provider have alternate justification for not trying **TWO** of the following: ☐***Yes*** ☐***No***
    - Trazodone
    - Eszopiclone
    - Temazepam
    - Zolpidem

CRITERIA FOR RENEWAL:
- N/A

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

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Ranolazine (Ranexa) Guideline

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

APPLICABLE AGENT(S):
- Ranolazine (Ranexa)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the Member have a documented diagnosis of chronic symptomatic angina, and has the initial prescription been written by a cardiologist? Note: Refills may be written by the primary care provider. ☐***Yes*** ☐***No***
2. Within a reasonable therapeutic time period at maximally tolerated doses, has the Member tried and failed a beta blocker or calcium channel blocker plus a long-acting nitrate in combination? ☐***Yes*** ☐***No***
3. According to documentation provided, member does not have any of the following:
   ☐***Yes*** ☐***No***
   - Hepatic cirrhosis
   - Pre-existing QT prolongation
   - Concurrent therapy with a strong CYP3A4 inhibitor such as ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir or saquinavir
   - Concurrent therapy with a CYP3A4 inducer such as rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine or St. John's wort
   - Acute renal failure, particularly in individuals with a baseline CrCl < 30 mL/min
4. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 12 Months (500 mg twice daily, may be increased to a maximum of 1,000 mg twice daily, as needed, based on clinical symptoms)
- Renewal Approval Duration: 12 Months

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Rufinamide (Banzel) Guideline

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

APPLICABLE AGENT(S):
- Rufinamide Suspension (Banzel)
- Rufinamide Tablets (Banzel)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a diagnosis of Lennox-Gastaut Syndrome (LGS)? ☐***Yes*** ☐***No***
2. Does the prescriber attest that the member does not have Familial Short QT syndrome? ☐***Yes*** ☐***No***
3. Is the member at least 1 year of age? ☐***Yes*** ☐***No***
4. Is this medication prescribed by or in consultation with a neurologist? ☐***Yes*** ☐***No***
5. Has the member tried and failed two formulary alternatives for LGS (e.g., clonazepam, felbamate, lamotrigine, topiramate) unless all are contraindicated, or clinically significant adverse effects are experienced? ☐***Yes*** ☐***No***
6. Please provide member's diagnosis: _____

DOSAGE AND ADMINISTRATION:
- Children Four Years and Older with Lennox-Gastaut Syndrome: Treatment should be initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3,200 mg/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 400-800 mg/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 3,200 mg/day, administered in two equally divided doses is reached. It is not known whether doses lower than 3,200 mg are effective

CRITERIA FOR RENEWAL:
1. Has the member seen improvement in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications? ☐***Yes*** ☐***No***

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

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University Health Plans

Serotonin (5HT3) Receptor Antagonists Guideline

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

APPLICABLE AGENT(S):
- Granisetron (tablets & solution)
- Dolasetron
- Ondansetron (>8 mg/dose)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Is the medication being requested for an FDA approved indication? ☐***Yes*** ☐***No***
2. Is the request for ondansetron over 8mg? ☐***Yes*** ☐***No***
3. Did the member trial a lower dose of ondansetron prior to request for dose greater than 8mg? ☐***Yes*** ☐***No***
4. Does the provided documentation indicate why a lower dose ondansetron has not been trialed? ☐***Yes*** ☐***No***
    a. Please provide documentation of why ondansetron dose under 8mg has not or cannot be trialed: _____
5. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Does the member have continued exposure to emetogenic treatment? ☐***Yes*** ☐***No***

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

Banner
University Health Plans

Sympathomimetics Guideline

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

APPLICABLE AGENT(S):
- Salmeterol Xinafoate Aerosol Powder Breath Activated (Serevent Diskus)
- Tiotropium Bromide-Olodaterol HCL Aerosol Solution (Stiolto Respimat)
- Umeclidinium-Vilanterol Aerosol Powder (Anoro Ellipta)

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have a documented diagnosis of COPD? ☐***Yes*** ☐***No***
2. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. Has the member seen improvement or positive response in target goals since starting this therapy (3-6 months) without experiencing adverse effects or contraindications?
   ☐***Yes*** ☐***No***

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

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University Health Plans

Tofacitinib (Xeljanz IR) Guideline

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

APPLICABLE AGENT(S) - NOTE (*) indicates PREFERRED medication:
- Tofacitinib citrate (Xeljanz IR)*

CRITERIA FOR INITIAL AUTHORIZATION:
1. Rheumatoid Arthritis
    - Prescribed by or in consultation with a rheumatologist
    - Age ≥ 18 years of age
    - Documentation submitted member has no latent or active tuberculosis infection
    - Hepatitis B HBsAg negative and HBcAb negative, or for known hepatitis B carriers, concurrent treatment with antiviral therapy or close monitoring
    - Documented diagnosis of moderate to severe rheumatoid arthritis (RA) per chart notes or prescriber attestation
        - Moderate to severe active rheumatoid arthritis, as indicated by **1 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
    - Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
        - Methotrexate
        - Hydroxychloroquine
        - Leflunomide
        - Sulfasalazine
2. Psoriatic Arthritis
    - Prescribed by or in consultation with a rheumatologist
    - Age ≥ 18 years of age
    - Documentation submitted member has no latent or active tuberculosis infection
    - Hepatitis B HBsAg negative and HBcAb negative, or for known hepatitis B carriers, concurrent treatment with antiviral therapy or close monitoring
    - Documented diagnosis of moderate to severe psoriatic arthritis (PsA)
    - Trial and failure of one of the following therapies for at least 3 consecutive months unless intolerant or contraindicated:
        - Methotrexate
        - Leflunomide
        - Sulfasalazine
3. Ulcerative Colitis

- Prescribed by or in consultation with a gastroenterologist
- Age ≥ 18 years of age
- Documentation submitted member has no latent or active tuberculosis infection
- Hepatitis B HBsAg negative and HBcAb negative, or for known hepatitis B carriers, concurrent treatment with antiviral therapy or close monitoring
- Diagnosis of moderately to severely active ulcerative colitis
    - Moderate to severe active ulcerative colitis, as indicated by **1 or more** of the following:
        - Anemia
        - Bowel movements 4 or more times per day
        - Urgency of defecation
        - Visible blood in stool
- Member has failed **AT LEAST** two of the following therapies verified per prescription claims history for ≥ 3 consecutive months, unless supported intolerance or contraindication submitted:
    - An amino salicylate such as sulfasalazine, mesalamine, basalazide, Apriso, or Pentasa
    - An oral corticosteroid or controlled ileal release budesonide
    - A thiopurine such as azathioprine
    - Methotrexate up to 25 mg once weekly

NOTE: Requests for XELJANZ IR will also require recent lab work for the following:

- Absolute lymphocyte count of 500/mm^3 (0.5 x10^9/L) or greater
- Absolute neutrophil count of 1000/mm^3 (1.0 x10^9/L) or greater
- Hemoglobin level 9 g/dL (90 g/L) or greater

CRITERIA FOR RENEWAL:

1. Documentation must be submitted supporting continued positive clinical response is occurring or stabilization of disease with improvement from pre-treatment baseline parameters.

LENGTH OF AUTHORIZATION:

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

Banner
University Health Plans

Vancomycin (Oral) Guideline

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

APPLICABLE AGENT(S):
- Vancomycin capsules and compounded solution

CRITERIA FOR INITIAL AUTHORIZATION:
1. Does the member have Clostridium difficile infection, Clostridium difficile infection with ileus or toxic colon and/or significant abdominal distention or Staphylococcal enterocolitis?
   ☐***Yes*** ☐***No***
2. Please provide member's diagnosis: _____

CRITERIA FOR RENEWAL:
1. N/A

LENGTH OF AUTHORIZATION:
- Initial Approval Duration: 10 days/7 to 10 days
- Renewal Approval Duration: 10 days/7 to 10 days

Last Modified:

1. 05/01/2021 – Population Health Team
2. 6/25/2021 – Population Health Team
3. 10/25/2021 – Population Health Team

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