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Provider Memorandum

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers
FROM: Cynthia Neuhofel, Pharm.D. Division of Medical Services Pharmacy Program
DATE: August 12, 2026
SUBJ: AR Medicaid Prior Authorization Edits and Preferred Drug List updates approved at the AR Medicaid DUR Board July 15, 2026 meeting for the following:

Preferred Drug List Full Review: Anaphylaxis agents

Preferred Drug List Full Review with PA Criteria: Calcitonin Gene-Related Peptide (CGRP) Antagonist; Immunomodulators, Atopic Dermatitis; Immunomodulators, Asthma and misc. indications; Epilepsy

Preferred Drug List Abbreviated Review: Medication Assisted Treatment; Triptans; Colony Stimulating Factors; Erythropoiesis Stimulating Agents; Urea Cycle Disorders; Vesicular Monoamine Transporter 2 Inhibitors; Ophthalmic Antibiotics; Otic Antibiotic and Antibiotic/Corticosteroid combo; Seizure Rescue

Manual Review PA Criteria: QUIOFIC (folic acid); DESMODA (desmopressin); YUVIWEL (navepegritide); KYGEVVI (doxecitine and doxribtimine); IMCIVREE (setmelanotide); CONTEPO (fosfomycin); SAPHNELO (anifrolumab); BAXFENDY (baxdrostat); HEPCLUDEX (bulevirtide); FILSPARI (sparsentan)

Quantity Claim Edits: Butalbital (non-codeine) products

Table of Contents

I. ANNOUNCEMENTS

1. QUARTERLY NEWSLETTER

As a service to our providers, we publish a quarterly provider newsletter with some updates for the Medicaid program and education materials. The quarterly newsletter is in addition to this DUR Board memorandum. Archived newsletters can be found on the Prime Therapeutics State Government Solutions portal under the pharmacy tab.
https://ar.primetherapeutics.com/provider-documents

The July 2026 quarterly newsletter can be found with the following link.
https://ar.primetherapeutics.com/documents/d/arkansas/arkansas-medicaid-quarterly-newsletter-july-2026-final

2. INFORMATIONAL DRUG UPDATES

a. VEPPANU (vepdegestrant) tablet

This medication has been added to the oncology policy.

https://ar.primetherapeutics.com/documents/d/arkansas/oncology_policy_04172024
VEPPANU is indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *estrogen receptor-1 (ESR1)*-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.

b. BEQALZI (sonrotoclax) tablet

This medication has been added to the oncology policy.

https://ar.primetherapeutics.com/documents/d/arkansas/oncology_policy_04172024

BEQALZI is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

c. YULITHIRA (everolimus) tablet

This medication has been added to the oncology policy.

https://ar.primetherapeutics.com/documents/d/arkansas/oncology_policy_04172024

YULITHIRA is indicated for:
1.1 Hormone Receptor-Positive, HER2-Negative Breast Cancer
1.2 Neuroendocrine Tumors (NET)
1.3 Renal Cell Carcinoma (RCC)

1.4 Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma
1.5 Tuberous Sclerosis Complex (TSC)-Associated Subependymal Giant Cell Astrocytoma (SEGA)

d. JAKAFI XR (ruxolitinib) tablet

This medication has been added to the oncology policy.

https://ar.primetherapeutics.com/documents/d/arkansas/oncology_policy_04172024

JAKAFI XR is indicated for:
1.1 Myelofibrosis
1.2 Polycythemia Vera
1.3 Acute Graft-Versus-Host Disease
1.4 Chronic Graft-Versus-Host Disease

e. FASENRA UPDATE WITH NEW INDICATION

FASENRA is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause.

Criteria for HES has already been DUR Board approved for NUCALA. FASENRA will be added to this criteria on the criteria document with 10/1/2026 update.

f. VYVGART/VYVGART HYTRULO UPDATE WITH INDICATION CHANGE

The criteria in the PA criteria document has been updated to match the current language with the removal of the requirement of patients needing to be AChR antibody positive. Also, test results documenting the presence of AChR antibodies will no longer be required.

3. NCPDP VERSION F6 INFORMATION

- National Council for Prescription Drug Programs (NCPDP) Version D.0 will be converted to version F6 based on a final CMS rule 0056-P which was published 12/13/2024.
- The rule requires modifications to:
    - Standards of pharmacy claims
    - Pharmacy batch claims
    - Medicaid subrogation
- Version F6 enables the following:
    - Modernization to adapt transactions to health care industry needs
    - Support transparency by improving clarity and reducing data exceptions
    - Readiness for future regulatory and industry changes
    - Improved member experience by reducing medication access delays
        - Reduces false rejections
        - Improves clarity to avoid false positives for prior authorization

        - Clarifies cost-share responses
        - Provides better support for utilization management and refill too soon
- Version F6 Transaction Changes:
    - New and updated claim segments, fields, and values, including retirement of select fields
    - Expanded dollar fields to support 11- and 14-digit values
    - Expanded Product Service ID (NDC) fields to 40 characters
    - Field name and size changes across multiple transaction elements
    - Changes to claim segment counts affecting transaction structure
    - 400+ external code list updates impacting validation and processing
    - Issuer Identification Number (IIN) replaces BIN and expands to 8 digits
    - New adjudicated program type field enabling more granular plan identification during adjudication
- Early option start with transition from D.0 to F6 begins 8/14/2027 with compliance required by 4/14/2028.
- **Early goal for implementation for Arkansas Medicaid is fall of 2027.**
- More communication will come when Medicaid is ready to accept the new layouts.
- References
    - Federal Register :: Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard
    - Proposed Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard (CMS-0056-P)

4. PHYSICIAN ADMINISTERED DRUGS UPDATE

https://ar.primetherapeutics.com/documents/d/arkansas/arkansas_medicaid_pad_criteria

5. PREFERRED DRUG LIST

PDL UPDATE EFFECTIVE OCTOBER 1, 2026
PRIOR AUTHORIZATION CRITERIA EFFECTIVE JULY 15, 2026

NOTE: Medications with a change in PDL status are notated as bold font.

a. CLASSES WITH FULL REVIEW WITHOUT CRITERIA

i. ANAPHYLAXIS AGENTS

Preferred Agents

- EPIPEN (epinephrine)
- EPIPEN JR (epinephrine)
- Epinephrine 0.15 mg, 0.3 mg injection (authorized generic for EPIPEN and EPIPEN JR)

Non-Preferred Agents

- AUVI-Q injection (epinephrine)
- Epinephrine 0.15 mg, 0.3 mg injection (generic for ADRENACLICK)
- Epinephrine 0.15 mg, 0.3 mg injection (unauthorized generic for EPIPEN and EPIPEN JR)
- NEFFY nasal spray (epinephrine)

b. CLASSES WITH FULL REVIEW WITH CRITERIA

i. CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONIST

No change for current PA criteria

MIGRAINE TREATMENT (PROPHYLACTIC AGENTS)

Preferred Agents

- AIMOVIG autoinjector (erenumab-aooe)
- EMGALITY 120 mg pen and syringe (galcanezumab)
- NURTEC ODT tablet (rimegepant)
- QULIPTA tablet (atogepant)

Non-Preferred Agents

- AJOVY syringe (fremanezumab-vfrm)
- EMGALITY 100 mg syringe (galcanezumab)

MIGRAINE TREATMENT (ACUTE)

Preferred Agents

- NURTEC ODT tablet (rimegepant)
- **UBRELVY tablet (ubrogepant)**

Non-Preferred Agents

- BREKIYA autoinjector (dihydroergotamine)
- **CAFERGOT tablet (ergotamine)**
- Diclofenac potassium powder pack (generic for CAMBIA)
- Dihydroergotamine injection (generic for D.H.E.45)
- Dihydroergotamine nasal spray (generic for MIGRANAL)
- ELYXYB solution (celecoxib)
- ERGOMAR SL tablet (dihydroergotamine)
- **MIGERGOT suppository (ergotamine)**
- REYVOW tablet (lasmiditan)
- ZAVZPRET nasal spray (zavegepant)

ii. IMMUNOMODULATORS, ATOPIC DERMATITIS

Preferred Agent(s)

- tacrolimus ointment (generic for PROTOPIC)

Preferred Injectable Agents with Criteria (*SPECIFIC MANUAL REVIEW CRITERIA)

- ADBRY* syringe and autoinjector (tralokinumab-ldrm)
- DUPIXENT* syringe and pen (dupilumab)
- **EBGLYSS* syringe and pen (lebrikizumab-lbkz)**

Preferred Topical Agents with Criteria

- **EUCRISA ointment (crisaborole)**
- **OPZELURA cream (ruxolitinib)**
- **VTAMA cream (tapinarof)**

Non-Preferred Agents (*SPECIFIC MANUAL REVIEW CRITERIA)

- ANZUPGO* cream (delgocitinib)
- CIBINQO* tablet (abrocitinib)
- NEMLUVIO* injection (nemolizumab-ilto)
- pimecrolimus cream (generic for ELIDEL)
- RINVOQ* tablet (upadacitinib)
- ZORYVE* 0.05% and 0.15% cream (roflumilast)
- ZORYVE* 0.3% foam (roflumilast)

APPROVAL CRITERIA FOR ATOPIC DERMATITIS

For Adbry, Cibinqo, Dupixent, Ebglyss, Nemluvio, and Rinvoq

- The medication must be prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- The beneficiary has a documented diagnosis of moderate to severe atopic dermatitis with at least **ONE (1)** of the following (baseline at time of biologic request documented on the request):
    - Baseline impacted body surface area (BSA) ≥ 10%;
    - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16;
    - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7;
    - Baseline Investigator's Global Assessment (IGA) score ≥ 3; **AND**
    - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in the official Compendia
- The beneficiary has no therapeutic duplication with other monoclonal antibodies prescribed for atopic dermatitis

- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The beneficiary must have a trial and failure of topical therapy and at a minimum must include the following:
    - One (1) topical corticosteroid entity over a minimum of 60 days use that is considered either high potency (Class-2) or superpotent (Class-1) for adults or medium potency for children (unless contraindicated); **AND**
    - One (1) topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., pimecrolimus or tacrolimus)
- The prescriber must submit all of the following:
    - Current chart notes
    - Documentation of previous therapies with trial length of each medication
    - BSA prior to topical/systemic therapies and current impacted BSA
    - Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
    - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history; **AND**
    - Letter of medical necessity over other treatment options for atopic dermatitis

RENEWAL REQUIREMENTS FOR ATOPIC DERMATITIS

For Adbry, Cibinqo, Dupixent, Ebglyss, Nemluvio, and Rinvoq

- The beneficiary is compliant on this medication
- The beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least **ONE (1)** of the following compared to baseline:
    - Decrease in severity scores;
    - Decrease in BSA impacted; **OR**
    - Decrease in need for systemic or topical rescue treatment
- The beneficiary has no therapeutic duplication with other monoclonal antibodies prescribed for atopic dermatitis
- The prescriber must submit:
    - Current chart notes; **AND**
    - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

APPROVAL CRITERIA FOR TOPICAL ATOPIC DERMATITIS AGENTS

POINT OF SALE (POS) CRITERIA FOR EUCRISA

- Billed diagnosis of atopic dermatitis within the last two (2) years
- 1 year lookback in Medicaid pharmacy history for topical therapy including a trial of at least **ONE (1)** of the following:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus); **OR**
    - One (1) claim for EUCRISA (crisaborole)
- If beneficiary does not meet the above, a prior authorization request will be required.

APPROVAL CRITERIA FOR EUCRISA (if beneficiary does not meet POS edit)

- The beneficiary must be ≥3 months of age
- The beneficiary must have uncontrolled mild to moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2–3 out of a 0–4 scale, or a diagnosis consistent with FDA indications with recent claim(s) for topical steroids **OR** topical calcineurin inhibitors (TCI) as defined:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- The prescriber must submit all of the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current IGA score; **AND**
    - Current baseline Itch Numerical Rating Scale (Itch NRS)

POINT OF SALE (POS) CRITERIA FOR OPZELURA

- Billed diagnosis of atopic dermatitis within the last two (2) years
- 1 year lookback in Medicaid pharmacy history for topical therapy including a trial of at least **ONE (1)** of the following:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus); **OR**
    - One (1) claim for OPZELURA (ruxolitinib)
- If beneficiary does not meet the above, a prior authorization request will be required.

APPROVAL CRITERIA FOR OPZELURA (if beneficiary does not meet POS edit)

- The beneficiary must be ≥ 2 years of age
- The beneficiary must have uncontrolled mild to moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2–3 out of a 0–4 scale with recent claim(s) for topical steroids **OR** topical calcineurin inhibitors (TCI) as defined:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- The prescriber must submit all of the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current IGA score; **AND**
    - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

POINT OF SALE (POS) CRITERIA FOR VTAMA (tapinarof)

- Billed diagnosis of atopic dermatitis within the last two (2) years
- 1 year lookback in Medicaid pharmacy history for topical therapy including a trial of at least **ONE (1)** of the following:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus); **OR**
    - One (1) claim for VTAMA (tapinarof)
- If beneficiary does not meet the above, a prior authorization request will be required.

APPROVAL CRITERIA FOR VTAMA (if beneficiary does not meet POS edit)

- The beneficiary must be ≥ 2 years of age
- The beneficiary must have uncontrolled atopic dermatitis with recent claim(s) for topical steroids **OR** topical calcineurin inhibitors (TCI) as defined:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days; **OR**
    - One (1) topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- The prescriber must submit the following:
    - Current chart notes

    - Documentation of previous therapies
    - Current IGA score; **AND**
    - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

APPROVAL CRITERIA FOR ZORYVE 0.05% and 0.15% CREAM (foam is listed separately in the PA criteria document)

- The beneficiary must be 2–5 years of age for Zoryve 0.05% and ≥ 6 years of age for Zoryve 0.15%.
- The beneficiary must have uncontrolled mild to moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2–3 out of a 0–4 scale with a trial and failure of topical therapy and at a minimum must include at least **TWO (2)** of the following:
    - One (1) topical corticosteroid that is considered either high potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis for a minimum of 30 days
    - One (1) topical calcineurin inhibitor (TCI) for a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
    - One (1) other preferred topical atopic dermatitis product for a minimum of 30 days (i.e., crisaborole, ruxolitinib, tapinarof)
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current IGA score
    - Current baseline Itch Numerical Rating Scale (Itch NRS); **AND**
    - Medical necessity over preferred topical products for atopic dermatitis
- If approved, PA will be approved for 2 months

APPROVAL CRITERIA FOR CHRONIC HAND ECZEMA

For ANZUPGO

- The beneficiary must be ≥ 18 years of age
- The beneficiary must have uncontrolled moderate to severe chronic hand eczema (CHE) defined by an Investigator's Global Assessment (IGA) score of 3–4 out of a 0–4 scale or Investigator's Global Assessment of Chronic Hand Eczema (IGA-CHE) score of 3–4 out of a 0–4 scale with recent topical therapy claims which includes at least the following:
    - One (1) topical corticosteroid either high potency (Class-2) or super potent (Class-1) over a minimum of 30 days; **AND**

    - One (1) topical calcineurin inhibitor TCI (i.e., tacrolimus, pimecrolimus) **OR** PDE4 inhibitor (i.e., crisaborole) over a minimum of 30 days
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies; **AND**
    - Current Investigator's Global Assessment (IGA) score or Investigator's Global Assessment of Chronic Hand Eczema (IGA-CHE)
- If approved, PA will be approved for 2 months

RENEWAL REQUIREMENTS FOR CHRONIC HAND ECZEMA

For ANZUPGO

- The beneficiary must have documented improvement in symptoms (i.e., reduced IGA or IGA-CHE score)
- The prescriber must submit the following:
    - Current chart notes; **AND**
    - Current Investigator's Global Assessment (IGA) score or Investigator's Global Assessment of Chronic Hand Eczema (IGA-CHE) score

QUANTITY EDITS FOR TOPICAL ATOPIC DERMATITIS AGENTS

For ANZUPGO

- 1 tube (30 gm/30 days)

For EUCRISA

- Max of 300 gm per year
    - 60 gm tube = 5 per year
    - 100 mg tube = 3 per year

For OPZELURA

- 4 tubes per year (1 per claim)

For VTAMA

- 6 tubes per year (1 per claim)

For ZORYVE

- 6 tubes per year (1 per claim)

iii. IMMUNOMODULATORS, ASTHMA and MISC INDICATIONS

***Denotes biosimilar**

Preferred Agents with Criteria

- DUPIXENT pen and syringe (dupilumab)
- FASENRA pen and syringe (benralizumab)
- **RHAPSIDO tablet (remibrutinib)**
- **TEZSPIRE pen and syringe (tezepelumab-ekko)**
- XOLAIR syringe and autoinjector (omalizumab)

Non-Preferred Agents

- NEMLUVIO pen (nemolizumab-ilto)
- NUCALA autoinjector, syringe, vial (mepolizumab)
- OMLYCLO* syringe (omalizumab-igec)
- XOLAIR vial (omalizumab)

FDA-APPROVED INDICATIONS

DUPIXENT:

- Moderate to severe atopic dermatitis
- Chronic rhinosinusitis with nasal polyposis
- Chronic Spontaneous Urticaria
- Moderate to severe asthma (either eosinophilic phenotype or oral steroid dependent)
- Eosinophilic Esophagitis
- Prurigo Nodularis
- Eosinophilic phenotype chronic obstructive pulmonary disease (COPD)
- Bullous Pemphigoid
- Allergic Fungal Rhinosinusitis

FASENRA:

- Severe asthma with an eosinophilic phenotype
- Eosinophilic Granulomatosis with Polyangiitis
- Hypereosinophilic Syndrome

RHAPSIDO:

- Chronic Spontaneous Urticaria

XOLAIR:

- Moderate to severe asthma with positive skin test or in vitro reactivity to allergen
- Chronic rhinosinusitis with nasal polyposis
- Chronic Spontaneous Urticaria
- IgE-Mediated Food Allergies

NEMLUVIO:

- Moderate to severe atopic dermatitis
- Prurigo Nodularis

NUCALA:

- Eosinophilic phenotype chronic obstructive pulmonary disease (COPD)
- Hypereosinophilic Syndrome
- Maintenance treatment of chronic rhinosinusitis with nasal polyps
- Severe asthma with an eosinophilic phenotype
- Eosinophilic Granulomatosis with Polyangiitis

TEZSPIRE:

- Severe asthma
- Chronic rhinosinusitis with nasal polyposis

APPROVAL CRITERIA FOR ASTHMA
(FOR DUPIXENT, FASENRA, NUCALA, TEZSPIRE, AND XOLAIR)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- The medication must be prescribed by or in consultation with specialist in pulmonology, allergy or immunology
- The beneficiary must have a diagnosis consistent with FDA indications.
    - NUCALA – add-on maintenance treatment of adult and pediatric beneficiaries 6 years of age and older with severe asthma and with an eosinophilic phenotype
    - FASENRA – add-on maintenance treatment of beneficiaries with severe asthma 6 years of age and older and with an eosinophilic phenotype
    - DUPIXENT – add-on maintenance treatment of adult and pediatric beneficiaries 6 years of age and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
    - TEZSPIRE – add-on maintenance treatment of adult and pediatric beneficiaries 12 years of age and older with severe asthma
    - XOLAIR – adults and pediatric beneficiaries 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids

- The beneficiary must have uncontrolled moderate to severe asthma while compliant with at least two asthma maintenance medications with one being an inhaled corticosteroid at a maximized dose (ICS/LABA combination products count as two medications) **AND** one of the following:
    - One or more exacerbations in the previous year defined as:
        - Requires treatments with systemic corticosteroids; **OR**
        - Requires medical treatment (e.g., emergency room visits or hospitalizations); **OR**
    - Oral corticosteroid dependent asthma
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for asthma
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried for asthma with response
    - Baseline labs (must fall within the manufacturer's requirements in the package insert)
        - Baseline blood eosinophil count for FASENRA, NUCALA, and DUPIXENT (if eosinophilic type) with eosinophils ≥ 150
        - Baseline serum IgE levels, body weight, and completed form for XOLAIR
    - Baseline Asthma Control Questionnaire (ACQ-5) for all beneficiaries or Asthma Quality of Life Questionnaire (AQLQ) scores for adults only; **AND**
    - Current Pulmonary Function Test results

RENEWAL REQUIREMENTS FOR ASTHMA
(FOR DUPIXENT, FASENRA, NUCALA, TEZSPIRE, AND XOLAIR)

- The beneficiary is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection
- The prescriber must submit the following:
    - Current chart notes with documentation of response to therapy after 12 months of treatment
    - Current PFTs
    - Current blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), and NUCALA
    - Current serum IgE level and body weight for XOLAIR; **AND**

    - Current Asthma Control Questionnaire (ACQ-5) for all beneficiaries or Asthma Quality of Life Questionnaire (AQLQ) scores for adults only
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy as indicated by at least one of the following:
    - The beneficiary must have an improvement in FEV1 over baseline after 12 months
    - The beneficiary must have fewer exacerbations
    - The beneficiary must have a decrease in blood eosinophil count or serum IgE or decrease in oral corticosteroid usage (depending on medication)
    - The beneficiary must have improved asthma control and quality of life scores

APPROVAL CRITERIA FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)
(FOR FASENRA AND NUCALA)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia (> 1.0 x 10^9 /L and/or > 10% of leucocytes)
- The beneficiary has a history of relapsing or refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids
- The beneficiary must be on a stable dose of oral prednisolone or prednisone of ≥ 7.5 mg/day for at least four weeks
- If the beneficiary is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four weeks
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for EPGA
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The beneficiary does not have life-threatening EGPA. Life-threatening EGPA would be defined as:
    - Severe alveolar hemorrhage or hemoptysis requiring transfusion or ventilation, or hemoglobin is < 8 g/dL

    - Rapidly progressive glomerulonephritis with creatinine > 2.5 mg/dL
    - Severe cardiac involvement including life-threatening arrhythmia, LVEF < 20%, NUHA Class III/IV or acute myocardial infarction
- The prescriber must submit the following:
    - Current chart notes
    - Current labs, including CBCs and LFTs if on methotrexate or azathioprine
    - Baseline Birmingham Vasculitis Activity Score (BVAS); **AND**
    - Medical necessity over corticosteroids and/or immunosuppressive therapy

RENEWAL REQUIREMENTS FOR EGPA (FOR FASENRA AND NUCALA)

- The beneficiary must be compliant on this medication
- The beneficiary must show a positive response to therapy with at least one of the following:
    - BVAS = 0 (no vasculitis); **OR**
    - Corticosteroid dose has been decreased to ≤ 4 mg/day
- The prescriber must submit the following:
    - Current chart notes
    - Current corticosteroid dose; **AND**
    - Current BVAS

APPROVAL CRITERIA FOR CHRONIC SPONTANEOUS URTICARIA (FOR DUPIXENT, RHAPSIDO, AND XOLAIR)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- The beneficiary must be diagnosed with chronic spontaneous urticaria (CSU) with wheals/hives with or without angioedema for > 6 consecutive weeks
- The medication must be prescribed by or in consultation with a dermatologist, allergist, or immunologist
- The beneficiary must minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, and friction from clothing)
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for CSU
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this

indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).

- The beneficiary must have at least one of the following despite treatment listed below:
    - Baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16
    - Baseline Itch Severity Score-7 (ISS7) must be ≥ 8; **OR**
    - Baseline Urticaria Control Test (UCT) must be < 12
- The beneficiary must have tried and failed the following unless there is a contraindication to their use:
    - Non-sedating H1-antihistamine (nsAH) for a minimum of 2 weeks; **AND**
    - nsAH at 4 times the normal daily dose for a minimum of 4 weeks
- The prescriber must submit the following:
    - Current chart notes
    - Baseline description of urticaria
    - Baseline UAS7 and/or ISS7 and/or UCT scores; **AND**
    - Previous therapies that were tried with treatment duration

RENEWAL REQUIREMENTS FOR CHRONIC SPONTANEOUS URTICARIA (FOR DUPIXENT, RHAPSIDO, AND XOLAIR)

- The beneficiary has been compliant with therapy (defined as 75% utilization)
- The beneficiary taking RHAPSIDO who develops bleeding should be evaluated for continuation considering the benefit versus the risk
- The beneficiary must have a positive response with a decrease in urticaria symptoms and an improvement in one of the following (must use same test as baseline):
    - UAS7;
    - ISS7; **OR**
    - UCT
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of current symptoms; **AND**
    - Current CSU test with at least one of the following (must use the same test as baseline):
        - Urticaria Activity Score-7 (UAS7)
        - Itch Severity Score-7 (ISS7) score; **OR**
        - Urticaria Control Test (UCT)

APPROVAL CRITERIA FOR NASAL POLYPS
(FOR DUPIXENT, NUCALA, TEZSPIRE, AND XOLAIR)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary must have a diagnosis of chronic rhinosinusitis with nasal polyposis
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- The medication is prescribed by or in consultation with specialist in pulmonology, allergy, immunology, or otolaryngology
- The beneficiary must have a trial and failure of three months of nasal corticosteroids (e.g., fluticasone, beclomethasone, budesonide)
- The beneficiary must have met **ONE (1)** of the following:
    - Previous treatment with oral corticosteroids for nasal polyps in the last two years; **OR**
    - Previous nasal surgery for nasal polyps
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for chronic rhinosinusitis with nasal polyposis
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The prescriber must submit the following:
    - Current chart notes with description of size/quantity of nasal polyps
    - Documentation of previous therapies tried
    - Requested dose
    - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
    - Current IgE and weight for XOLAIR request
    - Medical necessity over nasal corticosteroids, antileukotrienes, and surgery; **AND**
    - Documentation that concomitant nasal corticosteroids are prescribed

RENEWAL REQUIREMENTS FOR NASAL POLYPS
(FOR DUPIXENT, NUCALA, TEZSPIRE, AND XOLAIR)

- The beneficiary must demonstrate an improvement in size/quantity of polyps with an improvement of symptoms compared to baseline
- The beneficiary must be compliant with this medication and nasal corticosteroids
- The prescriber must submit the following:

- Current chart notes with description of polyps
- Current body weight for dose determination for XOLAIR; **AND**
- Requested dose

APPROVAL CRITERIA FOR EOSINOPHILIC ESOPHAGITIS (EOE) (FOR DUPIXENT)

For complete Eosinophilic Esophagitis (EOE) criteria, please refer to Eosinophilic Esophagitis

- The beneficiary must be aged 1 year and older, weighing at least 15 kg, or the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary must have a confirmed diagnosis of eosinophilic esophagitis (EOE) with an esophageal biopsy that indicates ≥ 15 eosinophils per high-power field (eos/hpf) and **ONE (1)** of the following:
  - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain); **OR**
  - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows)
- The beneficiary must have at least a 12-week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide)
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for EOE
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication (if applicable) before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The prescriber must submit the following:
  - Current chart notes
  - Previous therapies including dietary restrictions, procedures, or pharmacological treatment
  - Baseline eos/hpf after corticosteroid and PPI trials; **AND**
  - Baseline beneficiary determined Dysphagia Symptom Questionnaire (DSQ) score

RENEWAL REQUIREMENTS FOR EOSINOPHILIC ESOPHAGITIS (FOR DUPIXENT)

- The beneficiary demonstrates a positive response with one of the following after 6 months of treatment:
  - Achieved remission with ≤ 6 eos/hpf; **OR**
  - Decrease in DSQ score from baseline

- The prescriber must submit the following:
    - Current chart notes
    - Current beneficiary determined DSQ score; **AND**
    - Current eos/hpf

APPROVAL CRITERIA FOR COPD
(FOR DUPIXENT AND NUCALA)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- The medication must be prescribed by or in consultation with a pulmonologist
- The beneficiary has been diagnosed with eosinophilic phenotype chronic obstructive pulmonary disease (COPD) that is inadequately controlled on maintenance therapy with moderate to severe airflow limitation defined by the following:
    - Post-bronchodilator FEV1/FVC ratio < 0.7
    - Post-bronchodilator FEV1 of 30% to 70% predicted; **AND**
    - History of ≥ 2 moderate or ≥ 1 severe exacerbation within the past 12 months
- The beneficiary must have a trial and failure of maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (unless contraindicated) with a trial lasting for at least 3 months
- The beneficiary must have a blood eosinophilic count of at least 300 cells/µL as a baseline drawn in the last 12 months
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for COPD
- The beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The prescriber must submit the following:
    - Current chart notes with description of COPD symptoms and history of exacerbations for the last 12 months
    - Documentation of previous therapies tried
    - Current pulmonary function tests
    - Baseline labs including CBC with differential; **AND**
    - Documentation of smoking history

RENEWAL REQUIREMENTS FOR COPD (FOR DUPIXENT AND NUCALA)

- The beneficiary remains compliant on COPD maintenance therapy (inhalers and immunomodulator injection)
- The beneficiary must demonstrate a positive response to therapy as indicated by at least **ONE (1)** of the following:
    - Decrease in quantity and/or severity of exacerbations; **OR**
    - Improvement in lung function/FEV1 over baseline; **OR**
    - Improvement in COPD-related symptoms and/or quality of life
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of response to therapy compared to previous baseline with information on any exacerbations since last PA review; **AND**
    - Current PFTs

APPROVAL CRITERIA FOR HYPEREOSINOPHILIC SYNDROME (FOR NUCALA and FASENRA)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary must have a diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- The beneficiary has documented at least TWO (2) HES flares within the past 12 months while on stable HES therapy with at least **TWO (2)** of the following:
    - Chronic or episodic corticosteroids
    - Immunosuppressants; **OR**
    - Cytotoxic therapy
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for HES
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred option(s).
- The beneficiary has a baseline blood eosinophil count of at least 1,000 cells/µL
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried and response; **AND**

- Current labs, including CBCs and LFTs if on methotrexate or azathioprine

RENEWAL REQUIREMENTS FOR HYPEREOSINOPHILIC SYNDROME (FOR NUCALA and FASENRA)

- The beneficiary must be compliant with this medication
- The beneficiary has a positive response with a decrease in HES flares and a decrease in blood eosinophil count
- The prescriber must submit the following:
  - Current chart notes
  - Current labs, including CBCs; **AND**
  - Documentation of HES flares since beginning treatment

APPROVAL CRITERIA FOR PRURIGO NODULARIS (FOR DUPIXENT AND NEMLUVIO)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease or has a comorbidity of moderate to severe atopic dermatitis
- The medication must be prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis/prurigo nodularis
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologics with this indication before non-preferred options can be approved unless there is a beneficiary specific contraindication to the preferred options
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for prurigo nodularis
- The beneficiary must have a trial and failure of topical medications and at a minimum must include (unless contraindicated or inappropriate for the beneficiary's age):
  - At least one topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) or superpotent (Class-1) or medium potency for children; **AND**
  - At least one trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- The prescriber must submit the following:
  - Current chart notes

- Description of current status for baseline (i.e., BSA of nodules, peak pruritis Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA)
- Previous therapies tried; **AND**
- If there is no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

RENEWAL REQUIREMENTS FOR PRURIGO NODULARIS (FOR DUPIXENT AND NEMLUVIO)

- The beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline:
  - Decrease in pruritis
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- The prescriber must submit:
  - Current chart notes; **AND**
  - Current BSA and pruritis test scores (i.e., NRS, IGA)

APPROVAL CRITERIA FOR IGE-MEDIATED FOOD ALLERGIES (FOR XOLAIR)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- The beneficiary must be diagnosed with one or more IgE-mediated food allergies or a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- The prescriber must be an Allergy and Immunology specialist
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for IgE-mediated food allergies
- The prescriber must attest that the beneficiary has been counseled to continue to avoid the foods that cause allergic reactions as this medication is for accidental exposure only
- The beneficiary must continue to have injectable epinephrine on hand with a pharmacy claim within the last year
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication (if applicable) before non-preferred options can be approved

unless there is a beneficiary specific contraindication to the preferred option(s).

- The prescriber must submit the following:
    - Current chart notes
    - Baseline serum IgE level
    - Current weight
    - Dose requested (must be supported by the dosing chart in the package insert); **AND**
    - Skin prick test results confirming food allergies

RENEWAL REQUIREMENTS FOR IGE-MEDIATED FOOD ALLERGIES (FOR XOLAIR)

- The beneficiary remains compliant based on pharmacy claims (defined as 75%). If not compliant, the medical necessity for restarting therapy should be provided.
- The prescriber must submit the following:
    - Current chart notes
    - Serum IgE level is not required for compliant beneficiaries or those with a dose in the last year; dose interruptions lasting one year or more require a new serum IgE level
    - Current weight; **AND**
    - Dose requested (must be supported by the dosing chart in the package insert)

APPROVAL CRITERIA FOR BULLOUS PEMPHIGOID (FOR DUPIXENT)

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex
- The beneficiary must have a diagnosis of bullous pemphigoid with confirmation from tissue biopsy results
- The beneficiary must have tried and failed oral corticosteroids (e.g., prednisone or prednisolone)
- The beneficiary must use the requested biologic in combination with a tapering course of oral corticosteroids
- The beneficiary has no therapeutic duplication with any other monoclonal antibodies prescribed for bullous pemphigoid
- If the request is for a non-preferred medication, the beneficiary must have tried and failed at least two (2) preferred biologic(s) with this indication (if applicable) before non-preferred options can be approved

unless there is a beneficiary specific contraindication to the preferred option(s).

- The prescriber must submit the following:
    - Current chart notes
    - Tissue biopsy report confirming diagnosis read
    - Documentation of status at baseline (e.g., location of lesions, estimated BSA of lesions,
    - description of lesions)
    - Previous therapies tried (e.g., topical corticosteroids, oral corticosteroids, doxycycline, dapsone,
    - methotrexate, mycophenolate, azathioprine); **AND**
    - Plan for corticosteroid taper
- Initial PA approved for 3 months. If responsive, renewal PAs can be approved for 6 months

RENEWAL REQUIREMENTS FOR BULLOUS PEMPHIGOID (FOR DUPIXENT)

- The beneficiary is compliant with therapy (defined as 75% utilization)
- The beneficiary must demonstrate a positive response with decrease in quantity and severity of BP lesions compared to baseline
- The prescriber must submit the following:
    - Current chart notes
    - Documentation of the current status for a comparison to baseline (e.g., location of lesions, estimated BSA of lesions, description of lesions); **AND**
    - Status of corticosteroid taper

QUANTITY

- FASENRA – #1 pen/vial per 8 weeks (will need quantity override for first 3 months)
- DUPIXENT – #5 syringes per 50 days
- NUCALA – #3 prefilled syringes/autoinjectors per 28 days
- RHAPSIDO – #60 per 30 days
- TEZSPIRE – #1 syringe/vial per 28 days
- XOLAIR
    - #4 300 mg prefilled syringe/autoinjector per 28 days
    - #2 150 mg prefilled syringe/autoinjector per 28 days
    - #4 150 mg vial per 28 days
    - #2 75 mg prefilled syringe/autoinjector per 28 days

iv. EPILEPSY

No change for current PA criteria

Note: Beneficiaries compliant on taking a non-preferred agent will be able to continue that medication without a PA if there is a claim in their Medicaid profile in the previous 60 days. Many anticonvulsants have criteria established. See the notations below for clarification. Anticonvulsants have quantity limits as well based on the manufacturer's package inserts and support in MicroMedex.

***Point-of-sale criteria**
****Follows NPO rules (< 7 years of age OR NPO within the past 365 days)**
*****Manual review criteria**

Preferred Agents

- carbamazepine 100 mg chew tablet (generic for TEGRETOL)
- carbamazepine tablet (generic for TEGRETOL)
- clobazam suspension (generic for ONFI)
- clobazam tablet (generic for ONFI)
- divalproex DR tablet (generic for DEPAKOTE DR)
- divalproex ER tablet (generic for DEPAKOTE ER)
- ethosuximide capsule (generic for ZARONTIN)
- gabapentin capsule/tablet (generic for NEURONTIN)
- lacosamide solution (generic for VIMPAT)
- lacosamide tablet (generic for VIMPAT)
- lamotrigine tablet (generic for LAMICTAL)
- levetiracetam solution (generic for KEPPRA)
- levetiracetam tablet (generic for KEPPRA)
- oxcarbazepine suspension (generic for TRILEPTAL)
- oxcarbazepine tablet (generic for TRILEPTAL)
- phenytoin capsule (generic for DILANTIN)
- pregabalin capsule (generic for LYRICA)
- primidone tablet (generic for MYSOLINE)
- **ROWEEPRA tablet (levetiracetam) HCFA term 6/30/2027**
- SABRIL tablet (vigabatrin) – brand only
- **SUBVENITE tablet (lamotrigine)**
- TEGRETOL suspension (carbamazepine) – brand only
- topiramate tablet (generic for TOPAMAX)
- valproic acid capsule (generic for DEPAKENE)
- valproic acid solution (generic for DEPAKENE)
- vigabatrin powder pack (generic for SABRIL)
- zonisamide capsule (generic for ZONEGRAN)

Preferred Agents with Criteria

- gabapentin solution (generic for NEURONTIN)**
- **topiramate sprinkle** 15 mg and 25 mg (generic for TOPAMAX sprinkle)**

Non-Preferred Agents

- APTIOM (eslicarbazepine acetate)
- BANZEL suspension (rufinamide)
- BANZEL tablet (rufinamide)
- brivaracetam solution and tablet (generic for BRIVIACT)
- BRIVIACT solution (brivaracetam)
- BRIVIACT tablet (brivaracetam)
- carbamazepine 200 mg chew tab (generic for TEGRETOL)
- carbamazepine ER capsule (generic for CARBATROL)
- carbamazepine ER tablet (generic for TEGRETOL XR)
- carbamazepine suspension (generic for TEGRETOL)
- CARBATROL ER capsule (carbamazepine)
- CELONTIN capsule (methsuximide)
- DEPAKOTE DR tablet (divalproex)
- DEPAKOTE ER tablet (divalproex)
- DEPAKOTE sprinkle capsule (divalproex)
- DIACOMIT capsule (stiripentol)
- DIACOMIT powder packet (stiripentol)
- DILANTIN capsule (phenytoin)
- DILANTIN INFATAB tablet (phenytoin)
- DILANTIN suspension (phenytoin)
- divalproex sprinkle capsule (generic for DEPAKOTE)
- ELEPSIA XR tablet (levetiracetam)
- EPIDIOLEX solution (cannabidiol)*** (Epidiolex Oral Solution criteria)
- EPRONTIA solution (topiramate)
- EQUETRO capsule (carbamazepine)
- eslicarbazepine (generic for APTIOM)
- ethosuximide solution (generic for ZARONTIN)
- felbamate suspension (generic for FELBATOL)
- felbamate tablet (generic for FELBATOL)
- FELBATOL tablet (felbamate)
- FINTEPLA solution (fenfluramine)*** (Fintepla Solution criteria)
- FYCOMPA suspension (perampanel) – brand preferred over generic
- FYCOMPA tablet (perampanel)
- **gabapentin 200 mg capsule (generic for RELGAABI)**
- GABARONE tablet (gabapentin)
- KEPPRA solution (levetiracetam)
- KEPPRA tablet (levetiracetam)
- KEPPRA XR tablet (levetiracetam)

- lacosamide vial (generic for VIMPAT)
- LAMICTAL dispersible tablet (lamotrigine)
- LAMICTAL dose pack (lamotrigine)
- LAMICTAL ODT dose pack (lamotrigine)
- LAMICTAL ODT tablet (lamotrigine)
- LAMICTAL tablet (lamotrigine)
- LAMICTAL XR tablet (lamotrigine ER)
- LAMICTAL XR dose pack (lamotrigine)
- lamotrigine dispersible tablet (generic for LAMICTAL)
- lamotrigine dose pack (generic for LAMICTAL)
- lamotrigine ER tablet (generic for LAMICTAL XR)
- lamotrigine ODT dose pack (generic for LAMICTAL)
- lamotrigine ODT tablet (generic for LAMICTAL)
- levetiracetam ER tablet (generic for KEPPRA XR)
- levetiracetam tablet for suspension (generic for SPRITAM)
- methsuximide capsule (generic for CELONTIN)
- MOTPOLY XR capsule (lacosamide)
- ONFI suspension (clobazam)
- ONFI tablet (clobazam)
- oxcarbazepine ER tablet (generic for OXTELLAR XR)
- OXTELLAR XR tablet (oxcarbazepine) – brand preferred over generic when approved
- perampanel suspension and tablet (generic for FYCOMPA)
- phenobarbital elixir
- phenobarbital tablet
- PHENYTEK capsule (phenytoin ER)
- phenytoin chew tablet (generic for DILANTIN INFATAB)
- phenytoin ER capsule (generic for PHENYTEK)
- phenytoin suspension (generic for DILANTIN)
- **RELGAABI capsule (gabapentin)**
- rufinamide suspension (generic for BANZEL)
- rufinamide tablet (generic for BANZEL)
- SABRIL powder packet (vigabatrin)
- SPRITAM tablet for suspension (levetiracetam)
- SUBVENITE suspension (lamotrigine)
- **SUBVENITE tablet starter kit (lamotrigine)**
- SYMPAZAN film (clobazam)*** (Sympazan Film criteria)
- TEGRETOL tablet (carbamazepine)
- TEGRETOL XR tablet (carbamazepine ER)
- tiagabine tablet (generic for GABITRIL)
- TOPAMAX sprinkle (topiramate)
- TOPAMAX tablet (topiramate)
- topiramate ER capsule (generic for QUDEXY and TROKENDI XR)
- topiramate solution (generic for EPRONTIA)

- **topiramate sprinkle** 50 mg (generic for TOPAMAX sprinkle)**
- TRILEPTAL suspension (oxcarbazepine)
- TRILEPTAL tablet (oxcarbazepine)
- TROKENDI XR capsule (topiramate)
- vigabatrin tablet (generic for SABRIL)
- **VIGADRONE tablet (generic for SABRIL)**
- **VIGADRONE powder pack (generic for SABRIL)**
- VIGAFYDE solution (vigabatrin)
- VIMPAT solution (lacosamide)
- VIMPAT tablet (lacosamide)
- VIMPAT vial (lacosamide)
- XCOPRI tablet (cenobamate)
- XCOPRI titration pack (cenobamate)
- ZARONTIN capsule (ethosuximide)
- ZARONTIN solution (ethosuximide)
- ZONISADE suspension (zonisamide)
- **ZTALMY suspension (ganaxolone)*** (Ztalmy Suspension criteria)**

c. CLASSES WITH ABBREVIATED REVIEW WITHOUT CRITERIA

i. MEDICATION ASSISTED TREATMENT

Preferred Opioid Dependence Agents with NO Criteria

- buprenorphine sublingual tablet
- naltrexone 50mg tablet
- SUBOXONE Film (buprenorphine/naloxone)– brand only
- ZUBSOLV SL tablet (buprenorphine/naloxone)

As of 1/1/2020 the preferred oral agents for MAT therapy will no longer require a PA.

Effective 1/1/2025, the maximum daily allowed dose will increase to the equivalent of 32 mg of buprenorphine. At that time, a therapeutic duplication edit will be implemented for oral opioid use disorder (OUD) agents to prevent overlapping claims for multiple oral dosage forms. There will not be a therapeutic duplication edit place between the oral and injectable products.

Preferred Injectable Medication Assisted Treatment (MAT) Agents

- BRIXADI SQ syringe (buprenorphine extended release)
- SUBLOCADE SQ injection (buprenorphine extended release)
- VIVITROL IM suspension (naltrexone for extended release)

Preferred Injectable MAT Agents may be billed at point-of-sale in a pharmacy setting or through the beneficiary's medical benefits. No PA is required at the pharmacy.

Preferred Opiate Overdose Agents/Rescue Medications with NO Criteria

- KLOXXADO 8 mg nasal spray (naloxone)
- naloxone 0.4 mg/mL vial (generic for NARCAN)
- naloxone 2 mg/2 mL syringe (generic for NARCAN)
- naloxone 4 mg nasal spray (generic for NARCAN)
- NARCAN 4 mg nasal spray (naloxone)
- REXTOVY 4 mg nasal spray (naloxone)

Preferred Alcohol Dependence Agents with NO Criteria

- acamprosate DR 333 mg tablets
- disulfiram 250 mg and 500 mg tablets
- naltrexone 50 mg tablets

Non-Preferred Opioid Dependence Agents

- buprenorphine/naloxone SL tablets (generic for SUBOXONE tablets)
- buprenorphine/naloxone sublingual film (generic for SUBOXONE films)

Non-Preferred Injectable MAT Agents

- None

Non-Preferred Opiate Overdose Agents/Rescue Medications

- LIFEMS naloxone 2 mg/2 mL kit (naloxone)
- **lofexidine 0.18 mg tablet (generic for LUCEMYRA)**
- LUCEMYRA 0.18 mg tablet (lofexidine) – see criteria for LUCEMYRA
- nalmefene 2 mg/2 mL vial
- naloxone 0.4 mg/mL carpuject
- OPVEE nasal spray (nalmefene)
- ZURNAI 1.5 mg/0.5 mL autoinjector (nalmefene)

ii. TRIPTANS

Preferred Agents

- naratriptan tablet (generic for AMERGE)
- rizatriptan 5 mg and 10 mg MLT (generic for MAXALT MLT)
- rizatriptan 5 mg and 10 mg tablet (generic for MAXALT)
- sumatriptan succinate tablet (generic for IMITREX)
- zolmitriptan tablet (generic for ZOMIG)
- zolmitriptan ODT (generic for ZOMIG ZMT)

Preferred Agents with Criteria

- sumatriptan 6 mg/0.5 mL pen autoinjector (generic for IMITREX)
- sumatriptan 6 mg/0.5 mL vial (generic for IMITREX)
- sumatriptan 20 mg nasal spray (generic for IMITREX)
- sumatriptan 5 mg nasal spray (generic for IMITREX)

Non-Preferred Agents

- almotriptan malate tablet (generic for AXERT)
- eletriptan HBr tablet (generic for RELPAX)
- FROVA tablet (frovatriptan) (manufacturer obsolete 11/30/2025)
- frovatriptan succinate tablet (generic for FROVA)
- IMITREX kit (sumatriptan)
- IMITREX pen autoinjector (sumatriptan)
- IMITREX tablet (sumatriptan)
- MAXALT MLT (rizatriptan MLT)
- MAXALT tablet (rizatriptan)
- RELPAX tablet (eletriptan)
- sumatriptan succinate/naproxen sodium tablet (generic for TREXIMET)
- SYMBRAVO tablet (meloxicam/rizatriptan)
- TOSYMRA nasal spray (sumatriptan)
- ZEMBRACE SYMTOUCH pen (sumatriptan)
- zolmitriptan 2.5 mg and 5 mg nasal spray (generic for ZOMIG)
- ZOMIG tablet and nasal spray (zolmitriptan)

iii. COLONY STIMULATING FACTORS

Preferred Agents

- FYLNETRA syringe (pegfilgrastim-pbbk)
- NEUPOGEN vial and syringe (filgrastim)

Non-Preferred Agents

- **FILKRI syringe (filgrastim-LAHA)**
- FULPHILA syringe (pegfilgrastim-jmbd)
- GRANIX syringe and vial (tbo-filgrastim)
- LEUKINE vial (sargramostim)
- NEULASTA syringe and vial (pegfilgrastim)
- NEULASTA Onpro Kit (pegfilgrastim)
- NIVESTYM vial and syringe (filgrastim-aafi)
- NYPOZI syringe (filgrastim-txid)
- NYVEPRIA syringe (pegfilgrastim-apgf)
- RELEUKO syringe (filgrastim-ayow)
- ROLVEDON syringe (eflapegrastim-xnst)
- RYZNEUTA syringe (efbemalenograstim alfa-vuxw)
- STIMUFEND syringe (pegfilgrastim-fpgk)

- UDENYCA syringe and autoinjector (pegfilgrastim-cbqv)
- **UDENYCA ONBODY (pegfilgrastim-cbqv)**
- ZARXIO syringe (filgrastim-sndz)
- ZIEXTENZO syringe (pegfilgrastim-bmez)

iv. ERYTHROPOIESIS STIMULATING AGENTS

Preferred Agents with Criteria

- ARANESP syringe (darbepoetin alfa in polysorbate)
- EEPOGEN vial (epoetin alfa)
- RETACRIT vial (epoetin alfa)

Non-Preferred Agents with Criteria

- ARANESP vial (darbepoetin alfa in polysorbate)
- MIRCERA syringe (methoxy peg-epoetin beta)
- PROCRIT vial (epoetin alfa)
- REBLOZYL vial (luspatercept)

v. UREA CYCLE DISORDER

Preferred Agents with Criteria

- CARBAGLU tablet (carglumic acid) – brand name
- PHEBURANE pellet (sodium phenylbutyrate)

Non-Preferred Agents

- BUPHENYL powder (sodium phenylbutyrate)
- BUPHENYL tablet (sodium phenylbutyrate)
- carglumic acid tablet (generic for CARBAGLU)
- glycerol phenylbutyrate liquid (generic for RAVICTI)
- OLPRUVA pellet (sodium phenylbutyrate)
- RAVICTI liquid (glycerol phenylbutyrate)
- sodium phenylbutyrate powder (generic for BUPHENYL)
- sodium phenylbutyrate tablet (generic for BUPHENYL)

vi. VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITORS

Preferred Agents with Criteria

- AUSTEDO tablet (deutetrabenazine)
- AUSTEDO XR tablet (deutetrabenazine)
- AUSTEDO XR titration kit (deutetrabenazine)
- INGREZZA capsule and sprinkle (valbenazine)
- INGREZZA initiation pack (valbenazine)
- tetrabenazine tablet (generic for XENAZINE)

Non-Preferred Agents

- XENAZINE tablet (tetrabenazine)

vii. OPHTHALMIC ANTIBIOTICS

Preferred Agents

- bacitracin/polymyxin B ophthalmic ointment (generic for POLYCIN)
- CILOXAN (ciprofloxacin) 0.3% ophthalmic ointment
- ciprofloxacin 0.3% ophthalmic solution drops (generic for CILOXAN)
- erythromycin 0.5% ophthalmic ointment
- gentamicin 0.3% ophthalmic solution drops
- moxifloxacin 0.5% ophthalmic solution drops (generic for VIGAMOX)
- polymyxin B/trimethoprim ophthalmic solution drops (generic for POLYTRIM)
- tobramycin 0.3% ophthalmic solution drops (generic for TOBREX)

Non-Preferred Agents

- AZASITE (azithromycin) 1% ophthalmic solution drops
- bacitracin ophthalmic ointment 500 units/gm
- besifloxacin 0.6% ophthalmic suspension drops (generic for BESIVANCE)
- BESIVANCE (besifloxacin) 0.6% ophthalmic suspension drops – brand preferred
- gatifloxacin 0.5% ophthalmic solution drops (generic for ZYMAXID)
- **levofloxacin 0.5% ophthalmic drops (generic for QUIXIN)**
- moxifloxacin 0.5% ophthalmic solution drops (generic for MOXEZA)
- NATACYN (natamycin) 5% ophthalmic suspension drops – may be approved upon request after receiving documentation/attestation of fungal infection of the eye
- NEO-POLYCIN ophthalmic ointment (neomycin/bacitracin/Polymyxin B)
- neomycin/polymyxin B/bacitracin ophthalmic ointment
- neomycin/polymyxin B/gramicidin ophthalmic solution drops
- OCUFLOX (ofloxacin) 0.3% ophthalmic solution
- ofloxacin 0.3% ophthalmic solution drops (generic for OCUFLOX)
- POLYCIN (bacitracin/polymyxin B) ointment (manufacturer obsolete 12/26/2025)
- sulfacetamide 10% ointment, ophthalmic solution drops
- TOBREX (tobramycin) 0.3% ointment
- VIGAMOX (moxifloxacin) 0.5% ophthalmic solution drops

viii. OTIC ANTI-INFECTIVE AND ANTIBIOTIC/CORTICOSTEROID COMBOS

Preferred Agents

- acetic acid 2% otic solution
- acetic acid/HC otic solution
- ciprofloxacin/dexamethasone suspension (generic for CIPRODEX)
- neomycin/polymyxin/HC otic solution/suspension (generic for CORTISPORIN)
- ofloxacin otic drops (generic for FLOXIN)

Non-Preferred Agents

- CIPRO HC otic suspension (ciprofloxacin/hydrocortisone) – brand preferred
- ciprofloxacin/hydrocortisone otic suspension (generic for CIPRO HC)
- CORTISPORIN-TC otic suspension (neomycin/colist/hydrocortisone/thonzonium)
- ciprofloxacin otic solution (generic for CETRAXAL)

ix. SEIZURE RESCUE

Preferred Agents

- diazepam 2.5 mg kit (generic for DIASTAT)
- diazepam Rectal Gel System (generic for DIASTAT ACUDIAL)
- NAYZILAM nasal spray (midazolam)
- VALTOCO nasal spray (diazepam)

Non-Preferred Agents

- None

II. NEW OR REVISED PRIOR AUTHORIZATION DRUG CRITERIA

1. QUIOFIC (folic acid) 0.2 mg/mL oral solution

APPROVAL CRITERIA:

The recommendation is to add swallow criteria for this medication. The prescription will pay at point-of-sale if one of the following are met.

- Patient must be < 7 years of age; **OR**
- Patient has an NPO diagnosis in history

Patient not meeting swallow criteria as listed above will require prior authorization

- Prescriber must submit chart notes
- Prescriber must submit patient specific medical necessity over solid oral tablets of folic acid.

QUANTITY LIMITS:

- 5 mL (1 mg) per day = 2 bottles per month

2. DESMODA (desmopressin acetate) 0.05 mg/mL oral solution

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's packet insert or based on support from the official Compendia
- Beneficiary must be diagnosed with central diabetes insipidus (arginine vasopressin deficiency (AVP-D)) requiring antidiuretic replacement
- Beneficiary is not diagnosed with nephrogenic diabetes insipidus
- Beneficiary must not have a history of hyponatremia

- Beneficiary must not have moderate to severe renal impairment (defined as creatinine clearance (CLcr) less than 50 mL/min)
- Prescriber must submit the following:
    - Current chart notes
    - Therapies tried
    - If pediatric patient, treatment plan for ensuring fluid restriction
    - Current labs and baseline 24 hour urine volume
    - Patient specific medical necessity over desmopressin tablets or desmopressin nasal spray
- Initial PA approval for 3 months with subsequent approvals for 6 months

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must exhibit an improvement in symptoms (e.g., polyuria, nocturia, polydipsia) and urine volume
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of response to therapy
    - Documentation of continued need for the medication
    - Current labs, if warranted
    - Current 24 hour urine volume

3. YUVIWEL (navepegritide) 1.3 mg, 2.8 mg, and 5.5 mg kits

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's packet insert or based on support from the official Compendia
- Beneficiary must be diagnosed with achondroplasia (ACH) confirmed by both of the following:
    - Clinical presentation consistent with achondroplasia (e.g., proximal shortened arms and legs, macrocephaly, short fingers/toes) and radiographic findings (e.g., tubular bones, short pedicles on lateral spine, short femoral neck)
    - Genetic testing confirming the presence of fibroblast growth factor receptor 3 (FGFR3) gene variant
- Beneficiary must have open epiphyses
- Beneficiary will not be approved for YUVIWEL taken concomitantly with vosoritide (VOXZOGO) or any growth hormone medication
- Must be prescribed by, or in consultation with, a specialist knowledgeable in treating achondroplasia (e.g., geneticist or endocrinologist)
- Beneficiary must not have moderate or severe renal impairment (eGFR < 60 mL/min/1.73 m^2)
- Prescriber must submit the following:

- Current chart notes
- Current height, weight, and growth velocity as baseline
- Genetic test results and radiographic findings confirming the diagnosis
- Requested dose
- X-ray report demonstrating epiphyses status for patients 13-14 years of age and older

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive clinical response with an increase in height or increase in annualized growth velocity compared to baseline after 1 year
- Prescriber must submit the following:
  - Current chart notes
  - Current standing height, weight, and growth velocity
  - Confirmation of open epiphyses for patients 13-14 years of age and older
  - Requested dose
  - Letter of medical necessity for continued approval

QUANTITY LIMITS:

- 4 kits per 28 days

4. KYGEVVI (doxecitine and doxribtimine) 4 gm (2 gm each) powder

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's packet insert or based on support from the official Compendia
- Beneficiary must be diagnosed with thymidine kinase 2 deficiency (TK2d) with symptom onset on or before 12 years of age confirmed by genetic mutation in the TK2 gene
- Must be prescribed by a specialist with experience in treating TK2d (e.g., geneticist, neurologist, endocrinologist)
- Beneficiary with signs/symptoms of liver injury must have therapy interrupted until liver function tests return to baseline or stabilize. Consider re-starting at the last tolerated dose and increase the dose as tolerated
- Prescriber must submit the following:
  - Current chart notes with documentation of patient specific symptoms attributed to TK2d as baseline
  - Genetic testing confirming the TK2d diagnosis
  - Current labs including liver function tests
  - Current weight
  - Dose requested

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must have demonstrated a positive response defined as either slowing the rate of motor function decline and/or regaining motor milestones previously lost (e.g., required less ventilatory support or was able to remove feeding tube)
- Prescriber must submit the following:
    - Current chart notes with documentation of patient specific symptoms to compare to baseline
    - Current labs including liver function tests
    - Current weight
    - Dose requested

5. IMCIVREE (setmelanotide) 10 mg/mL solution

APPROVAL CRITERIA:

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- The beneficiary must be diagnosed with **ONE (1)** of the following:
    - Monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; **OR**
    - Monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS); **OR**
    - Acquired hypothalamic obesity (HO)
- Confirmation of diagnosis requires:
    - HO – Confirmed hypothalamic injury or dysfunction (e.g., craniopharyngioma) with rapid weight gain within the first year after injury/dysfunction onset
    - POMC, PCSK1, or LEPR deficiency – genetic testing that confirms variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance
    - BBS – Confirmed by presence of four major features associated with BBS or three major features plus two minor features; **AND**
        - Major features associated with BBS:
            - Rod-cone dystrophy
            - Polydactyly
            - Obesity
            - Learning disabilities
            - Hypogonadism in males
            - Renal abnormalities

        - Minor features associated with BBS:
            - Speech disorder/delay
            - Strabismus/cataracts/astigmatism
            - Brachydactyly/syndactyly
            - Developmental delay
            - Polyuria/polydipsia (nephrogenic diabetes insipidus)
            - Ataxia/poor coordination/imbalance
            - Mild spasticity (especially lower limbs)
            - Diabetes mellitus
            - Dental crowding/hypodontia/small roots/high arched palate
            - Left ventricular hypertrophy/congenital heart disease
            - Hepatic fibrosis
- The beneficiary must meet the following for obesity diagnosis:
    - POMC, PCSK1, or LEPR deficiency must have a baseline body mass index (BMI) ≥ 30 kg/m^2 or pediatric weight ≥ 95th percentile using growth chart assessment; **OR**
    - BBS must have a baseline BMI ≥ 30 kg/m^2 or pediatric weight ≥ 97th percentile using growth chart assessment; **OR**
    - HO must have a baseline BMI ≥ 30 kg/m^2 for adults or pediatric patients must have a BMI ≥ 95th percentile for age and sex.
- The medication must be prescribed by or in consultation with a specialist (e.g., endocrinologist, geneticist, obesity specialist)
- The beneficiary should not be approved or continue this therapy with any of the following:
    - Genetic testing does not confirm POMC, PCSK1, or LEPR deficiency or the variants are classified as benign or likely benign, and clinical symptoms do not support the BBS diagnosis, and there is no evidence of hypothalamus injury to support the HO diagnosis; **OR**
    - Doesn't meet obesity requirements; **OR**
    - Obesity is not determined to be related to POMC, PCSK1 or LEPR deficiency, BBS, or HO; **OR**
    - End stage renal disease (eGFR < 15 mL/min/1.73 m^2)
- Beneficiary with HO must be monitored closely if diagnosed with secondary adrenal insufficiency or central diabetes insipidus/arginine vasopressin deficiency
- The prescriber must submit all of the following:
    - Current chart notes
    - Current weight and BMI
    - Genetic testing confirming a diagnosis of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, **OR** clinical symptoms suggesting a BBS diagnosis, **OR** evidence of hypothalamus injury suggesting HO diagnosis; **AND**

    - Current estimated glomerular filtration rate (eGFR)
- Initial PA for 4 months

RENEWAL REQUIREMENTS:

- The beneficiary must remain compliant with therapy (defined as at least 75% utilization)
- The beneficiary diagnosed with POMC, PCSK1, or LEPR deficiency must have lost at least 5% of baseline body weight or 5% of baseline BMI for beneficiaries with continued growth potential after 12–16 weeks
- The beneficiary diagnosed with BBS must have lost at least 5% of baseline body weight or 5% of baseline BMI for beneficiaries < 18 years of age after 1 year with some improvement at 4 month review
- The beneficiary diagnosed with HO must at least a 5% reduction of BMI after 1 year with some improvement at 4 month review
- The beneficiary must continue to meet approval criteria
- The prescriber must submit the following:
    - Current chart notes; **AND**
    - Current weight and BMI

QUANTITY LIMITS:

- 9 vials per month

6. CONTEPO (fosfomycin disodium) 6 gm vial

APPROVAL CRITERIA:

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- Beneficiary must be diagnosed with complicated urinary tract infections (cUTI), including acute pyelonephritis, cause by susceptible isolates of *Escherichia coli* and *Klebsiella pneumoniae*
- Beneficiary with creatinine clearance <50 ml/min must have a reduced dose as outlined in the package insert
- Beneficiary must have serum electrolyte levels (sodium, potassium, calcium, magnesium, and phosphorus) monitored during treatment due to the high sodium content of CONTEPO
- Beneficiary with known QT prolongation or ventricular arrhythmias including a history of torsade de pointes should not take this medication
- Beneficiary that develops neutropenia (absolute neutrophil count less than 1500 cells/mm^3) should discontinue CONTEPO
- Prescriber must submit the following:
    - Current chart notes

- Culture/sensitivity results documenting resistance to typical first-line agents
- Current labs including CBC, renal function and electrolytes (monitor throughout treatment)
- Letter of medical necessity for the rationale of use over typical first-line agents
- Number of doses received if hospitalized

RENEWAL REQUIREMENTS:

- If the female beneficiary has had multiple complicated urinary tract infections (cUTI) in the last 1-2 months or if the male beneficiary has had a second cUTI, additional information must be provided including:
  - Consideration of anatomic abnormalities contributing to recurrent, complicated infections; **OR**
  - Consult with infectious disease specialist

QUANTITY LIMITS:

- #42 per claim

7. SAPHNELO (anifrolumab-fnia) 120 mg/0.8 mL pen/syringe

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration as specified in the manufacturer's package insert or supported in the official Compendia
- Beneficiary must be diagnosed with moderate to severe systemic lupus erythematosus (SLE) while receiving standard therapy along with the following:
  - Positive autoantibody test (e.g., anti-nuclear antibody [ANA] and/or anti-double-stranded DNA [anti- dsDNA]); **AND**
  - SLEDAI-2K score ≥6 points and/or Physician's Global Assessment [PGA] score ≥1
- The drug is prescribed by or in consultation with a rheumatologist.
- Beneficiary must not be diagnosed with severe active lupus nephritis or severe active central nervous system lupus
- Beneficiary is not receiving SAPHNELO in combination with BENLYSTA or another biologic (e.g., ACTEMRA, CIMZIA, ENBREL, HUMIRA, KINERET, ORENCIA, REMICADE, RITUXAN, SIMPONI, STELARA).
- The beneficiary is currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic and will remain on standard of care concomitantly with SAPHNELO.

- Prescriber must submit the following:
    - Current chart notes with documentation of any corticosteroid use/dose
    - Current labs including autoantibody test to support diagnosis
    - Medical necessity over supported immunosuppressive therapy alone (i.e., hydroxychloroquine, mycophenolate mofetil or azathioprine).

RENEWAL REQUIREMENTS:

- Beneficiary is not experiencing unacceptable toxicity (e.g., serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.).
- Beneficiary has a documented positive clinical response as evidenced by disease stability or improvement compared to pre-treatment baseline (e.g., SLEDAI-2K score, PGA score, and decrease in corticosteroid dose/usage)
- Beneficiary remains on at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic.
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of response to treatment

QUANTITY LIMITS:

- 4 syringes/pens per month

8. BAXFENDY (baxdrostat) 1 mg and 2 mg tablet

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's packet insert or based on support from the official Compendia
- Beneficiary must have uncontrolled hypertension (defined as systolic blood pressure ≥ 140) while on at least 2 antihypertensive agents including one diuretic
- Beneficiary must have eGFR ≥ 45 mL/min and serum potassium of ≥ 3.5 and < 5.0 mEq/L as baseline
- Beneficiary must be prescribed other antihypertensive drugs to be used concomitantly
- Prescriber must submit the following:
    - Current chart notes
    - Previous blood pressure medications trialed
    - Current labs including renal function, serum potassium and serum sodium
    - If has not trialed spironolactone, provide the medical necessity over the use of that medication

- Initial approval for 3 months with subsequent PA renewals for 6 months if medication is effective

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with a decrease in blood pressure compared to baseline
- Prescriber must submit the following:
    - Current chart notes
    - Current medication list
    - Current blood pressure

QUANTITY LIMITS:

Both strengths--#31/ 31 days

9. HEPCLUDEX (bulevirtide) vial

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's packet insert or based on support from the official Compendia
- Beneficiary must be diagnosed with chronic hepatitis delta virus (HDV) infection without cirrhosis or with compensated cirrhosis confirmed by all of the following:
    - Detectable serum HDV RNA level; **AND**
    - Elevated liver function tests (LFT) specifically ALT
- Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist
- Beneficiary must not have decompensated cirrhosis or hepatocellular carcinoma (HCC)
- Beneficiary must be treated for hepatitis B virus (HBV) infection concomitantly as clinically appropriate
- Prescriber must submit the following:
    - Current chart notes
    - Lab work confirming diagnosis of HBV and HDV along with liver function tests
    - Previous treatment for HBV, if applicable (e.g., entecavir, tenofovir, and plan for treating HBV
    - Attestation that beneficiary has been counseled on potential severe acute exacerbations of hepatitis D or hepatitis B if HEPCLUDEX is discontinued which would need to be monitored for at least 6 months after discontinuation

- Attestation that beneficiary or caregiver has been trained on proper reconstitution and administration

RENEWAL REQUIREMENTS:

- Beneficiary must be responding to HDV treatment after 52 weeks of treatment
  - Undetectable HDV RNA **OR** a ≥ 2 $\log_{10}$ IU/mL decline from baseline; **AND**
  - ALT normalization
- Beneficiary must not have developed decompensated cirrhosis or HCC
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including HDV RNA and LFTs

QUANTITY LIMITS:

- 30 vials/ 30 days

10. FILSPARI (sparsentan) 200 mg and 400 mg tablet

APPROVAL CRITERIA:

- The beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA-approved indication
- The beneficiary is prescribed no more than the maximum dose as specified in the manufacturer's package insert or supported in the official Compendia
- The beneficiary is diagnosed with **ONE (1)** of the following:
  - Primary immunoglobulin A nephropathy (IgAN) at risk for disease progression; **OR**
  - Focal segmental glomerulosclerosis (FSGS) needing to reduce proteinuria without nephrotic syndrome defined as urine protein excretion <3.5 g/day or nephrotic-range proteinuria and a normal serum albumin concentration
    - Designate FSGS subtype (i.e., primary, secondary, genetic)
- The beneficiary must discontinue any prescriptions of renin-angiotensin, aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren
- The beneficiary, prescriber, and pharmacy must all be certified with the FILSPARI REMS program
- The beneficiary should have tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) at maximally tolerated doses unless contraindicated
- The beneficiary diagnosed with primary FSGS should have tried and failed immunosuppression (e.g., glucocorticoid, calcineurin inhibitor (CNI)) unless contraindicated
- Prior to beginning FILSPARI, the beneficiary must receive the necessary supportive treatment as advised for all patients with persistent proteinuria,

including the use of RAS blockade, optimal BP control, and dietary salt restriction

- The beneficiary should not be approved with any of the following:
  - Baseline elevated aminotransferases > 3 times the ULN
  - Pregnancy (should be tested monthly)
  - Prescribed concomitant ACEI or ARB (cannot be on an ACEI or ARB with this med); **AND**
  - Clinically significant decrease in kidney function compared to baseline
- The prescriber must submit all of the following:
  - Current chart notes
  - Previous therapies
  - Current labs, including LFTs, eGFR, urine protein or UPCR
  - Confirmation of the IgAN diagnosis with renal biopsy results and labs
  - Confirmation of FSGS diagnosis along with FSGS subtype (i.e., primary, secondary, genetic) with renal biopsy results and labs
  - Attestation that the beneficiary has tested negative for pregnancy if of reproductive potential

RENEWAL REQUIREMENTS:

- The beneficiary has been compliant with therapy (defined as 75% utilization based on Medicaid claims)
- The beneficiary has documented improvement in proteinuria with a reduction in UPCR or urine protein from baseline
- The prescriber must submit the following:
  - Current chart notes
  - Current labs, including LFTs, eGFR, urine protein or UPCR; **AND**
  - Attestation that the beneficiary has tested negative for pregnancy if of reproductive potential

QUANTITY LIMITS:

- 200 mg--#31/31 days
- 400 mg--#62/31 days

11. BUTALBITAL MAXIMUM QUANTITY

The DUR Board voted to decrease the total quantity of butalbital (non-codeine) pills per month to more closely be aligned with the manufacturer package inserts. The scheduled changes for the maximum allowed per month are as follows:

- October 1, 2026—maximum per month will be #90 total
- April 1, 2027—maximum per month will be #60 total
- October 1, 2027—maximum per month will be #30 total

III. FRIENDLY REMINDERS

1. Any questions concerning various Medicaid topics (e.g., Medicaid enrollment, prescription coverage, provider manuals, and billing policies) may be researched using one of the following links.
   - **https://humanservices.arkansas.gov/divisions-shared-services/medical-services**
   - **https://humanservices.arkansas.gov/**
   - **https://ar.primetherapeutics.com/**

   Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member. For more information about PASSE, please refer to the website:
   https://humanservices.arkansas.gov/about-dhs/dms/passe/

2. **For vaccine billing and updates, visit the Welcome to Arkansas webpage.**
   - **https://humanservices.arkansas.gov/**
   - **https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/**

   For adult vaccines (ages 19 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:
   G0008 – Influenza immunization
   90471 – First vaccine administered
   90472 – Subsequent vaccines administered
   The injection administration code, **T1502,** will continue to be payable for beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only. If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211. Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website:
   https://humanservices.arkansas.gov/divisions-shared-services/medical-services/
   If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy:
   https://medicaid.afmc.org/services/arkansas-medicaid-management-information-system

3. **INCARCERATED PERSONS:**
   The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid beneficiaries who, on the date the prescription is filled, is incarcerated in a correctional or holding facility including juvenile correctional facilities and are detained pending disposition of charges or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid beneficiaries, including beneficiaries in a juvenile correctional facility, **the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment if billed to Medicaid**. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

4. **REGARDING MANUAL REVIEW PA REQUESTS:**

Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an exception to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a case-by-case basis through a manual review process. All manual review requests for prior authorization require, at a minimum, the prescriber to provide a letter explaining the medical necessity for the requested drug along with all written documentation to substantiate the medical necessity (e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc.). **Please note that starting the requested drug, including long-acting injectable antipsychotic agents, through either inpatient use, the use of office "samples", or by any other means, prior to a prior authorization request being reviewed and approved by the Medicaid Pharmacy Program does not necessitate Medicaid Pharmacy Program approval of the requested drug.**

5. **REGARDING EMERGENCY OVERRIDE:**
In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires prior authorization (e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug). **This provision applies only in an emergency when the Prime Therapeutics Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC beneficiaries and once per 60 days per drug class for LTC beneficiaries.

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, **https://ar.primetherapeutics.com/provider-documents**

6. **HARD EDIT ON EARLY REFILL:**
Non-controlled drugs:
The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits, or an approved PA must be in the system for the beneficiary for the higher dose or an early refill PA will not be approved.

Controlled drugs:
The hard edit disallowing early refills (ER) for controlled drugs sooner than 90% of days' supply expended was implemented January 20, 2021. This change includes opioids, CII stimulants, benzodiazepines, sedative hypnotics, etc.

7. **REFILL TOO SOON ACCUMULATION LOGIC:**
When a pharmacy refills a prescription claim early, the Medicaid system began adding together the accumulated "early days" filled. Each prescription is tracked by the Generic Sequence Number (GSN), which means the drug claim is the same generic name, same strength, and same dosage form, rather than tracking by prescription number or NDC.

Non-controlled drugs:
Once the beneficiary has accumulated an *extra* 12 days' supply for that GSN for non-controlled drugs, any incoming claim that is early will reject at point of sale. The accumulation edit is set so that the beneficiary cannot accumulate more than an *extra* 12 days' supply early during a 180-day period for non-controlled drugs.

Controlled drugs:
The RTS logic with Early Refill Accumulation Limit edit for controlled drugs will only allow an *extra* 7-days' supply accumulation through early fills in previous 180-day period.

8. **REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO BENEFICIARY:**
Pharmacies are required to reverse and credit back to Medicaid original prescriptions and refills if the medication was not provided to the beneficiary. Pharmacies should reverse and credit Medicaid within 14 days of the date of service for any prescription that was not provided to the beneficiary. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.

9. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:**
< 18 YEARS OF AGE:
Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Beneficiaries have an ongoing requirement for labs for metabolic monitoring every 6 months. When sending for the required metabolic labs, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.
For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form may be found at the following link.
https://ar.primetherapeutics.com/provider-documents
< 10 YEARS OF AGE:
Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent. All documentation, chart notes, signed informed consent, and required lab work must be submitted, and the manual review will be performed by the Medicaid Pharmacy Program psychiatrist.

10. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID BENEFICIARIES WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that beneficiary can be billed using the beneficiary's Medicaid ID. If medications are needed to treat remaining

family members, each prescription must be billed according to each family member's Medicaid ID number. Sanctions may be imposed against a provider for engaging in conduct that defrauds or abuses the Medicaid program. This could include billing a child's medication to a parent's Medicaid ID number and vice versa.

11. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:**
AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to $9 for Brand Drugs and $10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: **https://ar.primetherapeutics.com/provider-documents** A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website: **https://ar.primetherapeutics.com/provider-documents**

12. **OPIOID INFORMATION:**
To provide educational materials to prescribers and pharmacists on opioid dosing, opioid use disorder, medication assisted treatment and polypharmacy, an opioid information tab has been added to the Prime Therapeutics State Government Solutions website. **https://ar.primetherapeutics.com/provider-documents**

13. **HEPATITIS C TREATMENT INFORMATION:**
Educational information on treating Hepatitis C along with treatment consultations may be obtained through the Clinician Consultation Center.
    1) Link for the Clinician Consultation Center— **http://www.hepcap.org/hepatitis-c-consultation-warmline/**
    2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

    The clinical consultation staff may give advice on any of the following topics:
    - HCV staging & monitoring
    - Regimen selection & dosing
    - Drug interactions
    - HIV/HCV management strategies
    - Prior HCV treatment failure, including management of complex clinical problems such as cirrhosis and renal disease
    - HCV transmission & prevention
    - HCV screening & diagnostic testing
    - HCV in special populations (pregnancy, co-occurring substance use and/or alcohol use disorders, psychiatric disorders, post-transplant, ESRD/dialysis, pediatrics)

    The Clinician Consultation Center is not affiliated with Arkansas Medicaid, but the

information may be useful for providers in our state and provided only as an educational tool.

This advance notice provides you with the opportunity to contact, counsel, and change patients' prescriptions. If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at 501-320-6429.

If you have questions regarding this transmittal, or you need this material in an alternative format such as large print, please contact the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7895. For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the Gainwell Technologies Provider Assistance Center (PAC) at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.