ARKANSAS DEPARTMENT OF HUMAN SERVICES

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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Cynthia Neuhofel, Pharm.D. Division of Medical Services Pharmacy Program

DATE: November 23, 2022

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board October 19, 2022 meeting for the following:**
Manual review criteria for: Monoclonal antibodies (Dupixent®, Fasenra®, Nucala®, Tezspire®, Xolair®); Targeted Immunomodulators (Actemra®, Adbry®, Arcalyst®, Cibinqo®, Cimzia®, Cosentyx®, Enbrel®, Humira®, Ilaris®, Ilumya®, Kevzara®, Kineret®, Olumiant®, Orencia®, Otezla®, Rinvog®, Siliq®, Simponi®, Skyrizi®, Sotyktu®, Stelara®, Taltz®, Tremfya®, Xeljanz®); ADHD in adults; Ztalmy® (ganaxolone); Zoryve™ (roflumilast); Vtama® (tapinarof); Amvuttra™ (vutrisiran); Xaciato™ (clindamycin)
Point-of-Sale edits for: None
Preferred Drug List (PDL) therapeutic classes for DRC meeting November 9, 2022: inhaled antibiotics, non-triptan antimigraine, topical antiparasitics, inhaled long-acting beta agonists (LABA), inhaled short-acting beta agonists (SABA), inhaled long-acting muscarinic antagonists (LAMA), inhaled short-acting muscarinic antagonists (SAMA), inhaled corticosteroids (ICS), inhaled combination products (ICS/LABA), inhaled combination products (LABA/LAMA), inhaled combination products (ICS/LABA/LAMA), growth hormones, multiple sclerosis agents, pancreatic enzymes, pulmonary arterial hypertension (PAH), substance use disorder treatment (injection)

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I. ANNOUNCEMENTS

A. Pharmacist enrollment for provider type (PT) 95

Effective April 1, 2022, Arkansas Medicaid began accepting applications for individual pharmacist enrollment. This enrollment will allow pharmacists to have their own Medicaid ID and be an ordering, rendering, and prescribing provider (ORP).

- Pharmacists that intend to use their own NPI and be an ORP provider for pharmacy and medical claim billing must enroll with Arkansas Medicaid.
- The new enrollment type is atypical, provider type 95 – registered, non-credentialed with specialty code RX – Pharmacist.
- Submitting applications for this new individual pharmacist enrollment is via the Provider Application Portal, which is the most efficient way to submit applications. Paper applications may be submitted; however, those will take longer to process. The link to this new enrollment is the following: https://portal.mmis.arkansas.gov/armedicaid/provider/Home/tabid/135/Default.aspx, which would be the Provider Application Portal (Gainwell).
- Portal application requirements will be the online application, the pharmacist license, NPI, Taxonomy, and optional CLIA. See more below for additional details.
- If paper application must be used, the Practitioner Identification Form (PIN) must be filled out and submitted by faxing or mailing to the Provider Enrollment team. The Provider Enrollment team can be reached at 1-800-457-4454, or locally at 501-376-2211.
- **All pharmacies that intend to submit medical claims (including vaccine and immunization claims) on or after June 1, 2022 will require that an individual PT 95 RX NPI be submitted as the renderer for any medical claims. The PT 07 pharmacy NPI may not be submitted as the renderer.**

Additional application submission and overall tips:

- For the pharmacy license submitted, the pharmacy state license should match the state listed on the service location. The license should reflect pharmacist and should match the enrolling provider. Providers can submit a copy of their license card or a web verification from the state licensing board.
- The effective date for a pharmacist using their own NPI as an ORP provider will be the same day as the pharmacist was officially enrolled.
- For submitting CLIA, which is optional – the enrolling pharmacist provider must match either the laboratory name or the lab director's name. If the name on the application doesn't match either lab name or lab directors name, then the pharmacist provider has to submit a signed letter from the lab director giving permission for the pharmacist provider to use the CLIA. CLIA end date should always be 12-31-2299. As an optional requirement if all required items have been met, you can proceed to process the application without the CLIA if there is an issue with the CLIA submitted. Ensure the CLIA # is removed in this case.

II. PREFERRED DRUG LIST (PDL):

EFFECTIVE JANUARY 1, 2023
NOTE: Bolded medications indicate a change from the previous preferred drug list.

INHALED ANTIBIOTICS
Preferred Agents with Criteria
- Bethkis® (Tobramycin)
- Kitabis Pak® (Tobramycin)
- **Tobramycin (generic for Tobi®)**

Non-preferred Agents
- Arikayce® (amikacin liposome)—manual review required
- Aztreonam (generic for Cayston®)
- Cayston® (Aztreonam)
- Tobi Podhaler® (Tobramycin)
- Tobi® (Tobramycin)
- Tobramycin (generic for Bethkis®)
- Tobramycin pak (generic for Kitabis Pak®)

Approval criteria
- Diagnosis of cystic fibrosis in medical history

Denial criteria
- History of Cayston® in the past 50 days
- History of J Code for Tobramycin Injection in the past 60 days

Additional criteria
- Quantity limits apply

Approval criteria for Arikayce®:
- Will require manual review PA on a case-by-case basis
- Age ≥ 18 years old
- Patient must be diagnosed with refractory Mycobacterium avium complex (MAC) lung disease
    - Receiving ATS/IDSA guideline-based treatment with a multi-drug regimen for at least 6 months with persistently positive cultures
- Provide documentation of previous multi-drug MAC regimen
- Patient must be diagnosed with non-tuberculosis mycobacterial lung disease in accordance with the 2007 ATS/IDSA criteria:
    - Patient must have pulmonary symptoms with evidence of nodular bronchiectasis via radiograph and/or cavitary disease by CT
    - Appropriate exclusion of other diagnoses
    - Positive culture results from at least 2 separate sputum samples or positive culture via bronchial lavage or wash or via transbronchial lung biopsy
- Provide current labs including CBC and basic metabolic panel
- If child-bearing age, recommend a pregnancy test due to risk of congenital deafness

Denial criteria for Arikayce®:
- Patients with non-refractory MAC lung disease
- Currently takes medications associated with neurotoxicity, nephrotoxicity, and ototoxicity.
- Currently takes ethacrynic acid, furosemide, urea, or intravenous mannitol due to increased aminoglycoside toxicity.
- Pregnancy due to potential birth defects.
- FEV1 < 30% predicted
- Active pulmonary malignancy or active pulmonary TB
- Lung transplant recipient
- Conditions requiring continuous oxygen supplementation
- Smoking within the last 6 months

ANTIMIGRAINE AGENTS FOR PREVENTION

Preferred Agents with Criteria

- Emgality® (galcanezumab) injection 120 mg pen and syringe
- **Nurtec ODT® (rimegepant)**
- **Aimovig® (Erenumab-aooe) 70 mg and 140 mg autoinjector**

Non-Preferred Agents

- Ajovy® (fremanezumab-vfrm) injection 225mg syringe
- Emgality® (galcanezumab) injection 100 mg pen and syringe
- Qulipta tablets® (atogepant)

Approval Criteria for Preferred Agents with Criteria

- Any new medications for migraine prevention released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.
- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
- Recipient must have a diagnosis of either:
    - Chronic migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) with ≥ 15 headache days per month with
    - ≥ 8 migraine days per month (EMGALITY, AJOVY, or AIMOVIG); OR
    - Episodic migraine or episodic cluster headache (EMGALITY, NURTEC ODT, or QULIPTA); OR
- Diagnosis consistent with FDA indication; AND
- Recipient has documented failure of a 3-month trial of at least ONE agent from TWO of the following preventative classes:
    - Anticonvulsants (e.g., valproate, topiramate)
    - Antidepressants (e.g., amitriptyline, venlafaxine)
    - Beta blockers (e.g., propranolol, metoprolol, atenolol)
- Prescriber must submit the following:
    - Current chart notes; AND
    - Documentation of migraine frequency and severity/duration; AND
    - List of all therapies trialed with timeframes; AND
    - Attestation that medication overuse headaches have been ruled out.

Denial Criteria

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- If approved, recipient does not have a reduction from baseline in monthly migraine days or migraine severity; OR
- Recipient is not adherent to prescribed dose; OR
- Recipient has medication overuse headache caused by opiate overuse or other headache medication overuse as identified by the prescriber; OR
- Beneficiary is 65 years of age; OR
- Recipient has any of the following:
    - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
    - Requires continued use of a strong CYP3A inducer (rifampin) – NURTEC ODT
    - End stage renal disease (CrCl <15 mL/min) –NURTEC ODT
    - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA

ANTIMIGRAINE AGENTS FOR ACUTE MIGRAINE TREATMENT (no triptans)

Preferred Agents with Criteria

- Nurtec ODT® (rimegepant)

Non-Preferred Agents

- Migranal® nasal (dihydroergotamine mesylate)
- Ubrelvy® (ubrogepant)
- Reyvow® (lasmiditan succinate)
- Elyxyb® (celecoxib)
- Dihydroergotamine mesylate nasal (generic for Migranal®)
- Dihydroergotamine mesylate injection (generic for DHE-45®)
- Trudhesa nasal (dihydroergotamine mesylate)

Approval Criteria for Preferred Agents with Criteria

- Any new medications for acute migraine treatment released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.
- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
- Recipient must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) OR a diagnosis consistent with FDA indication; AND
- Recipient must have a failure of at least TWO (2) preferred 5HT1B/1D receptor agonists (triptans) using two (2) different chemical agents not just different dosage forms at maximally tolerated doses AND one of those trials should include a non-steroidal anti-inflammatory steroid (NSAID) unless recipient has one of the following contraindications:
    - For triptans
        - Ischemic coronary artery disease; OR
        - Arrhythmias; OR
        - History of stroke or transient ischemic attack (TIA); OR
        - Peripheral vascular disease; OR
        - Ischemic bowel disease; OR
        - Uncontrolled hypertension
    - NSAID allergy
- Prescriber must submit the following:
    - Current chart notes; AND
    - Documentation of migraine frequency and severity/duration; AND
    - List of all therapies trialed with timeframes; AND
- Attestation that medication overuse headaches have been ruled out

Denial Criteria

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient requires continued use of a strong CYP3A4 inhibitor (i.e. ketoconazole, itraconazole, clarithromycin, etc.) or a strong CYP3A4 inducer (rifampin) for both UBRELVY and NURTEC ODT; recipient requires concomitant use of P-gp (i.e. amiodarone, carvedilol, macrolides) or BCRP inhibitors (i.e. statins) for NURTEC ODT; OR
- Recipient has end stage renal disease (CrCl < 15ml/min) OR
- NURTEC ODT recipient has severe hepatic impairment (Child-Pugh Class C); OR
- UBRELVY recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh
- Class C) or severe renal impairment (CLcr 15-29 mL/min); OR
- Recipient does not have improvement while on the oral CGRP agonist.

TOPICAL ANTIPARASITICS

Preferred Agents

- Permethrin 1% topical liquid OTC (e.g., Lice Killing liquid, Lice Treatment)
- Piperonyl butoxide 4% /Pyrethrum extract 0.33% OTC (e.g., Lice Killing Shampoo, Complete Lice Treatment, Lice Killing shampoo)
- Permethrin 5% cream (generic for Elimite™)
- Natroba 0.9%™ (spinosad suspension)—**BRAND ONLY**

*BRAND Natroba may be filled once every 60 days. This medication should not, in general, require retreatment. However, if retreatment is required additional chart notes documenting reason for retreatment (re-infestation, product did not completely kill all nits, etc) will be needed.

Non-Preferred Agents

- Croton® lotion 10% (crotamiton)
- Eurax™ cream/lotion 10% (crotamiton)
- Ivermectin 0.5% lotion (generic for Sklice®)
- Lindane 1% shampoo
- Malathion lotion 0.5% (generic for Ovide®)
- Ovide® lotion 0.5% (malathion)
- Sklice® lotion 0.5% (ivermectin)
- Spinosad suspension 0.9% (generic for Natroba™)
- Vanalice™ gel (piperonyl butoxide, pyrethrins)

INHALED LONG-ACTING BETA AGONISTS (LABA)

Preferred Agents with Criteria

- Serevent Diskus® (salmeterol xiafoate)

Non-preferred Agents

- Arformoterol inhalation solution (generic for Brovana®)
- Brovana® inhalation solution (arformoterol)
- Formoterol fumarate inhalation solution (generic for Perforomist®)
- Perforomist® inhalation solution (formoterol fumarate)
- Striverdi Respimat® (olodaterol)

Approval Criteria for Preferred Long-Acting Beta Agonists

- COPD diagnosis in history in previous 2 years; AND
- Beneficiary is ≥ 40 years of age; AND
- No Therapeutic Duplication (TD) with overlapping days' supply between drugs in the same drug classification.

INHALED SHORT-ACTING BETA AGONISTS (SABA)

Preferred Agents

- Albuterol sulfate 0.63mg/3ml solution
- Albuterol sulfate 1.25mg/3ml solution
- Albuterol sulfate 2.5mg/0.5ml solution
- Albuterol sulfate 2.5mg/3ml solution
- Albuterol sulfate 5mg/ml solution
- Proventil HFA® (albuterol HFA)—**BRAND ONLY**
- Ventolin HFA® (albuterol HFA)—**BRAND ONLY**

Non-preferred Agents

- Albuterol HFA® (generic for Ventolin HFA®, Proventil HFA®)
- Levalbuterol HFA (generic for Xopenex HFA®)
- Levalbuterol inhalation solution (generic for Xopenex®)
- ProAir Digihaler® (albuterol sulfate inhalation powder)

- ProAir RespiClick® (albuterol sulfate inhalation powder)
- Xopenex HFA® (levalbuterol)
- Xopenex® inhalation solution (levalbuterol)

INHALED LONG-ACTING MUSCARINIC ANTAGONISTS (LAMA)

Preferred Agents with Criteria

- Spiriva Handihaler® (tiotropium bromide)

Non-preferred Agents

- Incruse Ellipta® (umeclidinium bromide)
- Lonhala Magnair® (glycopyrrolate)
- Spiriva Respimat® (tiotropium bromide)
- Tudorza Pressair® (aclidinium bromide)
- Yupelri® (revefenacin)

Approval criteria for Preferred Long-Acting Muscarinic Antagonists

- Diagnosis of COPD in Medicaid history in previous 2 years; AND
- No therapeutic duplication with overlapping days' supply between any medications in the same class AND
- Medicaid recipient is ≥ 40 years of age

INHALED SHORT-ACTING MUSCARINIC ANTAGONISTS (SAMA)

Preferred Agents with Criteria:

- Atrovent HFA® (ipratropium bromide)
- Combivent Respimat® (ipratropium/albuterol)
- Ipratropium bromide solution (generic for Atrovent® solution)
- **Ipratropium/albuterol sulfate (generic for Duoneb® inhalation solution)**

Non-preferred Agents

- None

Approval criteria for Preferred Short-Acting Muscarinic Antagonists

One of the following diagnoses or procedures:

- Anoxic brain injury (G93.1)
- COPD (J44.9, J44.1, J44.0)
- Heart transplant (Z94.1)
- Quadriplegic cerebral palsy (G80.0)
- Respiratory insufficiency
  J80 — Acute respiratory distress syndrome
  J96.10 — Chronic respiratory failure
  J96.20 — Acute and chronic respiratory failure
- Tracheostomy (Z93.0)
- Tracheomalacia congenital (Q32.0)

INHALED CORTICOSTEROIDS (ICS)

Preferred Agents without Criteria

- Asmanex Twisthaler® (mometasone furoate)
- **Flovent Diskus® (fluticasone)**
- Flovent HFA® (fluticasone propionate)—**BRAND ONLY**
- **Pulmicort Flexhaler® (budesonide)**

Preferred Agents with Criteria

- Budesonide respules (generic for Pulmicort Respules®)

Approval criteria for Budesonide Respules

- Criteria 1: Recipient < 4 years of age (maximum dose is 2 mg/day)
  OR
- Criteria 2: Regardless of age, recipient has a billed diagnosis of Eosinophilic Esophagitis
  - Age < 10 years—maximum dose is 2 mg/day
  - Age ≥ 10 years—maximum dose is 4 mg/day

Non-preferred Agents

- Alvesco® (ciclesonide)
- Armonair Digihaler® (fluticasone propionate)
- Arnuity Ellipta® (fluticasone furoate)
- Asmanex HFA® (mometasone furoate)
- Fluticasone HFA (generic for Flovent HFA®)
- Pulmicort Respules® (budesonide)
- QVAR Redihaler® (beclomethasone dipropionate)

INHALED COMBINATION PRODUCTS (ICS/LABA)

Preferred Agents with Criteria

- Advair Diskus® (fluticasone propionate/salmeterol)—**BRAND ONLY**
- **Advair HFA® (fluticasone propionate/salmeterol)**
- Dulera® (mometasone furoate/formoterol fumarate)
- Symbicort® (budesonide/formoterol fumarate)—**BRAND ONLY**

Approval Criteria for Symbicort® and Dulera® and Advair Diskus® and Advair HFA®

Criterion 1:

- COPD diagnosis in the past two years AND
- ≥ 40 years old

Criterion 2:

- Paid drug claim in drug history in the last six months for Advair Diskus®, Dulera®, Symbicort®

Criterion 3:

- Age: > 4 Years of Age AND
- Asthma diagnosis in the past two years

Criterion 4:

- Age > 4 Years of years old AND
- One of the following criteria below:
  - ≥ Three inhaled corticosteroid claims in the last 120 days, OR
  - ≥ Three oral steroid claims in the last 120 days, OR
  - Combination for ≥ three claims (as defined below) in the last 120 days:
    - One Inhaled Corticosteroid + 2 Oral Steroids
    - Two Inhaled Corticosteroids + 1 Oral Steroids

Quantity Limits

Symbicort®--#2 inhalers per month for 120 actuation size (If the recipient needs >8 puffs per day, a PA can be submitted to approve in additional inhaler.)
Dulera®--#2 inhalers per month
Advair Diskus® and Advair HFA®--#1 inhaler per month
NOTE: Advair Diskus® and Advair HFA® are not recommended for SMART therapy and should not be used for rescue.)

Non-preferred Agents

- AirDuo Digihaler® (fluticasone/salmeterol)
- AirDuo RespiClick® (fluticasone/salmeterol)
- Breo Ellipta® (fluticasone furoate/vilanterol)
- Budesonide/formoterol (generic for Symbicort®)—**GENERIC ONLY**
- Fluticasone/salmeterol (generic for Advair® Diskus)—**GENERIC ONLY**

- Fluticasone/salmeterol (generic for AirDuo® RespiClick)
- Fluticasone/vilanterol (generic for Breo Ellipta®)
- Wixela Inhub® (fluticasone/salmeterol)

INHALED COMBINATION PRODUCTS (LABA/LAMA)

Preferred Agents with Criteria

- **Anoro Ellipta® (umeclidinium/vilanterol)**
- Bevespi Aerosphere® (formoterol/glycopyrrolate)
- **Stiolto Respimat® (tiotropium/olodaterol)**

Non-preferred Agents

- Duaklir Pressair® (aclidinium/formoterol)

Approval Criteria for Preferred LABA/LAMA

Criterion 1:

- COPD diagnosis in the past two years; AND
- ≥ 40 years old; AND
- No therapeutic duplications within same class(es)

OR

Criterion 2: Paid drug claim in drug history for Bevespi® or Anoro Ellipta® in the last six months

INHALED COMBINATION PRODUCTS (ICS/LABA/LAMA)

Preferred Agents

- None

Non-preferred Agents

- Breztri® (budesonide, glycopyrrolate, formoterol)
- Trelegy Ellipta® (fluticasone, umeclidinium, vilanterol)

GROWTH HORMONES

Preferred Drugs that require manual review for prior authorization

- Genotropin® (somatropin)
- **Norditropin® (somatropin)**

Non-preferred Agents

- Humatrope® (somatropin)
- Nutropin AQ Pen® (somatropin)
- Omnitrope® (somatropin)
- Saizen® (somatropin)
- Skytrofa® (lonapegsomatropin-tcgd)
- Zomacton® (somatropin)
- Zorbtive® (somatropin)

Criteria for Growth Hormones

In children, we may need to question continuation when growth velocity is ≤ 2.5 cm/year.

Criterion 1:

- Recipient < 18 years of age
- Recipient has one of the following diagnoses:
    - Diagnosis of Prader-Willi Syndrome (PWS) with the following exceptions
        - Severe obesity (>225% of IBW)
        - Untreated severe obstructive sleep apnea
        - Untreated or uncontrolled diabetes, hypothyroidism, or adrenal insufficiency
    - Diagnosis of Turner Syndrome

    - Diagnosis of Noonan Syndrome
    - Diagnosis of chronic renal insufficiency or end-stage renal disease awaiting transplant
- Provocative GH stimulation test is not required
- Epiphyses should remain open during treatment and should be monitored beginning at 13-14 years of age. Bone age should be done at least yearly to verify that the epiphyses are open. Growth velocity can be taken into consideration to determine efficacy. If the growth velocity has slowed regardless of epiphyses status, use your best judgement on continuation.

Criterion 2:
- Recipient < 18 years of age
- Recipient has one of the following diagnoses:
    - Panhypopituitarism
    - Craniopharyngioma
    - Septo-optic dysplasia
- Provocative GH stimulation test and bone age are not required

Criterion 3:
- Recipient < 18 years of age
- Recipient has abnormal growth velocity and height below the mean for gender and age
- Recipient has one of the following diagnoses:
    - Growth Hormone Deficiency/Pituitary Dwarfism
    - Iatrogenic Pituitary Disorder
    - Unspecified disorder of the pituitary gland
- Epiphyses should remain open during treatment and should be monitored beginning at 12-14 years of age. Bone age should be done at least yearly to verify that the epiphyses are open. Growth velocity can be taken into consideration to determine efficacy. If the growth velocity has slowed regardless of epiphyses status, use your best judgement on continuation.
- Expected tests/labs for initial approval
    - Low growth hormone
    - Low IGF-1 and/or IFGBP-3 in addition to stim tests
    - Thyroid function test to rule out hypothyroidism
    - Delayed bone age—typically determined from x-ray of hand and wrist
    - MRI or CT scan to rule out pituitary gland issues
    - Provocative GH stimulation test unless recipient has one of the following:
        - Pituitary abnormality (pituitary anomaly, tumor, or irradiation)
        - Newborn with congenital pituitary abnormality, hypoglycemia, and GH < 5 mcg/L
        - Extreme short stature (e.g., height < -3 SD), normal nutrition, significantly reduced IGF-1 and/or IGFBP-3, and delayed bone age

Criterion 4:
- Recipient > 18 years of age and diagnosed with child onset GHD
- Has one of the following diagnoses:
    - Growth Hormone Deficiency/Pituitary Dwarfism
    - Iatrogenic Pituitary Disorder
    - Unspecified disorder of the pituitary gland
- Expected tests/labs
    - Failure of 2 provocative GH stimulation tests as an adult or after documented epiphyses closure
    - Low IGF-1 and/or IGFBP-3

Criterion 5:
- Recipient > 18 years of age
- Has one of the following diagnoses
    - Panhypopituitarism
    - Craniopharyngioma
    - Septo-optic dysplasia
- Continued symptoms with low GH and IGF-1. Labs should be measured yearly to determine GH dose.

MULTIPLE SCLEROSIS AGENTS

Preferred Agents without Criteria

- Avonex® (Interferon Beta – 1A injection)
- Copaxone® 20 mg injection (glatiramer)—**BRAND ONLY**
- **Dimethyl fumarate (generic for Tecfidera®)**

Non-Preferred Agents

- Aubagio® tablet (teriflunomide)
- Bafiertam® (monomethyl fumarate)
- Betaseron® (Interferon Beta – 1B injection)
- Copaxone® 40 mg injection (glatiramer)
- Extavia® (Interferon Beta – 1B injection)
- Fingolimod capsule (generic for Gilenya®)
- Gilenya® capsule (fingolimod)
- Glatiramer acetate 20 mg and 40 mg injection (generic for Glatopa®)
- Glatiramer acetate 20 mg and 40 mg injection (generic for Copaxone®)
- Glatopa® injection (glatiramer)
- Kesimpta® pen (ofatumumab)
- Mavenclad® tablet (cladribine)
- Mayzent® tablet (siponimod)
- Plegridy® pen and syringe (Peginterferon Beta – 1A)
- Ponvory® tablet (ponesimod)
- Rebif®/Rebif Rebidose (Interferon Beta – 1A/albumin)
- Tascenso ODT (fingolimod)
- **Tecfidera® (dimethyl fumarate)—BRAND ONLY**
- Vumerity® (diroximel fumarate)
- Zeposia® capsule (ozanimod hydrochloride)

PANCREATIC ENZYMES

Preferred Agents

- Creon®
- Zenpep®

Non-preferred Agents

- Viokace®
- Pertzye®

PULMONARY ARTERIAL HYPERTENSION AGENTS (PAH)

Preferred PAH Agents with No Criteria

- Treprostinil vials (generic for Remodulin®)
- **Veletri® vials (epoprostenol)—BRAND ONLY**

Preferred PAH Agents with PA Criteria

- **Ambrisentan tablets (generic for Letairis®)**
- Sildenafil tablets (generic for Revatio®)
- Sildenafil vials
- Tadalafil tablets (generic for Adcirca®)
- Tracleer® tablet (bosentan)—**BRAND ONLY**

Non-preferred Agents

- Adcirca® tablet (tadalafil)--**BRAND**
- Adempas® tablets (riociguat)
- Bosentan tablet (generic for Tracleer®)
- Epoprostenol vials (generic for Flolan®)

- Epoprostenol vials (generic for Veletri®)
- Flolan® vials (epoprostenol)
- **Letairis® tablets (ambrisentan)—BRAND**
- Opsumit® tablets (macitentan)
- Orenitram® tablets (treprostinil)
- Remodulin® vials (treprostinil)
- Revatio® suspension (sildenafil)—**BRAND PREFERRED OVER GENERIC (when approved)**
- Revatio® tablet (sildenafil)—**BRAND**
- Sildenafil suspension (generic for Revatio®)—**BRAND PREFERRED OVER GENERIC (when approved)**
- Tadliq® suspension (tadalafil)
- Tracleer® suspension (bosentan)
- Tyvaso® vial and Tyvaso® DPI (treprostinil)
- Uptravi® injection (selexipag)
- Uptravi® tablets (selexipag)
- Ventavis® inhalation (iloprost)

SUBSTANCE USE DISORDER TREATMENTS (injectable only)
https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Buprenorphine_Agents.pdf
https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_VivitrolIM.pdf

Preferred Manual Review MAT Injectables:

- Vivitrol® IM (naltrexone for extended-release injectable suspension) +

+ Vivitrol® may be billed at point-of-sale in a pharmacy setting or through the patient's medical benefits.

MAT Medical Program Billing:

- Sublocade® SQ Injection (buprenorphine extended-release) *

*The PA's for Sublocade® will be reviewed by the State Pharmacy Unit. Please provide the Statement of Medical Necessity for Buprenorphine Agents (see above link). However, Sublocade® is NOT billable currently at point-of-sale in a pharmacy setting. They will still need to be coded properly and billed through the medical program.

III. PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED):

EFFECTIVE OCTOBER 19, 2022

1. MONOCLONAL ANTIBODIES

APPROVAL CRITERIA FOR ASTHMA (Dupixent®, Fasenra®, Nucala®, Tezspire®, and Xolair®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy or immunology
- Recipient must have a diagnosis consistent with FDA indications. (Current indications as of 10/5/2022.)
  - **NUCALA**—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype
  - **FASENRA**—add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype
  - **DUPIXENT**—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
  - **TEZSPIRE**—add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype
  - **XOLAIR**—adults and pediatric patients 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
- Recipient must have moderate to severe asthma as defined by at least **TWO** of the following:

  - Pre-bronchodilator FEV1 < 80% for ≥ 18 years of age **OR** FEV1 < 90% for < 18 years of age
  - 2 or more exacerbations despite compliance on ICS plus an additional controller medication in the last year. Exacerbation is defined as:
    - Treatments with systemic corticosteroids
    - Medical treatments (e.g., emergency room visits or hospitalizations)
    - Combination of the 2 above
  - Documentation of functional impairment due to poor asthma control (e.g., impaired activities of daily living, continued dyspnea)
- Recipient must be 100% compliant on at least two asthma maintenance medications for the last 12 months
  - One medication must be an inhaled corticosteroid at a maximized dose
  - ICS/LABA combination products count as two medications
- Recipient has no therapeutic duplication with any other monoclonal antibodies
- Recipient must be a non-smoker
- Recipient with pre-existing helminth infection must be treated prior to beginning therapy
- 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)
    - Baseline serum IgE levels, body weight, and completed form for XOLAIR
  - Baseline Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only
  - Current Pulmonary Function Test results
  - If the request is for a non-preferred product, provide a letter of medical necessity for requested product over the preferred monoclonal antibody (currently FASENRA) and other therapies outlined in treatment guidelines.

CONTINUATION CRITERIA FOR ASTHMA:

- Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection
- 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
  - Current Asthma Control Questionnaire (ACQ-5) for all patients **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** (1) of the following:
  - Recipient must have an improvement in FEV1 over baseline after 12 months
  - Recipient must have fewer exacerbations
  - Recipient must have a decrease in blood eosinophil count **OR** serum IgE **OR** decrease in oral corticosteroid usage (depending on medication)
  - Recipient must have improved asthma control and quality of life scores

APPROVAL CRITERIA FOR ATOPIC DERMATITIS (Dupixent®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Recipient has a documented diagnosis of moderate to severe atopic dermatitis with at least TWO of the following (baseline at time of biologic 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
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists

- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
    - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
        - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children
        - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- Prescriber must submit
    - 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
    - Letter of medical necessity over other treatment options for atopic dermatitis

CONTINUATION CRITERIA FOR ATOPIC DERMATITIS:

- Recipient is compliant on this medication
- Recipient 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 severity scores; **OR**
    - Decrease in BSA impacted; **OR**
    - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
    - Current chart notes
    - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

APPROVAL CRITERIA FOR NASAL POLYPS (Dupixent®, Nucala®, and Xolair®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of chronic rhinosinusitis with nasal polyposis
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy, or immunology
- Recipient must have a trial and failure of at least TWO of the following:
- Intranasal saline with nasal corticosteroids for three (3) months (e.g., fluticasone, beclomethasone, budesonide)
    - Nasal corticosteroids with antileukotriene (e.g., montelukast) for three (3) months
    - Oral corticosteroid therapy for 45 days consecutively
    - At least one prior nasal surgery followed by nasal corticosteroids
- 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
    - Documentation that concomitant nasal corticosteroids are prescribed

CONTINUATION CRITERIA FOR NASAL POLYPS

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

- Current chart notes with description of polyps
- Current body weight for dose determination for Xolair®
- Requested dose

APPROVAL CRITERIA FOR EOSINOPHILIC ESOPHAGITIS (Dupixent®)

- Recipient must be ≥ 12 years of age and at least 40 kg OR the minim age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient 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** 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)
- Recipient must have at least a 12 week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide) and proton pump inhibitors (e.g., pantoprazole or omeprazole)
- 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
  - Baseline recipient determined Dysphagia Symptom Questionnaire (DSQ) score

CONTINUATION CRITERIA FOR EOSINOPHILIC ESOPHAGITIS:

- Recipient 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
- Prescriber must submit the following:
  - Current chart notes
  - Current recipient determined DSQ score
  - Current eos/hpf

APPROVAL CRITERIA FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (Nucala®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia (>$1.0x10^9$ /Liter and/or >10% of leucocytes)
- Recipient has a history of relapsing or refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids
- Recipient must be on a stable dose of oral prednisolone or prednisone of ≥7.5 mg/day for at least four (4) weeks
- If Recipient is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four (4) weeks
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has no therapeutic duplication with any other monoclonal antibodies
- Recipient 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
- 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)
  - Medical necessity over corticosteroids and/or immunosuppressive therapy

CONTINUATION CRITERIA FOR EGPA

- Recipient must be compliant on this medication
- Recipient 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
- Prescriber must submit the following:
  - Current chart notes
  - Current corticosteroid dose
  - Current BVAS

APPROVAL CRITERIA FOR HYPEREOSINOPHILIC SYNDROME (Nucala®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has documented at least 2 HES flares within the past 12 months while on stable HES therapy with at least TWO of the following:
  - Chronic or episodic corticosteroids
  - Immunosuppressants
  - Cytotoxic therapy
- Recipient has a baseline blood eosinophil count of at least 1000 cells/µL
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried and response
  - Current labs including CBCs and LFTs if on methotrexate or azathioprine

CONTINUATION CRITERIA FOR HYPEREOSINOPHILIC SYNDROME

- Recipient must be compliant on this medication
- Recipient has a positive response with a decrease in HES flares and a decrease in blood eosinophil count
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBCs
  - Documentation of HES flares since beginning treatment

APPROVAL CRITERIA FOR CHRONIC SPONTANEOUS URTICARIA (Xolair®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of chronic spontaneous urticaria (CSU) while remaining symptomatic despite H1 antihistamine treatment. CSU was formerly called chronic idiopathic urticaria (CIU)
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient should minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, friction from clothing)
- Recipient's IgE level and XOLAIR form for asthma are not required
- Recipient's baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16 despite previous treatment outlined below
- Recipient must have tried and failed the following:
  - 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; AND
  - Alternative nsAH at 4 times the normal daily dose for a minimum of 4 weeks OR H_2 antagonist; AND
  - Add a Leukotriene receptor antagonist to the nsAH or H_2 antagonist for a minimum of 4 weeks; AND
  - Add cyclosporine to the above treatment dosed at 4 mg/kg (based on ideal body weight) for a minimum of 8 weeks.
- Prescriber must submit the following:
  - Current chart notes
  - Baseline description of urticaria
  - Baseline UAS7

- Previous therapies tried with duration.
- Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
- Letter of medical necessity over other treatment options

CONTINUATION CRITERIA FOR CSU

- Recipient must be compliant on this medication
- Recipient must have a positive response with a decrease in UAS7 and decrease in urticaria symptoms
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of current symptoms
  - Current UAS7

APPROVAL CRITERIA FOR PRURIGO NODULARIS (Dupixent®)

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease **OR** has a comorbidity of moderate to severe atopic dermatitis
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
  - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
    - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** 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; **AND**
    - Intralesional corticosteroid use if a few large PN lesions
  - At least **ONE** trial of systemic immunomodulatory therapy from the following unless contraindicated (for recipients ≥ 10 years of age):
    - Cyclosporine for a minimum of 6 weeks
    - Azathioprine for a minimum of 12 weeks
    - Methotrexate for a minimum of 12 weeks
- 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
  - If no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

CONTINUATION CRITERIA FOR PN:

- Recipient 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; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
  - Current chart notes
  - Current BSA and pruritis test scores (i.e., NRS, IGA)

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2. TARGETED IMMUNOMODULATORS

APPROVAL CRITERIA FOR PLAQUE PSORIASIS
(Cosentyx®, Enbrel®, Humira®, Ilumya®, Otezla®, Siliq®, Skyrizi®, Stelara®, Taltz®, Tremfya®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient must trial ≥ 6 months with at least ONE product from each of the following (6 months of topical and 6 months of systemic):
  - Topical drug therapy with corticosteroids, calcipotriene, calcitriol, tazarotene, roflumilast, or tapinarof
  - Systemic drug therapy with methotrexate, acitretin, or cyclosporine
- Recipient must have tried and failed phototherapy or have a contraindication
- Recipient continues to have symptoms after trial of conventional therapy with at least ONE of the following:
  - Involvement of ≥10% body surface area (BSA)
  - Psoriasis Area and Severity Index (PASI) score ≥12
  - Plaque location severely impacts quality of life (i.e., head/neck, palms, soles of feet, genitalia)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current psoriasis description with BSA and PASI score
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR PSORIATIC ARTHRITIS AND RHEUMATOID ARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist treating psoriatic arthritis
- Recipient has a documented diagnosis of psoriatic arthritis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs
- Trial and failure with ≥ 6 months of any of the following:
  - Hydroxychloroquine
  - Methotrexate
  - Sulfasalazine
  - Leflunomide
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current labs as baseline (e.g., Erythrocyte Sedimentation Rate, C-Reactive Protein level)
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ULCERATIVE COLITIS

- Prescribed by or in consultation with a gastroenterologist
- Recipient has a documented diagnosis of moderate to severe ulcerative colitis as defined by **ONE** of the following:
  - Fecal calprotectin > 150 µg/g
  - Endoscopy Mayo subscore ≥ 2 or modified Mayo score (mMS) ≥ 5
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has been hospitalized for ulcerative colitis **OR** had a trial and failure with of ≥ 2 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
    - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
    - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
    - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current labs including inflammatory markers (i.e., fecal calprotectin, endoscopic Mayo subscore)
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Non-preferred agents require a 3-month trial and failure or a contraindication or intolerance to at least **ONE** preferred agent with this indication.

CONTINUATION CRITERIA FOR UC:

- Recipient has documented positive response after 2 months with mucosal healing defined as **ONE** of the following:
    - Endoscopy Mayo subscore ≤ 1
    - Fecal calprotectin ≤ 150 µg/g
    - Recipient that does not meet either of the above but has no other pharmacological or non-pharmacological options available
- Recipient must be compliant on this medication
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of response to therapy with description of current symptoms
    - Current Mayo subscore and fecal calprotectin

APPROVAL CRITERIA FOR CROHN'S DISEASE

- Prescribed by or in consultation with a gastroenterologist
- Recipient has a documented diagnosis of moderate to severe Crohn's Disease confirmed by assessment of stool frequency, abdominal pain score, and Simple Endoscopic Score for Crohn's Disease (SES-CD). Information for diagnosis is based on endoscopy and imagining results as well as elevated CRP and fecal calprotectin.
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has been hospitalized with Crohn's Disease or been diagnosed with a fistula or abscess **OR** had a trial and failure with ≥ 2 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
    - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
    - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
    - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
    - Methotrexate
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies and surgeries
    - Current labs including CBCs and inflammatory markers (i.e., fecal calprotectin, C-reactive protein)
    - Colonoscopy or imaging reports
    - Baseline stool frequency and abdominal pain score
    - Baseline Crohn's Disease Activity Index (CDAI) (clinical trials included patients with score ≥ 220) or Simple Endoscopic Score for Crohn's disease (SES-CD) (clinical trials included patients with score ≥ 6 or ≥4 for isolated ileal disease)
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.

CONTINUATION CRITERIA FOR CD:

- Recipient has documented positive response after 2 months with documented remission that does not require continued use of corticosteroids and one of the following:
  - SES-CD at least a 50% reduction from baseline or ≤ 2 for isolated ileal disease
  - Fecal Calprotectin < 150 µg/g
  - CRP < 5mg/L
  - CDAI < 150
  - Recipient that does not meet any of the above but has no other pharmacological or non-pharmacological options available
- Recipient remains compliant on this medication
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with description of current symptoms
  - Current labs including CBCs and inflammatory markers

APPROVAL CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS OR DEFICIENCY OF IL-1 RECEPTOR ANTAGONIST

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (JIA) or deficiency of IL-1 receptor antagonist (DIRA)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs (unless contraindication or intolerance)
- Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies with description of current symptoms
  - Current labs including CBCs and inflammatory markers
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ANKYLOSING SPONDYLITIS OR NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of either ankylosing spondylitis or nonradiographic axial spondyloarthritis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy (unless contraindication or intolerance) with nonsteroidal anti-inflammatory drugs at maximum doses (e.g., naproxen, celecoxib, ibuprofen)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ATOPIC DERMATITIS

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Recipient has a documented diagnosis of moderate to severe atopic dermatitis with at least **TWO** of the following (baseline at time of biologic 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
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Recipient must have a trial and failure of both topical and systemic medications and at a minimum must include:
  - Trials of topical drugs (unless contraindicated or inappropriate for the patient's age)
    - At least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children
    - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- Prescriber must submit 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 change in score with previous treatment
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Letter of medical necessity over other treatment options for atopic dermatitis

CONTINUATION CRITERIA FOR ATOPIC DERMATITIS:

- Recipient 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 severity scores; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit
  - Current chart notes
  - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

APPROVAL CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES

- Prescribed by or in consultation with a specialist in treating CAPS
- Recipient must have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) or neonatal-onset multisystem inflammatory disease (NOMID)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescriber must submit the following:
  - Current chart notes
  - Confirmation of the diagnosis with genetic test results if available
  - Baseline symptoms
  - Previous therapies tried
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR GIANT CELL ARTERITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a confirmed diagnosis of giant cell arteritis based on clinical symptoms and **ONE** of the following:
  - Temporal artery biopsy
  - Ultrasound of vessels
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescriber must submit the following:
  - Current chart notes
  - Documentation to confirm diagnosis with biopsy results and/or ultrasound report along with labs (i.e., CRP, ESR)
  - Medical necessity over high dose corticosteroids
  - Treatment plan for potential discontinuation in the future

APPROVAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DIEASE

- Prescribed by or in consultation with a rheumatologist, pulmonologist, or other specialist
- Recipient has a confirmed diagnosis of SSc-ILD based on clinical symptoms and the following:
  - PFTs indicate a decreased lung volume and decreased DLCO
  - High resolution CT indicates ground glass or reticular opacities
  - Lab work consistent with scleroderma
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of immunosuppressant therapy with mycophenolate or cyclophosphamide unless a contraindication or intolerance
- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - High resolution CT report
  - Current labs
  - Baseline 6 minute walk test
  - Medical necessity over immunosuppressant therapy +/- glucocorticoids
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR RECURRENT PERICARDITIS

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is diagnosed with recurrent pericarditis based on previous episode of acute pericarditis and has developed pleuritic chest pain. Lab work should support an inflammatory phenotype (elevated CRP, WBC, or ESR).
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient should not receive this medication if not diagnosed with an inflammatory phenotype.
- Recipient should have trial and failure with ALL of the following (unless there is a contraindication):
  - Colchicine + NSAID or aspirin—first line therapy
  - Colchicine + glucocorticoid—second line therapy
  - Colchicine + glucocorticoid + aspirin—third line therapy
- Prescriber must submit the following:
  - Current chart notes
  - Previous treatment for acute pericarditis
  - Electrocardiogram and echocardiogram results
  - Current labs including CBC, ESR, and CRP
  - Treatment plan including taper

APPROVAL CRITERIA FOR UVEITIS

- Prescribed by or in consultation with a rheumatologist, ophthalmologist, or other specialist for treating uveitis
- Recipient must be diagnosed with non-infectious intermediate, posterior, or panuveitis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ALL of the following:
  - Topical glucocorticoid (e.g., prednisolone, triamcinolone)
  - Systemic glucocorticoid at the maximum indicated dose unless a contraindication or intolerance (e.g., prednisone)
  - Immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME OR HYPERIMMUNOGLOBULIN D SYNDROME/MEVALONATE KINASE DEFICIENCY

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating TRAPS
- Recipient must be diagnosed with TNF Receptor Associated Periodic Syndrome (TRAPS) after infectious or neoplastic causes of recurrent fevers are excluded
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of NSAIDs and oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
  - Medical necessity for the use of this medication over NSAIDs and oral glucocorticoids
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR FAMILIAL MEDITERRANEAN FEVER

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating FMF
- Recipient must be diagnosed with Familial Mediterranean Fever (FMF)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of colchicine unless a contraindication or intolerance (treatment recommended indefinitely)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR STILL'S DISEASE

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient must be diagnosed with active Still's Disease (either Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA))
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- New onset AOSD
    - Trial and failure of NSAIDs OR oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance for mild to moderate disease
    - If macrophage activation syndrome is suspected, a biologic is warranted (UpToDate recommends anakinra in these patients)
- Established AOSD still needing therapy
    - Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
        - Methotrexate
        - Leflunomide
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of symptoms and criteria used for diagnosis
    - Previous therapies tried
    - Current weight for dose determination
- Non-preferred agents require a 3 month trial and failure or a contraindication or intolerance to at least ONE preferred agent with this indication.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ALOPECIA AREATA

- Prescribed by or in consultation with a dermatologist
- Recipient has a documented diagnosis of alopecia areata with >50% scalp hair loss or refractory disease
- Recipient does not have another cause of hair loss (i.e., androgenetic alopecia, chemotherapy-induced hair loss, or causes of hair loss other than alopecia areata)
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Recipient request would be denied if taking any of the following concomitantly:
    - JAK inhibitor
    - Other monoclonal antibodies or cytokine & CAM antagonists
    - Immunosuppressant
- Trial and failure of topical and/or intralesional corticosteroids
- Trial and failure with ≥ 6 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindicated):
    - Methotrexate
    - Leflunomide
    - Cyclosporine
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried with duration
    - Medical necessity over intralesional corticosteroids, topical steroids, and DMARDs
    - Letter of medical necessity
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

EFFECTIVE OCTOBER 19, 2022

3. MEDICATIONS USED FOR ADHD

APPROVAL CRITERIA FOR CII STIMULANTS AND NON-STIMULANTS FOR ADULTS

- Completed CII stimulant form is required for recipients ≥19 years of age
- Currently, atomoxetine does not require a prior authorization
- Recipient with ADHD
  - Recipient must have signs/symptoms in 2 or more settings using a standardized rating scale with at least one of the following:
    - Currently attends school (high school, college, or vocational)
    - Currently employed
    - Currently searching for employment (approval for maximum of 3 months without documentation of employment)
  - Recipient must have multiple symptoms of inattention and/or hyperactivity/impulsivity from the DSM-5 documented on the form for initial approval
  - Recipient with co-morbid conditions of bipolar disorder or schizophrenia must be controlled and adherent with appropriate medication therapy, or prescriber must provide adequate documentation as to why the co-morbid condition is no longer being treated
  - Prescriber must submit the following:
    - Completed CII stimulant form
    - Current chart notes
    - Documentation needed to support the diagnosis of ADHD
- Recipient without ADHD may be approved for one of the following: (each request is reviewed on a case-by-case basis for medical necessity)
  - Narcolepsy with sleep study results confirming diagnosis
  - Traumatic Brain Injury (TBI)
  - Fatigue due to underlying illness (i.e., cancer or multiple sclerosis)
  - Binge Eating Disorder (BED)—Vyvanse only

EFFECTIVE OCTOBER 19, 2022

4. ZTALMY® (ganaxolone) 50 mg/mL oral suspension

INDICATION:

ZTALMY is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

APPROVAL CRITERIA:

- Recipient must be ≥2 years of age
- Recipient must have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) OR a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient's seizures are refractory to current antiepileptic therapy with at least 2 previous trials with different MOA
- Recipients requiring a CYP3A4 inducer should avoid this medication. If unavoidable, the ZTALMY dose should be increased.
- Prescriber must order a dose titration and should not order a dose that exceeds the dose supported in the FDA approved package insert or MicroMedex®:
  - Weight ≤28 kg: maximum dose is 63 mg/kg/day
  - Weight >28 kg: maximum dose is 1,800 mg/day
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current weight
  - Genetic testing results confirming the presence of the CDKL5 mutation
  - Previous therapies tried with response
  - Baseline average daily seizure count
  - Attestation that the recipient/caregiver has been educated on titration schedule

CONTINUATION CRITERIA:
- Recipient demonstrates a positive response with a decrease in seizure frequency
- Prescriber must submit the following:
  - Current chart notes
  - Current dose (must be within manufacturer's guidance)
  - Response to therapy

QUANTITY EDITS:
For max dose of 1800 mg daily = 36 mL per day (1116 mL per 31 days)

EFFECTIVE OCTOBER 19, 2022

5. ZORYVE™ (roflumilast) 0.3% cream

INDICATION:
ZORYVE™ is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

APPROVAL CRITERIA:
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must trial ≥6 months of topical drug therapy with either corticosteroids, calcipotriene, calcitriol, tazarotene, or a combination
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA
  - Current Investigator's Global Assessment (IGA) score
  - Current Worst Itch-Numeric Rating Score (WI-NRS)
  - Medical necessity over all other topical treatment options

CONTINUATION CRITERIA:
- Recipient has a VTAMA claim on Medicaid profile in the last 60 days
- Recipient has a documented improvement in symptoms (i.e., decreased BSA, reduced IGA score, or WI-NRS)
- Prescriber must submit the following:
  - Current chart notes
  - Current BSA, IGA score, and WI-NRS

QUANTITY EDITS:
1 tube (60 gm)/ 30 days

EFFECTIVE OCTOBER 19, 2022

6. VTAMA® (tapinarof) 1% cream

INDICATION:
VTAMA ® (tapinarof) cream is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

APPROVAL CRITERIA:
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient must trial ≥6 months of topical drug therapy with either corticosteroids, calcipotriene, calcitriol, tazarotene, or a combination
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA
  - Current Investigator's Global Assessment (IGA) score
  - Current Worst Itch-Numeric Rating Score (WI-NRS)
  - Medical necessity over all other topical treatment options

CONTINUATION CRITERIA:
- Recipient has a VTAMA claim on Medicaid profile in the last 60 days
- Recipient has a documented improvement in symptoms (i.e., decreased BSA, reduced IGA score, or WI-NRS)
- Prescriber must submit the following:
  - Current chart notes
  - Current BSA, IGA score, and WI-NRS

QUANTITY EDITS:
1 tube (60 gm)/ 30 days

EFFECTIVE OCTOBER 19, 2022

7. AMVUTTRA™ (vutrisiran) 25 mg/0.5 mL syringe

INDICATION:
AMVUTTRA is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

APPROVAL CRITERIA:
- Prescribed by or in consultation with a neurologist or other specialist that treats polyneuropathy due to hATTR
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is diagnosed with polyneuropathy due to hereditary transthyretin-mediated (hATTR) amyloidosis **OR** a diagnosis consistent with any updated FDA approved indications
- Recipients with multisystem symptoms and/or family history must have the diagnosis confirmed with **ONE** of the following:
  - Confirmation of a TTR variant by genetic testing
  - Tissue biopsy confirming the presence of amyloid deposits
- Recipient does not have any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes
  - Medical necessity over preferred neuropathic pain agents
  - Attestation that Vitamin A is being monitored for possible supplementation
  - Baseline modified Neuropathy Impairment Score +7 (mNIS+7)
  - Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
  - Previous therapies tried
  - Current labs including LFTs and BMP
- Renewal requires prescriber to submit updated notes and labs with documentation of a positive response to therapy

QUANTITY EDITS:
1 syringe every 3 months

EFFECTIVE OCTOBER 19, 2022

8. XACIATO™ (clindamycin phosphate) 2% gel

INDICATION:
XACIATO is indicated for the treatment of bacterial vaginosis in females 12 years and older.

APPROVAL CRITERIA:
- Recipient is a female 12 years of age and older **OR** updated age allowance if indication changes
- Recipient has a confirmed diagnosis of bacterial vaginosis with the following:
  - Off-white vaginal discharge
  - Clue cells > 20% of total epithelial cells
  - Discharge pH >4.5
  - Positive whiff test
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Medical necessity over other treatment options available without a PA (e.g., oral or vaginal metronidazole, oral or vaginal clindamycin)

QUANTITY EDITS:
1 tube (8 gm)/ 30 days

9. 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://arkansas.magellanrx.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. **MAT (Medication Assisted Treatment) with buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: "Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care. As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities."

http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

3. **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 18 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 clients 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://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/

4. **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 clients 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 clients, including clients 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.

5. **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.**

6. **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 MMA Prescription Drug 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 clients and once per 60 days per drug class for LTC clients.

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://arkansas.magellanrx.com/provider/documents/.**

7. **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 client 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.

8. **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 client 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 client 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.

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

10. **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. Clients have an ongoing requirement for labs for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs for the antipsychotic agents, 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://arkansas.magellanrx.com/client/docs/rxinfo/MedInformedConsent.pdf**

    < 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.

11. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID CLIENTS WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that client can be billed using the client's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed accordingly 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.

12. **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://arkansas.magellanrx.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://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

13. **OPIOID INFORMATION ON THE MAGELLAN WEBSITE:** 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 Magellan Health website. https://arkansas.magellanrx.com/client/documents

14. **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 is to provide you 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 Magellan Medicaid Administration (MMA) 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 HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.