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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 13, 2024

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board October 16, 2024 meeting for the following:**

Manual review criteria for: Voquezna® (vonoprazan fumarate), OFEV® (nintedanib), Esbriet® (pirfenidone), Evrysdi® (risdiplam), Salicate™ (salicylic acid), Alkindi (hydrocortisone), Xolremdi™ (mavorixafor), Iqirvo® (elafibranor), Livdelzi® (seladelpar lysine), Ohtuvayre™ (ensifentrine), Winrevair™ (sotatercept), and Dupixent® (dupilumab)for COPD

Preferred Drug List (PDL) therapeutic classes with PA criteria: Oral and injectable antipsychotics, non-triptan migraine medications including CGRP antagonists

Preferred Drug List (PDL) therapeutic classes without PA criteria: Overactive bladder agents

Other important topics: Opioid Use Disorder (OUD) medication update

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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 educational materials. The quarterly newsletter is in addition to this DUR Board provider 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 October 2024 quarterly newsletter can be found with the following link. https://ar.primetherapeutics.com/documents/d/arkansas/arkansas-medicaid-quarterly-newsletter-october-2024-final

2) PREFERRED DRUG LIST

PDL UPDATE EFFECTIVE JANUARY 1, 2025

NOTE: Bolded medications indicate a change from the previous preferred drug list or PA status.

Non-preferred agents require prior authorization submission. Prescribers with questions on how to obtain a PA should call the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7976. Any PA request for off-label use will be reviewed on a case-by-case basis.

A. OVERACTIVE BLADDER AGENTS

Preferred agents

- Fesoterodine fumarate ER tablet (generic for Toviaz)
- **Myrbetriq ER tablet (mirabegron extended-release)—BRAND NAME ONLY**
- Oxybutynin chloride syrup, 5mg tablets (generic for Ditropan)
- Oxybutynin chloride ER tablet (generic for Ditropan XL Tablet)
- Solifenacin succinate tablet (generic for Vesicare)

Nonpreferred agents

- Darifenacin hydrobromide ER tablet (generic for Enablex)
- Detrol tablet (tolterodine tartrate)
- Detrol LA capsule (tolterodine tartrate ER)
- Flavoxate HCl tablet (generic for Urispas)
- Gemtesa tablet (vibegron)
- Mirabegron ER tablet (generic for Myrbetriq)
- **Myrbetriq ER granules (mirabegron)**
- Oxybutynin 2.5mg tablet
- Oxytrol patch (oxybutynin patch)
- Tolterodine tartrate tablet (generic for Detrol)
- Tolterodine tartrate ER capsule (generic for Detrol LA)
- Toviaz tablet (fesoterodine fumarate)
- Trospium chloride ER capsule (generic for Sanctura XR)
- Trospium chloride tablet (generic for Sanctura)
- Vesicare tablet (solifenacin succinate)
- Vesicare LS Suspension (solifenacin succinate)

B. ORAL AND INJECTABLE ANTIPSYCHOTICS

ORAL ANTIPSYCHOTIC AGENTS (ALL AGES)—

The previous general criteria still apply along with maximum dosing.

Approval Criteria for Adults ≥ 18 y/o

- New Starts for preferred medications that are below the maximum therapeutic dose (SEE DOSING CHARTS) will process at point-of sale (POS)
- A beneficiary may continue a drug or dose that is outside of the established criteria (e.g., continue a non-preferred status drug, continue dose higher than the maximum therapeutic dose), or continue therapy with > 2 antipsychotic agents if the beneficiary is "Stable and Compliant" on all antipsychotic drug therapy(-ies).
    - For the purposes of these criteria "Stable and Compliant" is defined as the patient has received at least 2 claims in the previous 120 days
- Preferred Oral liquids and orally disintegrating tablets (ODTs): Patients ≥ 18 y/o must have an NPO diagnosis code in the past year

Denial Criteria for Adults ≥ 18 y/o

- New starts to non-preferred medications will deny
- New starts above the maximum therapeutic dose of a medication will deny (SEE DOSING CHARTS)
- Therapeutic Duplication
    - TD with three or more oral antipsychotic agents will deny for new starts
    - TD for two or more oral antipsychotics and one long-acting injectable antipsychotic agents
- Failure to meet approval criteria

Approval Criteria-Children (< 18 y/o)

- At least one paid claim for an oral antipsychotic in the past 45 days, and monitoring for both glucose and lipid screening in the past 9 months
- Typical and Atypical antipsychotics:
    - All new start patients or patients changed to a different chemical entity will require a signed informed consent and a copy of a baseline metabolic lab test data.
    - https://ar.primetherapeutics.com/documents/268611/269351/Medication%20Informed%20Consent%20Document%20for%20Behavioral%20or%20Psychiatric%20Conditions%20-%20Clients%20under%2018%20years%20of%20age/b36b6864-5a6e-a661-ae93-52ab33495ee1
    - One therapeutic duplication for a change in therapy between two antipsychotics (oral or injectable) with > 25% remaining on the last fill on different dates of service allowed per 93 days.
    - PA required through manual review for recipients < 10 years of age.
- Oral liquids and orally disintegrating tablets (ODTs):
    - Patient must have an NPO code in the past year; **OR**
    - < 7 years of age AND meet criteria for atypical antipsychotics
- Seroquel XR continuation criteria requires ≥ 2 claims on the beneficiary's profile of the same GSN in the past 120 days
- Requested dose must be meet the dosing requirements by age on the dosing table

Denial Criteria for Children (< 18 y/o)

- Claims with a therapeutic duplication on the same date of service
- Requests for combination of antipsychotic products for patients <18 years of age
- Failure to meet approval criteria

First Generation Oral Antipsychotic Agents- Preferred

- Chlorpromazine tablet
- Fluphenazine tablet
- Haloperidol lactate concentrate solution**
- Haloperidol tablet
- Loxapine succinate capsule
- Perphenazine tablet
- Thioridazine tablet

Second Generation Oral Antipsychotic Agents- Preferred

- Aripiprazole tablet (generic for Abilify®)
- Clozapine tablet (generic for Clozaril®)
- Lurasidone tablet (generic for Latuda®)
- Olanzapine ODT** (generic for Zyprexa Zydis®)
- Olanzapine tablet (generic for Zyprexa®)
- Olanzapine/fluoxetine capsule (generic for Symbyax®)***
- Paliperidone tablet (generic for Invega®)
- Quetiapine tablet (generic for Seroquel®)
- Risperidone ODT**(generic for Risperdal®)
- Risperidone solution** (generic for Risperdal®)
- Risperidone tablet (generic for Risperdal®)
- Ziprasidone capsule (generic for Geodon®)

Preferred Agent(s) with Criteria

- **Vraylar® capsule (cariprazine)**

Vraylar® will have the following point-of-sale edits:

- Beneficiary must have a billed diagnosis of one of the FDA approved indications
    - Treatment of schizophrenia in adults
    - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
    - Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults
    - Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults
- Beneficiary with schizophrenia or bipolar disorder must have at least one antipsychotic in their Medicaid profile in the last 2 years
- Beneficiary with major depressive disorder must have at least two different antidepressants in their Medicaid profile in the last 2 years

First Generation Oral Antipsychotic Agents-Non-Preferred

- Chlorpromazine oral concentrate
- Fluphenazine Elixir/Solution
- Molindone tablet
- Perphenazine/Amitriptyline tablet
- Pimozide tablet
- Thiothixene capsule
- Trifluoperazine tablet

Second Generation Oral Antipsychotic Agents – Non-Preferred

- Abilify Mycite® tablet (aripiprazole)
- Abilify® tablet/discmelt/solution (aripiprazole)
- Aripiprazole ODT and solution (generic for Abilify®)
- **Asenapine SL tablet (generic for Saphris®)**
- Caplyta® (lumateperone)
- Clozapine ODT tablet (generic for Fazaclo®)
- Clozaril® tablet (clozapine)
- **Cobenfy™ capsule (xanomeline/trospium chloride)**
- Fanapt® tablet (iloperidone)
- Geodon® capsule (ziprasidone)
- Invega® tablet (paliperidone)
- Latuda® tablet (lurasidone)
- Lybalvi® tablet (olanzapine/samidorphan)
- Nuplazid® tablet/capsule (pimavanserin)
- Quetiapine ER tablet (generic for Seroquel® XR)
- Rexulti® tablet (brexpiprazole)
- Risperdal® tablet/solution/ODT (risperidone)
- Saphris® sublingual tablet (asenapine)
- Secuado® transdermal patch (asenapine)
- Seroquel® IR/XR tablet (quetiapine)
- Symbyax® capsule (olanzapine/fluoxetine)
- Versacloz® suspension (clozapine)
- Zyprexa® tablet/Zydis (olanzapine)

** ODT and Solutions are Preferred ONLY for Ages < 7 y/o or patients with a diagnosis of NPO in history
***Please see Second Generation Antidepressant criteria

From the General Medication Coverage Policy July 2023
general-medication-coverage-policy-july-2023-pdf
Before moving to a non-preferred oral antipsychotic medication, the beneficiary must have a documentation of trial and failure of at least TWO (2) different chemical entities **unless otherwise noted.**

COBENFY APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with schizophrenia **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a trial and failure of 2 other antipsychotics with differing mechanisms of action
- Beneficiary should not be approved or continue the medication if one or more of the following is met:
    - Has urinary retention
    - Has moderate or severe hepatic impairment
    - Has gastric retention
    - Has untreated narrow-angle glaucoma
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies tried and results
    - Medical necessity over preferred antipsychotics

INJECTABLE ANTIPSYCHOTICS

Preferred Agents with Criteria

- Abilify Asimtufii® (aripiprazole ER)
- Abilify Maintena® (aripiprazoleER)
- Aristada® (aripiprazole lauroxil ER)
- Aristada® Initio (aripiprazole lauroxil ER)
- Fluphenazine decanoate (generic for Prolixin® decanoate)
- Haloperidol decanoate (generic for Haldol® decanoate)
- Invega Hafyera® (paliperidone palmitate)
- Invega Sustenna® (paliperidone palmitate)
- Invega Trinza® (paliperidone palmitate)
- Perseris ER® kit (risperidone)—Discontinuing mid-2025
- Risperdal Consta® (risperidone microspheres) **BRAND ONLY**
- **Uzedy ER® (risperidone)**

Non-preferred Agents

- Risperidone ER microspheres (generic of Risperdal Consta®)
- Rykindo ER® (risperidone)
- Zyprexa Relprevv™ (olanzapine)

GENERAL APPROVAL CRITERIA FOR LONG-ACTING INJECTABLE ANTIPSYCHOTICS:

Long-Acting injectable antipsychotics will be available through POS edits for the preferred agents based on requirements in the package insert. Non-preferred agents follow the criteria below and require documentation of the medical necessity over preferred options.

- All requests for beneficiaries < 18 years of age will continue to require manual review.
- Each product will require a trial of oral tolerability
- No therapeutic duplication with another long-acting antipsychotic allowed in the past 23 days
- Allowed ≤ 1 oral antipsychotic used concomitantly
- If medication is changed between LAIs, the proper time between doses must have elapsed to prevent overlapping of doses.
- Beneficiary must either meet criterion 1 or criterion 2 for the claim to process without a PA.

Uzedy® is the only long-acting injectable that will be updated. The verbiage requiring the medical necessity over preferred options is being removed.

Point-of-sale approval criteria for Uzedy®

Uzedy® ER 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 200 mg, and 250 mg

- 50 mg, 75 mg, 100 mg, and 125 mg may be filled monthly; 150 mg, 200 mg and 250 mg may be filled every 2 months
- ~~Requires the medical necessity over preferred options~~

Criterion 1

- Requires previous history of oral risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

Criterion 2

- Uzedy® 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy® 100 mg, 150 mg, 200 mg and 250 mg claim in the last 90 days, or Perseris® in the last 45 days, or Risperdal Consta® in the last 45 days

C. <u>ANTIMIGRAINE AGENTS (excluding triptans)</u>

Preferred Agents with Criteria (used for migraine prevention)

- Aimovig® (erenumab-aooe) autoinjector
- Emgality® 120 mg (galcanezumab) pen and syringe
- Nurtec ODT® (rimegepant)
- **Qulipta® tablets (atogepant)**

Non-Preferred Agents (used for migraine prevention)

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

Preferred Agents with Criteria (used for acute migraine treatment)

- Nurtec ODT® (rimegepant)

Non-Preferred Agents (used for acute migraine treatment)

- **Diclofenac potassium powder pack (generic for Cambia®)**
- Dihydroergotamine injection (generic for D.H.E.45)
- Dihydroergotamine nasal spray (generic for Migranal®)
- Elyxyb® solution (celecoxib)
- Migranal® spray (dihydroergotamine)
- Reyvow® tablet (lasmiditan)
- Trudhesa® nasal spray (dihydroergotamine)
- Ubrelvy® tablet (ubrogepant)
- Zavzpret™ nasal spray (zavegepant)

<u>APPROVAL CRITERIA FOR ACUTE TREATMENT AGENTS:</u>

Any new medications for acute migraine treatment that are released will follow this same criterion and follow documentation in the manufacturer's label. PDL status will apply.

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3)
- Beneficiary must have a failure of at least **TWO** (2) preferred 5HT 1B/1D receptor agonists (triptans) using **TWO** (2) different chemical agents (not just different dosage forms) at maximally tolerated doses unless beneficiary has one of the following contraindications:
    - 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
- Beneficiary should not be approved or continue the medication if meet one of the following:
    - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – UBRELVY and NURTEC ODT
    - Requires continued use of a strong CYP3A4 inducer (i.e., rifampin) - UBRELVY and NURTEC ODT
    - Requires continued use of P-gp (i.e., amiodarone, carvedilol, macrolides) or BCRP substrates (i.e., statins) - REYVOW
    - End stage renal disease (CrCl < 15mL/min) – UBRELVY, NURTEC ODT, and ELYXYB
    - Severe hepatic impairment (Child-Pugh Class C) – REYVOW, NURTEC ODT, and ELYXYB
    - NSAID allergy or recent coronary artery bypass graft (CABG) surgery - ELYXYB

  - If beneficiary prescribed UBRELVY 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CrCl 15-29 mL/min)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of migraine frequency and severity/duration
  - List of all therapies trialed with timeframes
  - Attestation that medication overuse headaches have been ruled out

RENEWAL REQUIREMENTS:

- Beneficiary demonstrates a positive response with a decrease in the severity/duration of migraines
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of current migraine frequency and severity/duration

APPROVAL CRITERIA FOR PROPHYLAXIS AGENTS:

Any new medications for migraine prevention that are released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary 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; OR
  - Episodic migraine or episodic cluster headache; OR
  - Diagnosis consistent with FDA indication
- Beneficiary requesting an oral CGRP agent (including preferred medications) must have a documented failure of a **6-month** trial with at least **ONE** injectable CGRP agent or a contraindication to the use
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Continuation should not be approved if there is no reduction from baseline in monthly migraine days or migraine severity after 3 months
  - Diagnosed with medication overuse headache caused by opiate overuse or other headache medication overuse as identified by the prescriber
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
  - Requires continued use of a strong CYP3A inducer (i.e., rifampin) – NURTEC ODT
  - End stage renal disease (CrCl <15 mL/min) –NURTEC ODT
  - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of migraine frequency and severity/duration
  - List of all therapies trialed with timeframes
  - Attestation that medication overuse headaches have been ruled out
  - Medical necessity over other preventative classes (i.e., anticonvulsants, antidepressants, and beta blockers)

RENEWAL REQUIREMENTS:

- Beneficiary must have a reduction in monthly migraine days and migraine severity after 3rd month of treatment while remaining compliant with therapy
- Prescriber must submit the following:
  - Chart notes since previous PA approval
  - Documentation of current migraine frequency and severity
  - Beneficiary has decreased claims of acute migraine treatment

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

CRITERIA EFFECTIVE OCTOBER 16, 2024

1) VOQUEZNA (vonoprazan fumarate) 10 mg and 20 mg tablet

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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary prescribed a VOQUEZNA Dual or Triple Pak must be diagnosed with *Helicobacter pylori* or beneficiary prescribed VOQUEZNA must be diagnosed with **ONE (1)** of the following:
  - For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - For relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
  - In combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.
  - In combination with amoxicillin for the treatment of *H. pylori* infection in adults.
- Beneficiary with erosive esophagitis or heartburn must have had previous treatment failure with or a contraindication to all preferred proton pump inhibitors
- Beneficiary with *H. pylori* must have tried and failed (defined as failure to eradicate *H. pylori* infection after 14-day course of therapy) **ONE (1)** of the following:
  - Bismuth quadruple therapy unless contraindicated (e.g., bismuth, metronidazole, tetracycline and proton pump inhibitor); **OR**
  - Clarithromycin-based therapy unless contraindicated (e.g., clarithromycin, amoxicillin, and proton pump inhibitor)
- Prescribed by or in consultation with a gastroenterologist or infectious disease specialist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Requested duration of treatment for healing erosive esophagitis or relief of heartburn associated with erosive esophagitis exceeds 8 weeks
  - Requested duration of maintenance therapy for healed erosive esophagitis and relief of heartburn exceeds 6 months
  - Requested duration of treatment for heartburn associated with non-erosive gastroesophageal reflux disease exceeds 4 weeks
  - Requested duration of treatment for *H. pylori* exceeds 14 days
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Confirmation of *H. pylori* if that is the diagnosis
  - Letter of medical necessity requesting VOQUEZNA over guideline-recommended first-line treatment
  - VOQUEZNA requests require an endoscopy report confirming:
    - Current erosive esophagitis with treatment prescribed to heal erosive esophagitis; **OR**
    - Confirmed healed erosive esophagitis with treatment prescribed as maintenance therapy; **OR**
    - Confirmed lack of esophageal erosions but heartburn persists
- PA duration will be consistent with duration per the package insert

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity outlining the rationale for exceeding FDA approved treatment duration

CRITERIA EFFECTIVE OCTOBER 16, 2024

2) OFEV® (nintedanib) capsule & ESBRIET® (pirfenidone) tablet/capsule

OFEV APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with idiopathic pulmonary fibrosis, chronic fibrosing interstitial lung disease with progressive phenotype, **OR** systemic sclerosis-associated interstitial lung disease. Confirmation will require the following depending on diagnosis:
  - **Idiopathic pulmonary fibrosis (IPF)**
    - Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation of some of the following:
      - Basal and peripheral dominance
      - Honeycombing (usually subpleural)
      - Reticular opacities or ground-glass opacities
      - Traction bronchiectasis
      - Airspace enlargement with fibrosis
    - Baseline Pulmonary Function Tests (PFTs)
      - Forced vital capacity (FVC) is ≥50% predicted; **AND**
      - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-79% of predicted
    - Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out

  - **Chronic fibrosing interstitial lung diseases with progressive phenotype (also called progressive pulmonary fibrosis)** with a high-resolution CT scan indicating pulmonary fibrosis is affecting ≥10% of the lungs with at least **TWO** of the following criteria with at least **ONE** of the examples listed with the criteria in the last 24 months:
    - Worsening respiratory symptoms (e.g., increased dyspnea on exertion)
    - Radiological evidence of disease progression with at least **ONE** of the following examples:
      - Increased extent or severity of traction bronchiectasis and bronchiolectasis
      - New ground-glass opacity with traction bronchiectasis
      - New fine reticulation
      - Increased extent or increased coarseness of reticular abnormality
      - New or increased honeycombing
      - Increased lobar volume loss
    - PFTs indicate disease progression with at least **ONE** of the following examples:
      - FVC decline ≥10% predicted; **OR**
      - FVC decline ≥5% and <10% predicted with worsening symptoms or imaging; **OR**
      - DLCO decline (corrected for Hb) ≥10% predicted

  - **Systemic sclerosis-associated interstitial lung disease (SSC-ILD)** requires a diagnosis of systemic sclerosis (SSC) based on rheumatology guidelines and interstitial lung disease with the following:
    - High-resolution CT scan indicates pulmonary fibrosis is affecting ≥10% of the lungs
    - Baseline PFTs
      - Forced vital capacity (FVC) is ≥40% predicted; **AND**
      - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-89% of predicted

- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Likely to receive a lung transplant or has had a lung transplant
  - Has relevant airways obstruction (i.e., pre-bronchodilator $FEV_1/FVC < 0.7$)
  - Pregnant or breastfeeding
  - Currently smoking

  - Moderate or severe hepatic impairment (Child Pugh B or C). Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dose of OFEV.
  - Has gastrointestinal perforation
  - Severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease
  - Caution in beneficiaries with known risk of bleeding (benefit outweighing the risk should be provided)
- Prescriber must submit the following:
  - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
  - Dose requested (PA is entered for specific dose)
  - Current labs including liver function tests
  - Baseline pulmonary function tests (PFTs)
  - Baseline 6-minute walk test (6MWT)
  - Letter of medical necessity over immunosuppressant for SSC-ILD patients (i.e., mycophenolate)
  - Documentation verifying the smoking status with **ONE** of the following:
    - exhaled carbon monoxide level (eCO) <6ppm; **OR**
    - carboxyhemoglobin (COHb) levels of <3%; **OR**
    - urine cotinine concentration <200 ng/mL

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following
  - Current chart notes
  - Current labs including LFTs
  - Documentation of response to therapy with any of the following:
    - Current pulmonary function tests
    - Current 6MWT
    - Current CT scan results of lungs

QUANTITY EDITS:

100 mg #60/30 days
150 mg #60/30 days

ESBRIET APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with idiopathic pulmonary fibrosis (IPF). Confirmation will require the following:
  - Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation some of the following:
    - Basal and peripheral dominance
    - Honeycombing (usually subpleural)
    - Reticular opacities or ground-glass opacities
    - Traction bronchiectasis
    - Airspace enlargement with fibrosis
  - Baseline Pulmonary Function Tests (PFTs)
    - Forced vital capacity (FVC) is ≥50% predicted; **AND**
    - Carbon monoxide diffusing capacity (DLCO) is ≥30% predicted
  - Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Likely to receive a lung transplant or has had a lung transplant

  - Has relevant airways obstruction (i.e., pre-bronchodilator FEV_1/FVC <0.8)
  - Currently smoking
  - Severe hepatic impairment (Child Pugh C). Patients with mild to moderate hepatic impairment (Child Pugh A or B) should use ESBRIET with caution and consider dose modification or discontinuation if needed.
  - End-stage renal disease requiring dialysis. For patients with mild to severe renal impairment, monitor for adverse events and modify dose or discontinue as needed.
  - Develops Severe Cutaneous Adverse Reactions (SCAR)
- Prescriber must submit the following:
  - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
  - Strength of medication and dosage form requested (PA is entered for specific dose)
  - Current labs including liver function tests
  - Baseline pulmonary function tests (PFTs)
  - Baseline 6-minute walk test (6MWT)
  - Documentation verifying the smoking status with **ONE** of the following:
    - exhaled carbon monoxide level (eCO) <6ppm; **OR**
    - carboxyhemoglobin (COHb) levels of <3%; **OR**
    - urine cotinine concentration <200 ng/mL

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following
  - Current chart notes
  - Current labs including LFTs
  - Documentation of response to therapy with any of the following:
    - Current pulmonary function tests
    - Current 6MWT
    - Current CT scan results of lungs

QUANTITY EDITS:

267 mg tablet or capsule #270/30 days
801 mg tablet #90/30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

3) EVRYSDI® (risdiplam) solution

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with spinal muscular atrophy (SMA) by genetic testing with the following:
  - Documentation of SMN1 gene deletion or mutation; **AND**
  - Documentation of ≤ 4 copies of SMN2 gene whether a pre-symptomatic infant or symptomatic patient (SMA Type 1, 2, or 3)
- Prescribed by or in consultation with a neurologist experienced in treating SMA
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Dosage requested is not consistent with the beneficiary's age and weight
  - Pregnant
  - Requires a Multidrug and Toxin Extrude (MATE1) substrate such as metformin, cimetidine or acyclovir. If concomitant use cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the co-administered drug.
  - Beneficiary had previous administration of gene therapy (i.e., Zolgensma® [onasemnogene abeparvovec-xioi]) either in a clinical study or as part of medical care

  - Provider requests concomitant treatment with a SMN2-targeting antisense oligonucleotide (i.e., Spinraza® [nusinersen])
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies tried
  - Documentation of symptoms and age of onset if not pre-symptomatic
  - Current weight to verify dose requested
  - Genetic testing results
  - Documentation of pulmonary status (e.g., tracheostomy, hours on ventilation, etc.)
  - Negative pregnancy test for a female beneficiary of childbearing potential prior to beginning EVRYSDI therapy and/or has documentation of contraception use
  - Attestation that a female beneficiary of childbearing potential has been counseled about contraception
  - Attestation that a male beneficiary has been counseled about potential infertility with EVRYSDI therapy
  - Documentation that the beneficiary is receiving physical therapy
  - Baseline motor ability assessment results of one of the following:
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **OR**
    - Motor Function Measure Score (MFM-32); **OR**
    - Revised Upper Limb Module (RULM); **OR**
    - Hammersmith Infant Neurological Examination Module 2 (HINE-2); **OR**
    - Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
    - Bayley Scales of Infant and Toddler Development, Third Addition (BSID-III or Bayley-III)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- A symptomatic beneficiary must demonstrate a positive response in SMA associated signs and symptoms by either an improvement or no significant decline in motor function score compared to baseline assessment by using the same measuring scale as the baseline score **OR** demonstrating improvement or no significant decline in pulmonary function
- A beneficiary starting treatment prior to onset of symptoms must demonstrate a new motor milestone or maintained muscle function compared to pretreatment baseline with better outcomes than would be expected without treatment.
- Beneficiary has not received Zolgensma® since began Evrysdi® and beneficiary has not been ordered Spinraza® to be given concomitantly
- Prescriber must submit the following:
  - Current chart notes
  - Current weight
  - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage
  - Documentation of continued physical therapy
  - Documentation of response to therapy using the same measuring scale as the baseline score

QUANTITY EDITS:

Based on max dose of 5 mg per day, 3 bottles (240mL total) per 31 days

POINT-OF-SALE UPDATE EFFECTIVE JANUARY 1, 2025

4) OPIOID USE DISORDER UPDATE

Updates for Opioid Use Disorder (OUD) agents

- Maximum daily allowed dose will increase to the equivalent of 32 mg of buprenorphine. Examples:
  - Suboxone 8/2 mg films will increase from #93 to #124 films per month allowing for 32 mg of buprenorphine once daily
  - Suboxone 12/3 mg films will remain at a maximum of #62 films per month as increasing to 3 films per day would exceed the allowed maximum of 32 mg per day.

  - Zubsolv 5.7/1.4 mg is considered equivalent to Suboxone 8/2 mg; therefore, the maximum quantity will increase from #93 to #124 per month.
- There is limited evidence to support the medical necessity for the use of multiple dosage forms of OUD agents taken at the same time. Since we will be increasing the daily allowed dosage, prescriptions for multiple oral dosage forms will not be necessary. A therapeutic duplication edit for oral OUD products will be implemented on 01/01/2025. Example: Patients will not be able to fill prescriptions for both Suboxone films and buprenorphine SL tablets at the same time without prior authorization approval.
- Many patients started on the injectable OUD medications occasionally require oral buprenorphine supplements for approximately 4 months after beginning treatment. Therefore, there will not be a therapeutic duplication edit placed on the injectable products.

CRITERIA EFFECTIVE OCTOBER 16, 2024

5) SALICATE™ (salicylic acid) gel

APPROVAL CRITERIA:
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive keratin in hyperkeratotic skin disorders (e.g., verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis)
- At a minimum, beneficiary must have trial and failure of salicylic acid products over the counter
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Description of beneficiary's skin disorder as a baseline
  - Letter of medical necessity of this product over other treatment options available including products available over the counter

RENEWAL REQUIREMENTS:
- Beneficiary must demonstrate an improvement of excessive keratin compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

QUANTITY EDITS: 1 bottle every 30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

6) ALKINDI (hydrocortisone) sprinkle

APPROVAL CRITERIA:
- Beneficiary does not exceed the maximum age recommended in the manufacturer's package insert (<18 years of age)
- Beneficiary must be diagnosed with adrenocortical insufficiency
- Prescriber must submit the following:
  - Current chart notes
  - Dose requested
  - Medical necessity over hydrocortisone tablets or prednisolone solution which are available without prior authorization

RENEWAL REQUIREMENTS:
- Beneficiary continues to demonstrate the medical necessity of the sprinkle formulation

CRITERIA EFFECTIVE OCTOBER 16, 2024

7) XOLREMDI™ (mavorixafor) capsule

APPROVAL CRITERIA:
- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) that has genotype-confirmed variant of CXC chemokine receptor 4 (CXCR4) with low number of circulating mature neutrophils and lymphocytes **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have an absolute neutrophil count (ANC) ≤400 cells/μL at baseline
- Prescribed by or in consultation with an immunologist, hematologist or dermatologist
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Pregnant
  - Breastfeeding
  - Severe renal impairment (CrCl < 30 mL/min)
  - Moderate to severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including CBC with differential, liver function tests, and basic metabolic panel
  - Current weight
  - Dose requested
  - Pregnancy test for female patient of reproductive potential
  - Attestation that the female patient of reproductive potential has been counseled on the use of an effective method of contraception during treatment for 3 weeks after the final dose.

RENEWAL REQUIREMENTS:
- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a clinical benefit based on any of the following (compared to baseline):
  - Reduced frequency, duration or severity of infections
  - Fewer warts
  - Improved labs (e.g., absolute neutrophil count, white blood cell count, and absolute lymphocyte count)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of clinical response to treatment
  - Current labs including CBC with differential, liver function tests, and basic metabolic panel

QUANTITY EDITS:
#120/ 30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

8) IQIRVO® (elafibranor) tablet

APPROVAL CRITERIA:
- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary biliary cholangitis (PBC) confirmed by **TWO** of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times (1.67X) the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher
  - Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)

- Beneficiary with an inadequate response to UDCA alone must take Iqirvo® concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Pregnant
  - Complete biliary obstruction
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Baseline description of muscle pain or myopathy (evaluate periodically for new onset or worsening muscle pain, myopathy, or rhabdomyolysis)
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

RENEWAL REQUIREMENTS:
- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to Iqirvo® with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid (UDCA) concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase
  - Description of muscle pain or myopathy

QUANTITY EDITS:
#30 per 30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

9) LIVDELZI® (seladelpar lysine) capsule

APPROVAL CRITERIA:
- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary biliary cholangitis (PBC) confirmed by **TWO** of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times (1.67X) the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a tier of 1:40 or higher
  - Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take Livdelzi® concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Is pregnant
  - Has complete biliary obstruction
  - Requires OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors
  - Has end-stage renal disease and on dialysis
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response

- Labs including liver function tests with baseline alkaline phosphatase
- Current treatment plan
- Medical necessity over UDCA taken as monotherapy

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to Livdelzi® with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase

QUANTITY EDITS:

#30 per 30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

10) WINREVAIR™ (sotatercept) injection

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) Functional Class (FC) II or III **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Initially, must be prescribed by or in consultation with a cardiologist or pulmonologist
- Beneficiary has tried and failed a preferred medication from each of the following categories given as triple therapy for at least 90 days unless contraindicated:
  - Phosphodiesterase Inhibitors
  - Endothelin Receptor Antagonists
  - Prostacyclin Analogues
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Beneficiary is diagnosed with pulmonary hypertension WHO groups 2, 3, 4, or 5
  - Baseline platelet count is <50,000/mm^3
  - Experiencing serious bleeding
  - Pregnant
  - Breastfeeding
  - Current smoker without a smoking cessation plan
  - Has restrictive, constrictive, or congestive cardiomyopathy
  - Left ventricular ejection fraction < 45% on an echocardiogram within the previous 6 months
  - Any symptomatic coronary disease events in the previous 6 months
  - Considered Functional Class I or IV
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including hemoglobin (Hgb) and platelets
  - Attestation that Hgb and platelet levels are monitored before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required
  - Attestation that the patient has been counseled on signs and symptoms of blood loss
  - Attestation that a patient of reproductive potential has been counseled that WINREVAIR can impair fertility (male or female)
  - Attestation that a female patient of reproductive potential has been counseled to use contraception due to embryo-fetal toxicity
  - Attestation that a female patient has been counseled that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the final dose.
  - Baseline 6-minute walk distance (6MWD)
  - Baseline echocardiogram

RENEWAL REQUIREMENTS:
- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with stabilization of PAH
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including Hgb and platelets
  - Current 6-minute walk distance
  - Documentation that female of reproductive potential is continuing contraception and is not pregnant

QUANTITY EDITS:
Each strength #4 injections per month (for doses of 90 mg or 120 mg every 3 weeks)

CRITERIA EFFECTIVE OCTOBER 16, 2024

11) OHTUVAYRE™ (ensifentrine) inhalation suspension

APPROVAL CRITERIA:
- Beneficiary must be ≥40 years of age
- Beneficiary must be diagnosed with chronic obstructive pulmonary disease with severity defined by
  - Pre- and Post-bronchodilator FEV1/FVC ratio of <0.70; **AND**
  - Post-bronchodilator FEV1 ≥30 % and ≤70% of predicted normal; **AND**
  - History of ≥ 2 moderate or ≥ 1 severe exacerbation(s) requiring hospitalization within the past 12 months
- Beneficiary has exacerbation(s) while compliant for at least 3 months on **ONE** of the following with continued pulmonary function tests meeting the defined severity listed above:
  - LAMA/LABA combination if blood eosinophil count <300 cells/µL (drawn in the last 12 months)
  - LAMA/LABA/ICS combination if blood eosinophil count ≥300 cells/µL (drawn in the last 12 months)
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Current smoker that refuses to start a cessation plan
- Prescriber must submit the following:
  - Current chart notes with previous and current therapies
  - Current pulmonary function tests as baseline
  - Documentation of smoking history
  - If currently smoking, provide smoking cessation plan
  - Medical necessity over Daliresp® (roflumilast) tablet

RENEWAL REQUIREMENTS:
- Beneficiary is compliant with therapy (defined as 75% utilization)
- 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
- Beneficiary must remain a non-smoker
- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - Attestation that the beneficiary continues to refrain from smoking

QUANTITY EDITS:
#60 ampules (1 carton)/30 days

CRITERIA EFFECTIVE OCTOBER 16, 2024

12) DUPIXENT® (dupilumab) injection for COPD

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 from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- 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; **AND**
  - Post-bronchodilator FEV1 of 30% to 70% predicted; **AND**
  - History of ≥ 2 moderate or ≥ 1 severe exacerbation(s) within the past 12 months
- 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
- Beneficiary must have a blood eosinophilic count of at least 300 cells/μL as a baseline drawn in the last 12 months
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- 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
  - Documentation of smoking history

RENEWAL REQUIREMENTS:

- Beneficiary remains compliant on COPD maintenance therapy (inhalers and immunomodulator injection)
- 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
- 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
  - Current PFTs

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. **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 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**

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 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.

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 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**

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 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.

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 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.

9. **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.

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. Beneficiaries 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://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.

11. **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.

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://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

13. **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**

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 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 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.