ARKANSAS DEPARTMENT OF HUMAN SERVICES

P.O. Box 1437, Slot S415 · Little Rock, AR 72203-1437
Phone: 501-683-4120 · Fax: 1-800-424-5851

**MEMORANDUM**

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: May 25, 2022

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board April 20, 2022 meeting for the following:**
**Manual review criteria for:** Livmarli™ (maralixibat), Livtencity™ (maribavir), Tarpeyo™ (budesonide), Apretude (cabotegravir), Leqvio® (inclisiran), Recorlev® (levoketoconazole), Besremi® (ropeginterferon), Vonjo™ (pacritinib), Pyrukynd® (mitapivat), Oxervate™ (cenegermin)

**Point-of-Sale edits for:** Antiemetics in pregnancy **(**Diclegis® and Bonjesta®) (doxylamine/pyridoxine)

**Preferred Drug List (PDL) therapeutic classes: (May 11, 2022 Drug Review Committee meeting)**
Antipsychotics, Bowel Prep Agents, Cystine Depleting Agents/Penicillamine Agents, Proton Pump Inhibitors

## Table of Contents

# I. ANNOUNCEMENTS

## A. POLYPHARMACY EDITS

Effective April 18, 2022, concomitant fills for any of the following will prompt a severity level 3 drug to drug interaction message at point-of-sale requiring the pharmacy to override the DUR rejection with approved DUR codes.

- Opioid and antipsychotics
- Opioid and gabapentin
- Opioid and muscle relaxers
- Opioid and sedative hypnotics

PA restrictions will remain in place.

The following codes can be used to override the DUE rejection.
**Response for Service Code:** Drug-Drug (DD)
**Professional Service Code**: M0, P0, or R0
**Result of Service:** 1A, 1B, 1C, 1D, 1E, 1F, 1G, 2A, or 2B

## B. COVID-19 VACCINATION UPDATES

***Review the Department of Human Services COVID response page for updates to any new billing guidance. Updates for Providers - Arkansas Department of Human Services**

## C. MAGELLAN CALL CENTER UPDATE

A new and improved IVR system will be implemented this summer at our Magellan Call Center. This system will allow more features and enable greater customer satisfaction. As always, the Provider NPI, Member Medicaid ID, and the Member DOB are the minimally required information. Other required information may include the Provider Medicaid number and Member address, if further authentication is needed. New features with this system will include voice prompts as well as touch-tone prompts, a call-back option, and other ways to authenticate members such as their zip code.

**EFFECTIVE JULY 1, 2022:**

# II. PREFERRED DRUG LIST (PDL):

**NOTE:** Any products in **bold print** represent a **change in status** from the previous preferred drug list. Brand names are listed for reference unless specifically denoted as **BRAND NAME ONLY** as preferred.

****ODT and solutions are preferred ONLY for patients <7 years of age or patients with an NPO diagnosis in history.**

## 1. ORAL/TOPICAL ANTIPSYCHOTICS (for all ages)

****All current criteria remains in place. Criteria can be found in the document at the link below.**
**https://arkansas.magellanrx.com/client/docs/rxinfo/PACriteria.pdf**

**PREFERRED AGENTS**
**First Generation Antipsychotic Agents**

- **Chlorpromazine tablets (generic for Thorazine®)**
- Fluphenazine tablets (generic for Prolixin®)
- Haloperidol Lactate Concentrate solution** (generic for Haldol®)
- Haloperidol tablets (generic for Haldol®)
- Loxapine capsules (generic for Loxitane®)
- Perphenazine tablets (generic for Trilafon®)
- Thioridazine tablets (generic for Mellaril®)

**Second Generation Antipsychotic Agents**

- Aripiprazole tablets (generic for Abilify®)
- Clozapine tablets (generic for Clozaril®)
- Olanzapine ODT** (generic for Zyprexa®)
- Olanzapine tablets (generic for Zyprexa®)
- Paliperidone ER tablets (generic for Invega®)
- Quetiapine tablets (generic for Seroquel®)
- Risperidone ODT** (generic for Risperdal®)
- Risperidone solution** (generic for Risperdal®)
- Risperidone tablets (generic for Risperdal®)
- Ziprasidone capsules (generic for Geodon®)

**NON-PREFERRED AGENT WITH CRITERIA*****

- **Latuda® tablets (lurasidone)**

*****Claims for Latuda for recipients ≥18 years of age will process at POS without a PA if the recipient's Medicaid profile indicates paid claims of ≥ 2 preferred agents in the last 24 months.

**NON-PREFERRED AGENTS**

**First Generation Antipsychotic Agents**

- Chlorpromazine oral concentrate (generic for Thorazine®)
- Fluphenazine elixir/solution (generic for Prolixin®)
- Molindone tablets (generic for Moban®)
- **Perphenazine/Amitriptyline tablets (generic for Etrafon®)**
- **Pimozide tablets (generic for Orap®)**
- **Thiothixene capsules (generic for Navane®)**
- **Trifluoperazine tablets (generic for Stelazine®)**

**Second Generation Antipsychotic Agents**

- Abilify Mycite® tablets (aripiprazole)
- Abilify® tablets/discmelt/solution (aripiprazole)
- Aripiprazole ODT/solution (generic for Abilify®)
- Asenapine SL (generic for Saphris®)
- Caplyta® capsules (lumateperone)
- Clozapine ODT tablets (generic for Fazaclo®)
- Clozaril® tablets (clozapine)
- Fanapt® tablets (iloperidone)
- Fanapt® titration pack (iloperidone)
- Geodon® capsules (ziprasidone)
- Invega® tablets (paliperidone)
- **Lybalvi® tablets (olanzapine/samidorphan)**
- **Nuplazid® tablets/capsules (pimavanserin)**
- Olanzapine/fluoxetine capsules (generic for Symbyax®)
- Quetiapine ER tablets (generic for Seroquel® XR)
- Rexulti® tablets (brexpiprazole)
- Risperdal® tablets/solution/ODT (risperidone)
- Saphris® sublingual (asenapine)
- **Secuado® transdermal (asenapine)**
- Seroquel® XR/IR tablets (quetiapine)
- Symbyax® capsules (olanzapine/fluoxetine)
- Versacloz® suspension (clozapine)
- Vraylar® capsules (cariprazine)

- Vraylar® titration pack (cariprazine)
- Zyprexa® tablets/Zydis (olanzapine)

## 2. BOWEL PREP AGENTS

**PREFERRED AGENTS**
- Gavilyte™-C solution
- Gavilyte™-G solution
- Gavilyte™-N solution
- GoLYTELY® solution
- Moviprep® powder pack—**BRAND NAME ONLY**
- PEG-3350 with electrolytes solution (generic for NuLYTELY®)
- PEG-3350 with flavor packs solution

**NON-PREFERRED AGENTS**
- Clenpiq® solution
- OsmoPrep® tablets
- PEG-3350 with electrolytes powder pack (generic for Moviprep®)
- Plenvu® powder pack
- Suprep® solution
- Sutab® tablets

## 3. CYSTINE DEPLETING AGENTS/PENICILLAMINE AGENTS

**PREFERRED AGENTS**
- **Cuprimine® (penicillamine) capsules—BRAND NAME ONLY**
- **Depen® (penicillamine) tablets—BRAND NAME ONLY**
- Potassium citrate tablets (generic for Urocit-K®)
- **Thiola® tablets (tiopronin)—BRAND NAME ONLY**
- **Thiola® EC tablets (tiopronin)**

**NON-PREFERRED AGENTS**
- Penicillamine capsules (generic for Cuprimine®)
- Penicillamine tablets (generic for Depen®)
- Tiopronin tablets (generic for Thiola®)
- Urocit-K® ER tablets (potassium citrate)

## 4. PROTON PUMP INHIBITORS

**PREFERRED AGENTS**
- Omeprazole capsules (generic for Prilosec®)
- Pantoprazole tablets (generic for Protonix®)

**NON-PREFERRED AGENTS WITH CRITERIA**
- Nexium® packets for suspension (esomeprazole)** —**BRAND NAME ONLY**
- **Protonix® suspension (pantoprazole)** —BRAND NAME ONLY**

**Approval criteria for non-preferred agents with criteria**
- Nexium® suspension (packets)
  - Recipient ≤ 4 years of age
- Protonix® suspension
  - Recipient < 7 years of age **OR**
  - History of NPO within the past 365 days

**NON-PREFERRED AGENTS**

- Aciphex® tablets (rabeprazole)
- Dexilant® capsules (dexlansoprazole)
- Dexlansoprazole capsules (generic for Dexilant®)
- Esomeprazole 24 hour (generic for Nexium® 24 hour)
- Esomeprazole capsule (generic for Nexium®)
- Esomeprazole suspension (generic for Nexium®)
- Lansoprazole capsules (generic for Prevacid®)
- Lansoprazole solutab (generic for Prevacid®)
- Nexium® capsules (esomeprazole)
- Omeprazole OTC (generic for Prilosec® OTC)
- Omeprazole/sodium bicarbonate capsules/packets (generic for Zegerid®)
- Pantoprazole suspension (generic for Protonix®)
- Prevacid® capsules (lansoprazole)
- Prevacid® solutab (lansoprazole)
- Prilosec® suspension (omeprazole)
- Protonix® tablets (pantoprazole)
- Rabeprazole tablets (generic for Aciphex®)
- Zegerid® capsules/packets (omeprazole/sodium bicarbonate)

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

**EFFECTIVE JUNE 27, 2022**

### 1. ANTIEMETICS DURING PREGNANCY

**INDICATIONS for medications used for nausea and vomiting with and without pregnancy:**

**DICLEGIS** is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

**BONJESTA** is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. BONJESTA has not been studied in women with hyperemesis gravidarum.

**ZOFRAN** is a 5-HT receptor antagonist indicated for the prevention of:

- nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m.
- nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
- nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
- postoperative nausea and/or vomiting.

**EMEND** is a NK1 receptor antagonist indicated for:

- Prevention of chemotherapy induced nausea and vomiting
- Prevention of postoperative nausea and vomiting
- Chronic continuous use is not recommended

**AKYNZEO** is a combination drug in the 5HT and NK1 receptor antagonist class indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

**PHENERGAN** is indicated for:

- Perennial and seasonal allergic rhinitis.
- Vasomotor rhinitis.
- Allergic conjunctivitis due to inhalant allergens and foods.
- Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.
- Amelioration of allergic reactions to blood or plasma.
- Dermographism.
- Anaphylactic reactions, as adjunctive therapy to epinephrine and other standard measures, after the acute manifestations have been controlled.
- Preoperative, postoperative or obstetric sedation.
- Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery.
- Therapy adjunctive to meperidine or other analgesics for control of postoperative pain.
- Sedation in both children and adults, as well as relief of apprehension and production of light sleep from which the patient can be easily aroused.
- Active and prophylactic treatment of motion sickness.
- Antiemetic therapy in postoperative patients.

**APPROVAL CRITERIA:**

**Point-of-sale criteria for Diclegis®:**

- Recipient has a billed diagnosis of pregnancy or a lab value confirming pregnancy within the last 9 months without documentation of delivery or pregnancy termination.
- Recipient not meeting point-of-sale criteria will require a PA request with documentation of current pregnancy.

**Bonjesta® criteria:**

- Manual review on a case-by-case basis
- Confirmation of pregnancy
- Medical necessity over Diclegis®

**Promethazine, 5HT-3 antagonists, and NK-1 antagonists:**

- No change—promethazine does not require a PA, 5HT-3 antagonists and NK-1 antagonists will remain on the preferred drug list with ondansetron as preferred option
- Quantity limits still apply

**QUANTITY EDITS:**

Diclegis®--#124/31 days
Bonjesta®--#62/31 days
Ondansetron--#15/ claim

**EFFECTIVE APRIL 20, 2022**

**2. LIVMARLI™ (maralixibat)**

**INDICATION:**

LIVMARLI is indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

**APPROVAL CRITERIA:**

- Recipient must be ≥1 year of age; **AND**
- Recipient must have a confirmed diagnosis of Alagille syndrome with a baseline presence of cholestatic pruritis **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient has elevated serum bile acid concentration; **AND**
- Recipient has documented failure of ursodeoxycholic acid (Ursodiol) **AND** a bile acid sequestrant unless there is a documented contraindication; **AND**

- Recipient should continue ursodeoxycholic acid concomitantly; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including serum bile acid level, LFTs, and fat-soluble vitamins (A,D,E, and INR); **AND**
  - Current weight for dose determination; **AND**
- Initial approval for 3 months

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has documented hepatic decompensation; **OR**
- Prescriber orders a daily dose >28.5 mg; **OR**
- Recipient is not concurrently ordered ursodeoxycholic acid; **OR**
- Recipient should discontinue LIVMARLI if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 380 mcg/kg per day.

**CONTINUATION CRITERIA:**

- Recipient must have a documented decrease in pruritis and/or a decrease in serum bile acid after dose titration; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including bile acids, serum levels of fat-soluble vitamins, and LFTs; **AND**
  - Dose required

**QUANTITY EDITS:**
3 bottles (90 mL)/ 30 days

**EFFECTIVE APRIL 20, 2022**

**3. LIVTENCITY™ (maribavir)**

**INDICATION:**
LIVTENCITY is indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

**APPROVAL CRITERIA:**

- Recipient must be ≥ 12 years of age and weigh at least 35 kg; **AND**
- Recipient must have received either a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) with diagnosed CMV that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Recipient must not exceed the following dosages:
  - 800 mg per day
  - If co-administered with carbamazepine: 1600 mg per day
  - If co-administered with phenytoin or phenobarbital: 2400 mg per day
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Labs confirming active CMV infection with CMV DNA level and CBC; **AND**
  - Negative pregnancy test if of reproductive potential; **AND**
  - Documentation of previous therapies; **AND**
  - Current weight; **AND**
- Initial PA request approved for maximum of 2 months

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient's treatment plan includes concomitant use with valganciclovir or ganciclovir; **OR**
- Recipient has end state renal disease or severe hepatic impairment; **OR**
- Prescriber ordered as prophylaxis therapy; **OR**
- Recipient has been diagnosed with central nervous system CMV disease including CMS retinitis; **OR**
- Prescriber orders for dose outside of recommendation by the manufacturer

**CONTINUATION CRITERIA:**

- Recipient has documented plasma CMV DNA level above the lower limit of quantification (>137 IU/mL) which confirms CMV viremia clearance has not occurred; **AND**
- Prescriber must submit the following:
  - Chart notes; **AND**
  - Response to therapy; **AND**
  - Treatment plan if needed beyond 8 week

**QUANTITY EDITS:**
#124/31 days

**EFFECTIVE APRIL 20, 2022**

**4. TARPEYO™ (budesonide)**

**INDICATION:**

TARPEYO is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

**APPROVAL CRITERIA:**

- Recipient must be ≥18 years of age; **AND**
- Must be prescribed by or in consultation with a nephrologist; **AND**
- Recipient must have a diagnosis of immunoglobulin A nephropathy (IgAN) with proteinuria **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Recipient must have eGFR ≥35 mL/min/1.73 m2 and proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g) at baseline despite ACEi or ARB therapy; **AND**
- Recipient must be on a stable dose of maximally tolerated RAS inhibitor unless contraindicated for at least 90 days; **AND**
- Recipient must be prescribed in combination with an ACEi or ARB; **AND**
- Recipient must have trialed and failed corticosteroids; **AND**
- Recipient will take a maximum of 9 months of therapy at the maximum dose of 16 mg per day followed by 2 weeks of tapered dose at a maximum dose of 8 mg per day (unless new data supports continued use); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Previous treatment; **AND**
  - Confirmation for the diagnosis of IgAN with renal biopsy and labs; **AND**
  - Current labs including eGFR, urine protein or UPCR; **AND**
  - Medical necessity over corticosteroids and immunosuppressants available without a PA; **AND**
- Initial PA for 3 months

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has severe hepatic impairment; **OR**
- Prescriber orders for >9 months of therapy (unless new data supports continued use)

**CONTINUATION CRITERIA:**

- Recipient has been compliant with therapy (defined as: 75% utilization based on Medicaid claims); **AND**
- Recipient has documented improvement in proteinuria with a reduction in UPCR from baseline; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs

**QUANTITY EDITS:**
#124/31 days

**EFFECTIVE APRIL 20, 2022**

**5. APRETUDE (cabotegravir)**

**INDICATION:**
APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

**APPROVAL CRITERIA:**

- Recipient must be ≥12 years of age weighing at least 35 kg; **AND**
- Recipient must be at-risk for sexually acquired HIV-1 infections; **AND**
- Recipient must have a current negative HIV-1 test; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current HIV test results; **AND**
  - Medical necessity over oral PrEP options (e.g., generic Truvada); **AND**
  - Document if recipient will have the 28 day oral lead-in therapy or begin with APRETUDE; **AND**
  - Attestation that the prescriber has counseled the patient about the importance of compliance; **AND**
- Prior authorization will be approved for 12 months.

**DENIAL CRITERIA:**

- Recipient has a positive HIV test either prior to initiating APRETUDE or during treatment; **OR**
- Medical necessity over oral PrEP options was not provided

**CONTINUATION CRITERIA:**

- Recipient remains compliant on every other month injections. Recipient would be considered noncompliant if they missed more than 2 injections in a year; **AND**
- Recipient remains HIV negative; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current HIV test results

**QUANTITY EDITS:**
1 injection every 2 months (quantity override will be needed for first 2 months during loading doses)

**EFFECTIVE APRIL 20, 2022**

**6. LEQVIO® (inclisiran)**

**INDICATION:**
LEQVIO® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

**APPROVAL CRITERIA:**
- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Recipient must be compliant on maximally tolerated statin doses AND ezetimibe use concomitantly; **AND**
- Recipient should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the recipient has a contraindication; **AND**
- If approved, recipient must continue statin at maximally tolerated dose
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Chart notes during trials of statins and ezetimibe; **AND**
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly; **AND**
  - Treatment goals with goal LDL-C; **AND**
  - Medical necessity over PCSK9 inhibitors; **AND**
  - Diet plan for lowering cholesterol; **AND**
  - If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; **AND**
- Initial approval for 3 months

**DENIAL CRITERIA:**
- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe.

**CONTINUATION CRITERIA:**
- Recipient is compliant on statin therapy in addition to LEQVIO; **AND**
- Recipient has an improvement in LDL-C since beginning LEQVIO; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including lipids

**QUANTITY EDITS:**
#1 dose per 6 months (except for the extra dose needed at 3 months)

**EFFECTIVE APRIL 20, 2022**

**7. RECORLEV® (levoketoconazole)**

**INDICATION:**
RECORLEV is indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

RECORLEV is not approved for the treatment of fungal infections. The safety and effectiveness of RECORLEV for the treatment of fungal infections have not been established.

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Cushing's syndrome with hypercortisolemia and surgery is not an option or has not been curative **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Prescriber must be an endocrinologist; **AND**
- Recipients with hypokalemia or hypomagnesemia will need to delay initiation until resolved; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of surgery status; **AND**
    - Current labs including:
        - Urine free cortisol levels (normal is <150 nmol/24 hours OR 3.5-45 mcg/24 hours); **AND**
        - Liver function tests; **AND**
        - Comprehensive metabolic panel; **AND**
    - Baseline electrocardiogram; **AND**
- Recipient should have a trial and failure of ketoconazole and mitotane unless contraindicated or recipient cannot tolerate both medications

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic cholelithiasis, or history of drug induced liver injury due to ketoconazole; **OR**
- Recipients that develop hypocortisolemia should decrease the dose or discontinue the medication; **OR**
- Recipient continues to have hypercortisolemia despite maximum recommended dosage of 1200 mg per day; **OR**
- Recipient takes other medications that cause QT prolongation or has any of the following:
    - Prolonged QTcF interval >470 msec at baseline
    - History of torsades de pointes
    - Ventricular tachycardia
    - Ventricular fibrillation
    - Long QT syndrome

**CONTINUATION CRITERIA:**

- Recipient has a positive response with a decrease in urine free cortisol levels and decrease in symptoms; **AND**
- Prescriber must submit the following:
    - Current chart notes with response to therapy; **AND**
    - Current labs including cortisol, LFTs and CMP; **AND**
    - Any new ECG reports since last PA

**QUANTITY EDITS:**
#248/31 days

**EFFECTIVE APRIL 20, 2022**

**8. BESREMi® (ropeginterferon alfa-2b)**

**INDICATION:**
BESREMi is indicated for the treatment of adults with polycythemia vera.

**APPROVAL CRITERIA:**

- Recipient must be ≥18 years of age; **AND**
- Recipient must have a diagnosis of polycythemia vera **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Recipient meets one of the following:

  - Males: Hemoglobin > 16.5 g/dL or hematocrit ≥ 49% or increased red cell mass; **OR**
  - Females: Hemoglobin > 16 g/dL or hematocrit ≥ 48% or increased red cell mass;
- Accompanied by one or more the following: (per UpToDate)
  - Splanchnic vein thrombosis
  - unusual thrombosis
  - Aquagenic pruritus
  - Splenomegaly
  - Leukocytosis
  - Thrombocytosis
  - Microvascular symptoms
  - Documentation of JAK2 V617F mutation (per clinical trial)
- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history in previous 3 months. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant of hydroxyurea; **AND**
- Recipient of reproductive potential must have a negative pregnancy test; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current negative pregnancy test results if of reproductive potential; **AND**
  - If recipient takes hydroxyurea, provide the discontinuation taper schedule and initial BESREMi dose must be 50 mcg every 2 weeks; **AND**
  - Current labs including CBC, LFTs; **AND**
  - Medical necessity over Pegasys; **AND**
  - Monitoring plan for patients with underlying depression diagnosis

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); **OR**
- Recipient has a history or active serious or untreated autoimmune disease; **OR**
- Recipient is an immunosuppressed transplant patient; **OR**
- Recipient has a diagnosis of severe psychiatric disorder (i.e., severe depression, suicidal ideation, or suicide attempt)

**CONTINUATION CRITERIA:**

- Recipient has seen a positive response to therapy after 6 months with an improvement in one of the following:
  - Hematocrit
  - Platelets
  - Leukocytes
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current negative pregnancy test results if of reproductive potential; **AND**
  - Current labs

**QUANTITY EDITS:**
#2 injections per month

**EFFECTIVE APRIL 20, 2022**

**9. VONJO™ (pacritinib)**

**INDICATION:**
VONJO is indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 × $10^9$/L. This indication is approved under accelerated approval based on spleen volume reduction.

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with intermediate or high-risk primary or secondary myelofibrosis with platelets <50 × $10^9$/L **OR** a diagnosis consistent with FDA approved indication or Compendia support; **AND**
- Recipient should have a treatment plan for diarrhea; **AND**
- Recipient has palpable splenomegaly ≥5 cm; **AND**
- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant to hydroxyurea; **AND**
- Recipient must taper off other kinase inhibitors; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBCs with differential and coagulation testing; **AND**
    - Baseline electrocardiogram

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient requires concomitant use of strong CYP3A4 inhibitors or inducers; **OR**
- Recipient has active bleeding; **OR**
- Recipient has a baseline QTc >480 msec; **OR**
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); **OR**
- Recipient has an eGFR <30 mL/min; **OR**
- Recipient has had a splenectomy; **OR**
- If approved, the recipient may be denied renewal if does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; **OR**
- Recipient is unable to tolerate the minimum dose of 100 mg once daily

**CONTINUATION CRITERIA:**

- Recipient must remain compliant on therapy; **AND**
- Recipient must show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBCs with differential and coagulation testing

**QUANTITY EDITS:**
#124/31 days

**EFFECTIVE APRIL 20, 2022**

**10. PYRUKYND® (mitapivat)**

**INDICATION:**
PYRUKYND is indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

**APPROVAL CRITERIA:**

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a confirmed diagnosis of pyruvate kinase (PK) deficiency with hemolytic anemia **OR** a diagnosis consistent with FDA approved indication or Compendia support; **AND**
- Recipient's baseline hemoglobin should be ≤ 10 g/dL; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including baseline hemoglobin, LFTs; **AND**

- Dose requested (initial dose should be 5 mg twice daily); **AND**
- Test results for variants of the PKLR gene; **AND**
- Previous treatment including transfusion frequency and RBC units required for baseline; **AND**
- Medical necessity over other treatment options; **AND**
- Attestation that prescriber has counseled the patient on compliance importance and the requirement to taper if discontinuing

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber is requesting a dose > 50 mg twice daily; **OR**
- Recipient has moderate or severe hepatic impairment; **OR**
- Recipient requires either a strong CYP3A inhibitor or strong CYP3A inducer and a dose modification may be needed for use with a moderate CYP3A inhibitor or moderate CYP3A inducer; **OR**
- Recipient has 2 non-missense variants; **OR**
- Recipient has seen no benefit by 24 weeks of therapy based on hemoglobin level or transfusion frequency

**CONTINUATION CRITERIA:**

- Recipient has seen a positive response from the maximum dose with either a ≥1.5 g/dL increase in hemoglobin or a at least a 33% reduction in number of RBC units transfused 1/3 compared to baseline; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs; **AND**
  - Dose requested

**QUANTITY EDITS:**
#62 per month of each strength

**EFFECTIVE APRIL 20, 2022**

**11. OXERVATE™ (cenegermin-bkbj)**

**INDICATION:**
OXERVATE™ is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis. OXERVATE™ can be used in adults and children 2 years of age and older.

**APPROVAL CRITERIA:**

- Recipient must be ≥ 2 years of age; **AND**
- Recipient must have a diagnosis of neurotrophic keratitis **OR** a diagnosis consistent with FDA approved indication or Compendia support; **AND**
- Recipient must have stage 2 or stage 3 neurotrophic keratitis; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documented trials of the following; **AND**
    - Stage 2: Artificial tears, lubricant ointments, prophylactic antibiotic eye drops, and topical corticosteroids (if inflammation)
    - Stage 3: All products for stage 2 plus N-acetylcysteine, tetracycline, OR medroxyprogesterone
  - Stage of neurotrophic keratitis; **AND**
  - Medical necessity over surgery with amniotic membrane; **AND**
  - Medical necessity if requesting for > 8 weeks of therapy

**QUANTITY EDITS:** 1 vial per day per affected eye

## 12. 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.**