

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



#### MEMORANDUM

- Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers TO:
- Cynthia Neuhofel, Pharm.D. Division of Medical Services Pharmacy Program FROM:

DATE: May 15, 2024

#### SUBJ: AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board April 17, 2024 meeting for the following:

Manual review criteria for: Accrufer® (ferric malgol) capsule, Adthyza Thyroid® (thyroid, pork) tablet, Xolair® (omalizumab) injection, Agamree® (vamorolone) suspension, Fabhalta® (iptacopan) capsule, Wainua<sup>™</sup> (eplontersen sodium) injection, Zilbrysg® (zilucoplan sodium) syringe, Zoryve® (roflumilast) foam, Rivfloza™ (nedosiran sodium) syringe/vial, Zurzuvae™ (zuranolone) capsule, Filsuvez® (birch triterpenes) gel, Voquezna® (vonoprazan) tablet, Voquezna® (vonoprazan with amoxicillin +/- clarithromycin) pak

Preferred Drug List (PDL) therapeutic classes without PA criteria: Injectable Medication Assisted Treatment (Brixadi® (buprenorphine), Sublocade® (buprenorphine), Vivitrol® (naltrexone))

Preferred Drug List (PDL) therapeutic classes with PA criteria: Triptans, inhaled corticosteroids (ICS), inhaled corticosteroid/long-acting beta agonist combination (ICS/LABA)

**Policy:** Pharmacy Oncology Drug Management Policy

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#### I. ANNOUNCEMENTS

#### 1) PRICING INQUIRIES

As of 2/19/2024, the email for pricing inquiries for Arkansas Medicaid claims will be changed to <u>ArkansasPricingInquiries@primetherapeutics.com</u>.

Please use this email for any future correspondence.

#### 2) <u>COPAY OVERAGES</u>

The Division of Medical Services (DMS), Pharmacy Program, routinely reviews determinations that a Medicaid member has paid copays for prescriptions over their aggregate cap, where that member is due a refund of their copay(s) paid out of pocket per Federal regulations. See 42 CFR 447.56(f) and link: <u>https://www.ecfr.gov/current/title-42/part-447/section-447.56#p-447.56(f)</u>.

In the event a Medicaid member is due a copay refund, a letter will be sent to the member's pharmacy requesting that the claim be rebilled and the member be refunded the overage. If the pharmacy does not reverse the identified claim(s) within 35 business days of the date of the letter, the claim(s) will be reversed, as the member is due a copay refund, based on the member's current eligibility at the time of the impacted claim(s).

#### 3) DIABETIC SUPPLIES UPDATE

Per Arkansas Act 393 of 2023, diabetic supplies including Continuous Glucose Monitors (CGM) will be changing to a pharmacy claim type submission by both pharmacies and DME providers in the next few months. Until the go live date is announced by DHS, the current DME billing rules are in place to ensure Medicaid members have access to their needed diabetic supplies. Further communications will be provided closer to the go live date.

#### 4) HEPATITIS C CRITERIA UPDATE

Arkansas Medicaid has updated the prior authorization criteria for Hepatitis C reviews. The requirement for a certain fibrosis score, which dictates the amount of fibrosis in the liver, has been removed from the criteria. Fibrosis scores will no longer determine treatment eligibility. Also, the sobriety requirement has been removed. Each prior authorization request received will continue to be reviewed on a case-by-case basis. All PA requests must be from a hepatologist, gastroenterologist, infectious disease specialist, or a prescriber working under the direct supervision of one of these specialties. The updated prior authorization form can be found at the link below.

#### https://ar.magellanrx.com/documents/268611/269351/Hepatitis%20C%20Virus%20Medication %20Therapy%20Request%20Form/b0b28e2d-f05a-ea1d-16a4-6c0502aa4a8d

#### 5) 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/ Magellan Rx portal under the pharmacy tab. <u>https://ar.magellanrx.com/provider-documents</u> The April 2024 quarterly newsletter can be found with the following link. <u>https://ar.magellanrx.com/documents/d/arkansas/arrx\_newsletter\_202404</u>

#### 6) <u>PREFERRED DRUG LIST</u> PDL UPDATE EFFECTIVE JULY 1, 2024

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

Non-preferred agents require a prior authorization submission. Prescribers with questions on how to obtain a PA should call the Prime Therapeutics/ Magellan Rx 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/ Magellan Rx pharmacy unit at 1-800-424-7976. Any PA request for off-label use will be reviewed on a case-by-case basis.

#### A. INJECTABLE MEDICATION ASSISTED TREATMENT

#### PREFERRED DRUG LIST

#### Preferred Agents:

- Brixadi® SQ syringe (buprenorphine extended-release)
- Sublocade® SQ Injection (buprenorphine extended-release)
- Vivitrol® IM (naltrexone for extended-release injectable suspension)

#### Non-Preferred Agents:

None

#### B. TRIPTANS

#### PREFERRED DRUG LIST

#### Preferred agents WITHOUT criteria

- Naratriptan HCI tablet (generic for Amerge®)
- Rizatriptan 10mg MLT (generic for Maxalt MLT)
- Rizatriptan 10mg tablet (generic for Maxalt)
- Rizatriptan 5mg MLT (generic for Maxalt MLT)
- Rizatriptan 5mg tablet (generic for Maxalt)
- Sumatriptan succinate tablet (generic for Imitrex)
- Zolmitriptan tablet (generic for Zomig®)
- Zolmitriptan ODT (generic for Zomig® ZMT)

#### Preferred agents WITH criteria

- Sumatriptan 4mg/0.5ml kit refill (generic for Imitrex®)
- Sumatriptan 6mg/0.5ml kit refill (generic for Imitrex®)
- Sumatriptan 6mg/0.5ml vial (generic for Imitrex®)
- Sumatriptan 20 mg nasal spray (generic for Imitrex®)
- Sumatriptan 5 mg nasal spray (generic for Imitrex®)

#### **Non-Preferred Agents**

- Almotriptan malate tablet (generic for Axert®)
- Eletriptan HBr tablet (generic for Relpax®)
- Frova® tablet (frovatriptan)
- Frovatriptan succinate tablet (generic for Frova®)
- Imitrex® kit (sumatriptan)
- Imitrex® tablet (sumatriptan)
- Maxalt® MLT (rizatriptan MLT)
- Maxalt® tablet (rizatriptan)
- Relpax tablet (eletriptan)

- Sumatriptan 4mg/0.5ml syringe
- Sumatriptan 6mg/0.5ml syringe
- Sumatriptan succinate/naproxen sodium tablet (generic for Treximet®)
- Tosymra® nasal spray (sumatriptan)
- Zembrace Symtouch® pen (sumatriptan)
- Zolmitriptan 2.5 mg nasal spray (generic for Zomig®)
- Zolmitriptan 5 mg nasal spray (generic for Zomig®)
- Zomig® tablet (zolmitriptan)

#### Approval criteria for preferred agents WITH criteria

- Preferred Injection (sumatriptan injection 4 mg or 6 mg)
  - Any serotonin 5-HT 1 receptor agonist within past 365 days
- Preferred Nasal Spray (sumatriptan nasal spray 5 mg or 20 mg) must meet one (1) of the following criteria:
  - Trial and failure of 2 different chemical entities for 5-HT 1 receptor agonists in the last 12 months with either of the following:
    - 1 preferred oral tablet <u>AND</u> 1 preferred oral disintegrating tablet (ODT) from 2 different chemical entities; OR
    - 2 preferred oral disintegrating tablets (ODT) from 2 different chemical entities

#### 

 5-HT 1 receptor agonist nasal spray in history within past 365 days with history for look back starting 7/1/2024

#### Denial criteria for all agents:

• Therapeutic duplication of any serotonin 5-HT 1 receptor agonist

#### C. INHALED CORTICOSTEROIDS

#### PREFERRED DRUG LIST

Preferred agents WITHOUT criteria

- Arnuity Ellipta® (fluticasone furoate)
- Asmanex Twisthaler® (mometasone furoate)
- Pulmicort Flexhaler® (budesonide)
- QVAR Redihaler® (beclomethasone dipropionate)

#### Preferred agents WITH criteria

- Alvesco® HFA (ciclesonide)
- Budesonide ampules for nebulizer (generic for Pulmicort Respules®)

#### Non-preferred agents WITHOUT criteria

- Armonair Digihaler® (fluticasone propionate)—discontinued 6/1/2024
- Asmanex HFA® (mometasone furoate)
- Fluticasone Diskus (generic for Flovent Diskus®)
- Pulmicort Respules® (budesonide)

#### Non-preferred agents WITH criteria

• Fluticasone HFA (generic for Flovent HFA®)

#### Approval criteria for Budesonide Respules (Point-of-Sale criteria)

- Criteria 1: Beneficiary < 4 years of age (maximum dose is 2 mg/day) OR
- Criteria 2: Regardless of age, beneficiary has a billed diagnosis of eosinophilic esophagitis
  - Age < 10 years—maximum dose is 2 mg/day
  - Age ≥ 10 years—maximum dose is 4 mg/day

#### Approval Criteria for Alvesco HFA

- Beneficiary must be ≥12 years of age or the minimum age recommended in the manufacturer's package insert
- Prescriber must submit documentation of the medical necessity for Alvesco HFA over a preferred inhaled powder ICS formulation or preferred ICS/LABA product

#### Approval Criteria for Fluticasone HFA (Point-of-Sale criteria)

If one of the following criteria are not met, a prior authorization réquest will be required:

- Criteria 1:
  - Claim for a beneficiary < 7 years of age for fluticasone HFA will pay without a prior authorization
  - Beneficiaries < 7 years of age should transition to a preferred inhaled powder ICS formulation or preferred ICS/LABA product when possible
- OR Critoria
- Criteria 2:
  - Point-of-sale criteria for fluticasone HFA for eosinophilic esophagitis (EoE)
    - Regardless of age, beneficiary with a billed diagnosis of EoE will not require a prior authorization
    - If there is no billed diagnosis of EoE, a prior authorization request must be submitted with documentation of medical necessity.

Eosinophilic esophagitis (EoE)—Submit documentation supporting an EoE diagnosis.

**Asthma**— Beneficiaries  $\geq$  7 years of age with asthma should transition to an inhaled powder ICS formulation or ICS/LABA product that are available without a PA if possible (consider GINA guidelines). If ICS HFA product is still needed, submit documentation of medical necessity over preferred powder ICS products or preferred ICS/LABA combination products. Alvesco® is the preferred ICS HFA product when an ICS HFA formulation is deemed medically necessary.

**NOTE**: Consider SMART therapy with a preferred ICS-formoterol for use as an as needed (PRN) and regular daily treatment instead of a single agent inhaled corticosteroid (per GINA and EPR-3 Guidelines).

#### D. INHALED CORTICOSTEROIDS/LONG-ACTING BETA AGONISTS

#### PREFERRED DRUG LIST

#### Preferred Agents with Criteria

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

#### Non-preferred Agents

- AirDuo Digihaler® (fluticasone/salmeterol) discontinued 6/1/2024
- Airsupra® (budesonide/albuterol)
- Breo Ellipta® (fluticasone furoate/vilanterol)
- Breyna® (budesonide/formoterol)
- Budesonide/formoterol (generic for Symbicort®)—GENERIC ONLY
- Fluticasone/salmeterol (generic for Advair® Diskus)—GENERIC ONLY)
- Fluticasone/salmeterol (generic for AirDuo® RespiClick)
- Fluticasone/salmeterol HFA (generic for Advair® HFA)—GENERIC ONLY
- Fluticasone/vilanterol (generic for Breo Ellipta®)
- Wixela Inhub® (fluticasone/salmeterol)

## Point-of-sale Approval Criteria for Symbicort®, Dulera®, Advair HFA/Diskus®, and AirDuo RespiClick®

Criterion 1:

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

#### Criterion 2:

- Paid drug claim in drug history in the last six months for
  - Advair Diskus®
    - Advair HFA®
    - o Dulera®
  - Symbicort®
  - AirDuo RespiClick®

#### Criterion 3:

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

#### Criterion 4:

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

#### **Quantity limits**

- Symbicort®-#2 inhalers per month for 120 actuation size
  - If the recipient needs > 8 puffs per day, a PA can be submitted to approve an additional inhaler.
- Dulera®–#2 inhalers per month
- Advair Diskus® and Advair HFA®-#1 inhaler per month
- AirDuo RespiClick®–#1 inhaler per month

(\*\*NOTE\*\* Advair Diskus®, Advair HFA® and AirDuo RespiClick® are not recommended for SMART therapy and should not be used for rescue.)

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

#### CRITERIA EFFECTIVE IMMEDIATELY; POINT-OF-SALE EDIT EFFECTIVE JULY 1, 2024

1) EOHILIA (budesonide) 2 mg/10 mL suspension

#### POINT-OF-SALE APPROVAL CRITERIA:

- Beneficiary must have a billed diagnosis of eosinophilic esophagitis (EoE) in the last 2 years
- Beneficiary must be ≥11 years of age or meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must be prescribed no more than 4 mg per day
- Beneficiary will be allowed up to 12 weeks of treatment (request for more than 12 weeks will require a prior authorization)

- Currently, data for treatment with EOHILIA beyond 12 weeks has not been shown to be safe and effective for the treatment of EoE.
- If beneficiary is positively responding to EOHILIA, continuation may be considered after EGD at 12 weeks.
- Prescriber must submit the following:
  - o Current chart notes
  - EGD report after 12 weeks of therapy
  - Medical necessity over fluticasone HFA and budesonide respules

#### **QUANTITY EDITS:**

#60 doses (1 carton) per 30 days

#### **EFFECTIVE IMMEDIATELY**

#### 2) ONCOLOGY POLICY

For up-to-date information on oncology medications, the drug portal on the Prime Therapeutics/ Magellan Rx website has an oncology tab with updated documents. A prior authorization form must be completed with all prior authorization (PA) requests. The link to the form: Forms & Documents -<u>Arkansas (magellanrx.com)</u> In addition to the policy and PA form, the tab also includes a list of oncology medications available with a pharmacy claim and has PA criteria covered by this policy. The tab can be found using this link: <u>Provider Documents - Arkansas (magellanrx.com)</u>

#### Pharmacy Oncology Drug Management Policy

This policy will outline the prior authorization review process for oncology drugs covered under the pharmacy benefit for Arkansas Medicaid beneficiaries. This policy does not impact criteria or prior authorization reviews for products covered as a medical benefit.

Cancer treatment options and protocols change so frequently that the published prior authorization criteria is many times outdated. In reviewing oncology drug prior authorization requests, the pharmacy clinical review team considers safety and efficacy for each request that is reviewed on a case-by-case basis.

#### Policy guidelines

- Prior authorization criteria for oncology drugs covered under this policy will be based on the FDA approved label and support found in the NCCN treatment guidelines with NCCN level of evidence 1 or 2a.
- Requests for an indication, dosage, age, or duration of treatment outside of the FDA approved label and NCCN treatment recommendations are considered off-label.
- Off-label requests will be reviewed for medical necessity on a case-by-case basis while referencing official compendia peer-reviewed literature, and tumor board (case conference) review along with documentation submitted with the request.
- All prior authorization requests must be submitted by or in consultation with an oncologist or hematologist.
- Documentation supporting the prior authorization request must be submitted at the time of the request.

When submitting an initial prior authorization request for an oncology product, providing all pertinent information with the initial request will expedite reviews. At a minimum, the prescriber must submit:

- Current chart notes
- Type of cancer with documentation of any mutations
- All previous therapies tried with timelines and response (i.e., medications and surgeries)

- Current labs specific to the type of cancer and treatment requesting (e.g., complete blood count, renal function labs, liver function panel, etc.)
- Specific imaging requirements per the package insert (e.g., MRI or CT imaging)
- Letter of medical necessity outlining the rationale for the treatment requested especially if the request is off-label
- Current weight or body surface area
- Dose requested
- Pregnancy test results if recommended in the package insert
- ECOG performance status score and medical necessity of treatment with ECOG score of 4

For prior authorization renewal requests, the prescriber must submit the following:

- Current chart notes
- Current lab work
- Current weight or body surface area
- Dose requested
- Documentation of current response to treatment
- Attestation that the patient exhibits a positive response from treatment without intolerable side effects

Initial requests may be approved for 3 months, unless otherwise noted, with renewal pending a positive response to treatment without intolerable side effects. Prior authorization renewals may be approved for 3-6 months depending on the level of monitoring required for the treatment.

#### **EFFECTIVE IMMEDIATELY**

#### 3) Approval Criteria for IgE-Medicated Food Allergies (Xolair®)

This criteria pertains to the new IgE-mediated food allergies indication. The criteria for Xolair's other indications are not updated at this time.

- 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 must be diagnosed with one or more IgE-mediated food allergies <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be an Allergy and Immunology specialist
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Prescriber must attest that the beneficiary has been counseled to continue to avoid the foods that cause allergic reactions as this medication is for accidental exposure only
- Beneficiary must continue to have injectable epinephrine on hand with a pharmacy claim within the last year
- Prescriber must submit the following:
  - Current chart notes
    - Baseline serum IgE level
    - o Current weight
    - Dose requested (must be supported by the dosing chart in the package insert)
    - Skin prick test results confirming food allergies

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

#### **QUANTITY EDITS:**

#4 300 mg prefilled syringe/auto inject per 28 days

- #2 150 mg prefilled syringe/auto inject per 28 days
- #4 150 mg vial per 28 days
- #2 75 mg prefilled syringe/auto inject per 28 days

#### EFFECTIVE IMMEDIATELY

#### 4) AGAMREE (vamorolone) 40 mg/mL suspension

- 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 must be diagnosed with Duchenne Muscular Dystrophy (DMD) <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary has received all appropriate immunizations according to current ACIP guidelines at least two weeks prior to initiation (at least 4 to 6 weeks prior for live attenuated or live vaccines)
- Dose modifications
  - Mild to moderate hepatic impairment—2 mg/kg once daily with a maximum of 100 mg for beneficiaries more than 50 kg (Severe hepatic impairment will be denied)
  - Coadministration with CYP3A4 inhibitors—4 mg/kg once daily with a maximum of 200 mg for beneficiaries more than 50 kg
- Prescriber must specialize in the treatment of DMD and/or neuromuscular disorders
  - Prescriber must submit the following:
    - Current chart notes
      - Documentation of the mutation in the dystrophin gene
      - Information on previous glucocorticosteroids tried including explanation of failure or adverse effect caused by the steroid that is not also caused by AGAMREE
      - Letter of medical necessity with a significant reason specific to the beneficiary that AGAMREE is needed over other glucocorticosteroids (e.g., prednisone, prednisolone, deflazacort)
      - Current weight and dose requested
      - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
      - A baseline assessment of ambulatory function using the Time to Stand Test (TTSTAND) has been documented prior to initiating AGAMREE therapy

- Beneficiary demonstrates a positive response to vamorolone treatment with clinical improvement in ambulatory function as measured by the Time to Stand Test (TTSTAND) compared to baseline after 24 weeks
- Beneficiary lacks clinically significant or intolerable adverse effects related to treatment
  - Prescriber must submit the following:
    - Current chart notes
      - Current weight and dose requested

QUANTITY EDITS: 3 bottles per 30 days

#### **EFFECTIVE IMMEDIATELY**

#### 5) FABHALTA (iptacopan hcl) 200 mg capsule

- 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 must be diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) with absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins confirmed by high-sensitivity flow cytometry <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation of FABHALTA, and recipient must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy
- Prescriber and pharmacy must be enrolled in the REMS program
- Beneficiary currently taking eculizumab (SOLIRIS) or ravulizumab (ULTOMIRIS) must follow the required dose initiation per the package insert
- The medication is prescribed by or in consultation with a hematologist
- Beneficiary must be clinically symptomatic (e.g., fatigue, dyspnea, pain, thrombosis, etc.) and have abnormal labs (e.g., low hemoglobin (Hgb), high lactate dehydrogenase (LDH))
- Beneficiary has baseline Hgb level < 10 g/dL with or without previous C5 inhibitors
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment (eGFR < 30 mL/min/1.73 m<sup>2</sup>)
    - Severe hepatic impairment (Child-Pugh class C)
    - Active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b)
    - If no vaccinations against encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of FABHALTA and no antibiotic drug prophylaxis
    - o Ordered to be used concomitantly with a C5 inhibitor
    - Pregnant or breastfeeding
- Prescriber must submit the following:
  - Current chart notes
  - o Documented symptoms as a baseline
  - Documentation of previous therapies
  - Current labs including complete blood count (CBC), comprehensive metabolic panel (CMP), lactate dehydrogenase (LDH)
  - o Recent history of blood transfusions
  - Pregnancy test results (if applicable)

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary has an improvement in hemoglobin and/or LDH levels compared to baseline
- Beneficiary has an improvement in overall clinical presentation (e.g., fatigue, dyspnea, reduction in transfusions)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC, CMP, and LDH

#### QUANTITY EDITS:

#60/ 30 days

#### EFFECTIVE IMMEDIATELY

6) WAINUA (epiontersen sodium) 45 mg/0.8mL injection

#### **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 must be diagnosed with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) <u>**OR**</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary with multisystem symptoms and/or family history with the diagnosis confirmed with **ONE** of the following:
  - Confirmation of a transthyretin (TTR) variant by genetic testing
  - Tissue biopsy confirming the presence of amyloid deposits
- This medication must be prescribed by or in consultation with a neurologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- Prescriber must submit the following:
  - o Current chart notes
  - o Medical necessity over preferred neuropathic pain agents
  - o Attestation that Vitamin A is being monitored for possible supplementation
  - Baseline modified Neuropathy Impairment Score +7 (mNIS+7) and Norfolk Quality of Life-Diabetic neuropathy (QoL-DN) total score
  - Previous therapies tried
  - Current labs including liver function tests (LFTs) and basic metabolic panel (BMP)

#### **RENEWAL REQUIREMENTS:**

- Beneficiary must remain compliant on therapy (defined as 75%)
- Beneficiary must demonstrate a positive response with either reduced or stable mNIS+7 and/or QoL-DN scores with improvement in neuropathy
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs and BMP

#### QUANTITY EDITS:

# 1/ 30 days

#### 7) ZILBRYSQ (zilucoplan sodium) 16.6 mg, 23 mg, 32.4 mg syringe

#### **APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with generalized myasthenia gravis (gMG) and are antiacetylcholine receptor (AChR) antibody positive <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a neurologist or other specialist knowledgeable in treating gMG
- Prior to initiating treatment with ZILBRYSQ, the beneficiary must have a baseline Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV and a MG-Activities of Daily Living (MG-ADL) total score ≥6
- Beneficiary must have completed or updated meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to first dose of ZILBRYSQ or the provider must administer the meningococcal vaccine as soon as possible and begin antibacterial drug prophylaxis
- Beneficiary must have tried and failed an acetylcholinesterase (AChE) inhibitor (e.g., pyridostigmine) <u>AND</u> immunosuppressive therapies (e.g., glucocorticoids, azathioprine, or mycophenolate) while on a stable dose or have a documented contraindication or intolerance to those agents
- Prescribers and pharmacies must be certified in the ZILBRYSQ Risk Evaluation Mitigation Strategy (REMS) program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Dose requested is not consistent with weight based dosing from the package insert
  - Beneficiary is not AChR antibody positive
  - o Beneficiary has a current unresolved Neisseria meningitidis infection
  - Beneficiary has suspected or confirmed pancreatitis
  - Baseline MG-ADL total score is <6 or designated as MGFA class I or class V</li>
- Prescriber must submit the following:
  - o Current chart notes
  - o Documentation of previous therapies tried with response
  - Serologic test confirming the presence of anti-AChR antibodies
  - Baseline lipase and amylase levels
  - Current body weight
  - Dose requested
  - Baseline MG-ADL total score and MGFA class
- Initial PA will be for 3 months

#### **RENEWAL REQUIREMENTS:**

- Beneficiary must demonstrate a positive clinical response compared to baseline with an improvement in symptoms and/or improvement in the MG-ADL total score
- Prescriber must submit the following:
  - o Current chart notes
  - o Current MG-ADL total score
  - Current body weight
  - Dose requested
- Renewal PAs can be approved for 6 months

#### QUANTITY EDITS:

16.6 mg/0.416 mL—#28 per 28 days 23 mg/0.574 mL—#28 per 28 days 32.4 mg/0.81 mL—#28 per 28 days

#### EFFECTIVE IMMEDIATELY

#### 8) <u>RIVFLOZA (nedosiran sodium) 80 mg vial, 128 mg and 160 mg syringe</u>

#### 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 must be diagnosed with primary hyperoxaluria type 1 (PH1) <u>**OR**</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- PH1 must be confirmed by **ONE** of the following:
  - Molecular genetic testing confirming a mutation in the alanine-glyoxylate aminotransferase (AGXT) gene
  - Liver biopsy results demonstrating reduced alanine-glyoxylate aminotransferase (AGXT) activity
- Beneficiary must have relatively preserved kidney function (≥30 mL/min/1.73 m<sup>2</sup>)
- Must be prescribed by or in consultation with a urologist or nephrologist
- Beneficiary has tried high dose pyridoxine and did not obtain an adequate response (defined as had < 30% reduction in urinary or plasma oxalate concentration)</li>
- Beneficiary should not be approved or continue this therapy with any of the following:
  - eGFR < 30 mL/min/1.73 m<sup>2</sup>
  - Prescribed concomitant lumasiran (OXLUMO)
  - Does not have genetic testing confirming a mutation in the AGXT gene or liver biopsy confirming reduced AGXT activity
  - $\circ$   $\;$  Dose is not consistent with weight-based dosing in the package insert
  - Moderate or severe hepatic impairment
  - Diagnosed with any other primary hyperoxaluria type besides PH1
- Prescriber must submit the following:
  - Current chart notes
  - o Documentation of previous therapies tried
  - Current labs including eGFR, urinary or plasma oxalate levels
  - Genetic testing results confirming a mutation in the AGXT gene or liver biopsy results
  - Current weight and dose requested

#### **RENEWAL REQUIREMENTS:**

- Beneficiary must have reduced urinary or plasma oxalate levels
- Beneficiary continues to have stable kidney function (continues to meet approval criteria)
- Prescriber must submit the following:
  - Current chart notes
  - o Current labs including eGFR, urinary or plasma oxalate levels
  - Current weight and dose requested

#### QUANTITY EDITS:

- 80 mg (0.5 mL) single-dose vial—2 vials per month (for patients 9-11 years of age weighing less than 50kg)
- 128 mg (0.8 mL) single-dose pre-filled syringe—1 syringe per month

#### **EFFECTIVE IMMEDIATELY**

#### 9) ZURZUVAE (zuranolone) 20 mg, 25 mg, 30 mg capsule

#### **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 must be diagnosed with moderate to severe postpartum depression (PPD) with onset of symptoms no earlier than the third trimester and no later than 4 weeks following delivery <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be ≤12 months postpartum (<365 days)
- Beneficiary should not be approved with any of the following:
  - $\circ$  More than 12 months postpartum
  - Currently pregnant
  - Requesting more than one (1) 14-day course
- Prescriber must submit the following:
  - o Current chart notes
  - Previous therapies tried
  - Date of delivery
  - Dose requested
    - Typical dose is 50 mg once daily in the evening for 14 days
    - If patient experiences CNS depressant effects within the 14-day period, dose may be decreased to 40 mg once daily in the evening for the remainder of the 14-day period. The prescriber should contact the specialty pharmacy that filled the member's initial ZURZUVAE prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course.
    - Dose should be reduced to 30 mg for the following:
      - Concomitant use with strong CYP3A4 inhibitor (e.g., ketoconazole)
      - Severe hepatic impairment (Child-Pugh C)
      - Moderate or severe renal impairment (eGFR <60 mL/min/1.73 m<sup>2</sup>)
  - Attestation that the beneficiary has been counseled on CNS depression risk for infants during breastfeeding. Breastfeeding should be temporarily stopped during the 14 day treatment and for 7 days after if possible.
  - Attestation that the beneficiary is not currently pregnant

#### **QUANTITY EDITS:**

One (1) 14-day course

#### 10) FILSUVEZ (birch triterpenes) 10% gel

#### **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 must be diagnosed with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB and JEB
- Beneficiary must have wound(s) that are 10-50 cm<sup>2</sup> and lasting 21 days 9 months
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Ordered concomitant beremagene geperpavec-svdt (VYJUVEK)
  - Diagnosed with EB simplex
- Prescriber must submit the following:
  - o Current chart notes
  - Genetic testing results confirming DEB or JEB
  - Previous therapies tried
  - Baseline description of wound(s)
  - Number of tubes expected per month NOTE: For the initial 3 months, the beneficiary may be authorized #30 tubes every 30 days to determine response to treatment. If the beneficiary responds to FILSUVEZ at the 3 month evaluation, more than 1 tube per dressing change will be approved, if needed.
  - Directions on frequency of application
  - Attestation that patient/caregiver has been counseled on proper use
- Initial PA for 3 months; if demonstrates efficacy, subsequent PAs can be approved for 6 months

#### **RENEWAL REQUIREMENTS:**

- Prescriber must submit the following:
  - Current chart notes
  - Response to therapy with description of wound(s)
  - Medical necessity for continued use
- Treated wounds will be evaluated at 3 months for a positive clinical response with request for PA continuation reviewed on a case-by-case basis. Positive response may include:
  - Decrease in wound size
  - Increase in granulation tissue
  - Complete wound closure
- If beneficiary is receiving a positive clinical response at 3 months, the next PA can be approved for 6 months.

#### QUANTITY EDITS:

#30 per 30 days initially to determine response to treatment. If the beneficiary responds to FILSUVEZ, more than 1 tube per dressing change will be approved, if needed.

#### 11) VOQUEZNA (vonoprazan) tablet & VOQUEZNA Dual and Triple Pak

#### **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.
  - in combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.
  - o 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 exceeds 8 weeks
  - Requested duration of maintenance therapy for healed erosive esophagitis and relief of heartburn exceeds 6 months
  - 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
- 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

#### QUANTITY EDITS:

10 mg and 20 mg--#31/31 days; Dual and Triple Pak--#112/14 days

#### 12) ZORYVE (roflumilast) 0.3% foam

#### **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 must be diagnosed with seborrheic dermatitis <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-bycase basis.
- Based on the Investigator Global Assessment (IGA), the beneficiary must have moderate to severe seborrheic dermatitis which would be an IGA score of 3-4 with current standard of care treatment (i.e., topical antifungals, topical corticosteroids, topical calcineurin inhibitors)
- Beneficiaries with scalp seborrheic dermatitis must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione)
  - Prescription antifungal shampoo (e.g., ketoconazole)
  - High-potency topical corticosteroids
- Beneficiaries with non-scalp seborrheic dermatitis (body and face) must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Topical antifungal (e.g., ketoconazole, ciclopirox)
  - Low-potency topical corticosteroids for face and medium-potency topical corticosteroids for body
  - Topical calcineurin inhibitor (e.g., tacrolimus)
- Prescriber must submit the following:
  - o Current chart notes
  - o Documentation of previous therapies tried with duration and response
  - Current BSA impacted
  - Current Investigator's Global Assessment (IGA) score (between 0-4)
  - Current Worst Itch-Numeric Rating Score (WI-NRS) (between 0-10)
  - o Medical necessity over all other topical treatment options
- Initial approval will be for 2 months

#### RENEWAL REQUIREMENTS:

- For continuation, the beneficiary must demonstrate clinical improvement with decreased IGA score and WI-NRS. IGA score must show a 2-grade improvement compared to baseline.
  - Prescriber must submit the following:
    - o Current chart notes
    - Documentation of response to therapy
    - Medical necessity for continuation of therapy

#### QUANTITY EDITS:

60 gm (1 container) per 30 days

#### 13) ACCRUFER (ferric maltol) 30 mg capsule

#### **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 must be diagnosed with iron deficiency <u>OR</u> 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 baseline hemoglobin less than 12 mg/dL and baseline ferritin < 30 mcg/L</li>
- Beneficiary must have tried and failed other ferrous products (i.e., sulfate, gluconate, or fumarate) or have a contraindication
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and ferritin panel
  - Expected cause of iron deficiency

#### **RENEWAL REQUIREMENTS:**

- Beneficiary continues to be at risk for iron deficiency (e.g., chronic kidney disease, inflammatory bowel disease)
- Beneficiary had a positive response with increased ferritin and/or hemoglobin
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and ferritin panel

#### **QUANTITY EDITS:**

#60/30 days

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#### EFFECTIVE IMMEDIATELY

14) ADTHYZA THYROID (thyroid, pork) 15 mg, 30 mg, 60 mg, 90 mg, & 120 mg tablet

- 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 must be diagnosed with hypothyroidism or require TSH suppression <u>OR</u> 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 tried and failed levothyroxine and Armour® Thyroid
  - Prescriber must submit the following:
    - o Current chart notes
    - o Current labs including TSH and serum T4
    - Medical necessity over levothyroxine and Armour® Thyroid
    - o Medical necessity for patients who are pregnant or have cardiovascular disease
- Initial approval for 6 months

#### 15) 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: <u>https://humanservices.arkansas.gov/about-dhs/dms/passe/</u>

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. <u>https://humanservices.arkansas.gov/</u> <u>https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/</u> 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: <a href="https://humanservices.arkansas.gov/divisions-shared-services/medical-services/">https://humanservices.arkansas.gov/divisions-shared-services/</a>

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: <a href="https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/">https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/</a>

#### 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, <u>on the date the prescription is filled</u>, 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. <u>REGARDING MANUAL REVIEW PA REQUESTS</u>: 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, <u>including long-acting injectable antipsychotic agents</u>, 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 <u>not</u> necessitate Medicaid Pharmacy Program approval of the requested drug.
- 6. <u>REGARDING EMERGENCY OVERRIDE</u>: 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, <a href="https://ar.magellanrx.com/provider-documents">https://ar.magellanrx.com/provider-documents</a>

#### 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. <u>REFILL TOO SOON ACCUMULATION LOGIC:</u> 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 <u>extra</u> 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 <u>extra</u> 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 <u>extra</u> 7days' supply accumulation through early fills in previous 180-day period.

#### 9. <u>REVERSE AND CREDIT MEDICAID PRESCRIPTIONS NOT PROVIDED TO BENEFICIARY:</u>

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. <u>https://ar.magellanrx.com/forms-documents</u>

#### < 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. <u>THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS</u> 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 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://ar.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://ar.magellanrx.com/forms-documents

#### 13. OPIOID INFORMATION ON THE PRIME THERAPEUTICS / 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 Prime Therapeutics / Magellan Rx website. <u>https://ar.magellanrx.com/provider-documents</u>

#### 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 Prime Therapeutics/ Magellan Rx 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.