ARKANSAS DEPARTMENT OF HUMAN SERVICES

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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: February 14, 2024

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board January 17, 2024 meeting for the following:**
Manual review criteria for: Furoscix® (furosemide), Imcivree® (setmelanotide), Vyjuvek™ (beremagene geperpavec), targeted immunomodulator criteria for gout flares, Sohonos™ (palovarotene), Ojjaara (momelotinib), Xdemvy™ (lotilaner), Opfolda™ (miglustat), Likmez™ (metronidazole)

Preferred Drug List (PDL) therapeutic classes without PA criteria: Ophthalmic antibiotics, otic antibiotics

Preferred Drug List (PDL) therapeutic classes with PA criteria: Erythropoiesis Stimulating Agents (Epogen® (epoetin alfa), Procrit® (epoetin alfa), Aranesp® (darbepoetin alfa), Mircera® (methoxy peg-epoetin beta), Reblozyl® (luspatercept), Retacrit® (epoetin alfa)); Urea Cycle Disorders (Buphenyl® (sodium phenylbutyrate), Carbaglu® (carglumic acid), Olpruva™ (sodium phenylbutyrate), Pheburane® (sodium phenylbutyrate), and Ravicti® (glycerol phenylbutyrate))

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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 ArkansasPricingInquiries@primetherapeutics.com.

Please use this email for any future correspondence.

2) 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.

3) HEPATITIS C 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. Each prior authorization request received will continue to be reviewed on a case-by-case basis. The updated Hepatitis C PA form link:
Arkansas Medicaid Hepatitis C Prescription Drug Program (magellanrx.com)

4) PREFERRED DRUG LIST

PDL UPDATE EFFECTIVE APRIL 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800- 424-7976. Any PA request for an off-label use will be reviewed on a case-by-case basis.

A. OPHTHALMIC ANTIBIOTICS

PREFERRED DRUG LIST
Preferred Agents:

- Bacitracin/polymyxin B (generic for Polycin®) ophthalmic ointment
- **Ciloxan® (ciprofloxacin) 0.3% ophthalmic ointment**
- Ciprofloxacin 0.3% ophthalmic solution drops (generic for Ciloxan®)
- Erythromycin 0.5% ophthalmic ointment
- Gentamicin 0.3% ophthalmic solution drops
- **Moxifloxacin 0.5% ophthalmic solution drops (generic for Vigamox®)**
- Polymyxin B/trimethoprim ophthalmic solution drops (generic for Polytrim®)
- Tobramycin 0.3% ophthalmic solution drops (generic for Tobrex®)

Non-Preferred Agents:

- Azasite® (Azithromycin) 1% ophthalmic solution drops
- Bacitracin ophthalmic ointment 500 units/gm
- Besivance® (besifloxacin) 0.6% ophthalmic suspension drops
- Gatifloxacin 0.5% solution (generic for Zymaxid®)

- Moxifloxacin 0.5% ophthalmic solution drops (generic for Moxeza®)
- Natacyn® (natamycin) 5% ophthalmic suspension drops
- Neomycin/polymyxin B/bacitracin ophthalmic ointment
- Neomycin/polymyxin B/gramicidin ophthalmic solution drops
- Ocuflox® (ofloxacin) 0.3% ophthalmic solution
- Ofloxacin 0.3% ophthalmic solution drops (generic for Ocuflox®)
- Polycin® (bacitracin/polymyxin B) ointment
- Sulfacetamide 10% ointment
- Sulfacetamide 10% ophthalmic solution
- Tobrex® (tobramycin) 0.3% ointment
- **Vigamox® (Moxifloxacin) 0.5% ophthalmic solution drops- BRAND NAME**
- Zymaxid® (gatifloxacin) 0.5% ophthalmic solution drops

B. OTIC ANTIBIOTICS

PREFERRED DRUG LIST

Preferred agents

- Ciprodex® suspension (ciprofloxacin and dexamethasone suspension)—**BRAND NAME**
- **Ciprofloxacin/dexamethasone suspension (generic for Ciprodex®)**
- Neomycin/polymyxin/HC solution/suspension (generic for Cortisporin®)
- Acetic acid 2% solution
- Ofloxacin drops (generic for Floxin®)

Non-Preferred Agents

- Cipro HC® suspension (ciprofloxacin/hydrocortisone)
- Cortisporin-TC® suspension (neomycin/colist/hydrocortisone/thonzonium)
- Ciprofloxacin Otic solution (generic for Cetraxal®)
- Ciprofloxacin/fluocinolone solution (generic for Otovel®)
- Otovel® 0.3%-0.025% solution (ciprofloxacin/fluocinolone)

C. ERYTHROPOIESIS STIMULATING AGENTS

PREFERRED DRUG LIST

Preferred agents with Criteria

- **Aranesp® (darbepoetin alfa in polysorbate) syringe**
- Epogen® (epoetin alfa) vial
- **Retacrit® (epoetin alfa) vials**

Non-preferred Agents

- Aranesp® (darbepoetin alfa in polysorbate) vial
- Mircera® (methoxy peg-epoetin beta) syringe
- **Procrit® (epoetin alfa) vial**
- **Reblozyl® (luspatercept) vial**

POS APPROVAL CRITERIA for Preferred Agents:

- The Magellan system reviews lab results for the previous 30 days for a hemoglobin (Hgb) level.
- If a Hgb level is available and ≤ 10 g/dL, a claim will process at point-of-sale without a prior authorization.
- If hemoglobin level is not available in the Magellan system or the beneficiary does not meet the above lab requirement, a prior authorization request must be submitted.

D. UREA CYCLE DISORDER AGENTS (new PDL class)

PREFERRED DRUG LIST

Preferred Agents with Criteria

- Carbaglu® (carglumic acid) tablets—**BRAND NAME**
- Pheburane® (sodium phenylbutyrate) pellets

Non-preferred Agents

- Buphenyl® (sodium phenylbutyrate) powder
- Buphenyl® (sodium phenylbutyrate) tablet
- Carglumic Acid (generic for Carbaglu®) tablets—**GENERIC**
- Olpruva™ (sodium phenylbutyrate) pellets
- Ravicti® (glycerol phenylbutyrate) liquid
- Sodium phenylbutyrate powder (generic for Buphenyl®)
- Sodium phenylbutyrate tablet (generic for Buphenyl®)

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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with:
  - Buphenyl®—urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Carbaglu®—
    - Acute or chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
    - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia OR
    - Maintenance therapy for the treatment of chronic hyperammonemia
    - Acute hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA) as adjunctive therapy (BRAND NAME ONLY)
  - Olpruva™—urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS) and weigh at least 20 kg or have a body surface area of at least 1.2m^2
  - Pheburane®— urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Ravicti®—urea cycle disorders and cannot be managed by dietary protein restriction and/or amino acid supplementation alone
- Medication must be prescribed by or in consultation with a provider experienced in managing UCDs (e.g., geneticist)
- Beneficiary is unable to maintain a plasma ammonia level within normal range with standard of care treatment (i.e., protein restriction and essential amino acid supplementation when appropriate)
- Beneficiary must continue dietary management with protein restriction with dietary plan provided
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies tried with response
  - Current weight and body surface area (BSA)
  - Current labs including plasma ammonia and complete metabolic panel
  - Dose requested must fall within the parameters from the individual product package insert
    - Pheburane® pellets or Buphenyl® tablets/powder (maximum daily dose of 20 gm)
      - 450 to 600 mg/kg/day orally in patients weighing < 20 kg
      - 9.9 to 13 g/m^2/day orally in patients weighing ≥ 20 kg

        - Carbaglu® tablets
            - Acute treatment for NAGS—100-250 mg/kg
            - Chronic treatment for NAGS—10-100 mg/kg
            - Acute treatment for PA or MMA—150 mg/kg/day for ≤15 kg OR 3.3 g/m^2/day for >15 kg
            - If diagnosed with PA or MMA, provide number days treated while hospitalized. Patient should have a maximum of 7 days total.
        - Olpruva™ pellets (maximum daily dose of 20 gm)
            - 9.9-13 g/m^2/day
        - Ravicti® liquid (maximum daily dose of 17.5 mL (19 gm))
            - 4.5 to 11.2 mL/m^2/day (5 to 12.4 g/m^2/day)
    - For non-preferred products, beneficiary must have tried and failed preferred products with documented uncontrolled hyperammonemia despite compliance in the previous year or have documented contraindication/intolerance to preferred products.
    - If the beneficiary has a G-tube, the medical necessity of Ravicti® over sodium phenylbutyrate powder will need to be provided.

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
    - Current chart notes with documentation of current clinical presentation
    - Current plasma ammonia level
    - Current weight and/or BSA and dose requested
- Beneficiary must demonstrate an improvement in clinical presentation and/or decrease in plasma ammonia compared to baseline
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:

None since dose based on BSA

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

EFFECTIVE IMMEDIATELY

1) FUROSCIX® (furosemide) 80 mg/mL 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed New York Heart Association (NYHA) Class III chronic heart failure and being treated for congestion due to fluid overload **OR** 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 cardiologist
- Beneficiary must have tried and failed oral furosemide (160 mg) and one of the following:
    - Torsemide (40 mg)
    - Bumetanide (4 mg)
- Beneficiary must be adherent to CHF therapies (i.e., ACE/ARB, beta blockers, salt restrictions)
- Beneficiary must have documented recent weight gain and increased edema or other symptoms of extracellular volume expansion (e.g., jugular venous distention, pulmonary congestion or rales)
- Beneficiary must have had recent renal lab work done
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Current and previous therapies for heart failure
    - Medical necessity over oral and IV furosemide and other diuretics class

- Current and baseline weight
- Confirmation that beneficiary has a history of at least one prior hospitalization or emergency department visit due to heart failure exacerbations and/or fluid overload, and the beneficiary is stable enough to avoid hospitalization at the time of administration
- Current labs
- Attestation that Furoscix® will be used short-term then transitioned back to oral diuretics as soon as practical.

RENEWAL REQUIREMENTS:

- Beneficiary continues to have fluid overload
- Prescriber must submit the following:
  - Current chart notes
  - Continued treatment plan for fluid overload
  - Current weight and description of edema

QUANTITY EDITS:

#2 per claim

EFFECTIVE IMMEDIATELY

2) IMCIVREE® (setmelanotide) 10 mg/mL solution

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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency or Bardet-Biedl syndrome (BBS) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Confirmation of diagnosis requires:
  - POMC, PCSK1, or LEPR deficiency—genetic testing that confirms variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance
  - BBS—Confirmed by presence of four major features associated with BBS **OR** three major features plus two minor features
    - Major features associated with BBS:
      - Rod-cone dystrophy
      - Polydactyly
      - Obesity
      - Learning disabilities
      - Hypogonadism in males
      - Renal abnormalities
    - Minor features associated with BBS:
      - Speech disorder/delay
      - Strabismus/cataracts/astigmatism
      - Brachydactyly/syndactyly
      - Developmental delay
      - Polyuria/polydipsia (nephrogenic diabetes insipidus)
      - Ataxia/poor coordination/imbalance
      - Mild spasticity (especially lower limbs)
      - Diabetes mellitus
      - Dental crowding/hypodontia/small roots/high arched palate
      - Left ventricular hypertrophy/congenital heart disease
      - Hepatic fibrosis

- Beneficiary must meet the following for obesity diagnosis
  - POMC, PCSK1, or LEPR deficiency must have a baseline body mass index (BMI) ≥30 kg/m^2 or pediatric weight ≥ 95th percentile using growth chart assessment
  - BBS must have a baseline BMI ≥30 kg/m^2 or pediatric weight ≥ 97th percentile using growth chart assessment
- Must be prescribed by or in consultation with a specialist (e.g., endocrinologist, geneticist, obesity specialist)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Genetic testing does not confirm POMC, PCSK1, or LEPR deficiency or the variants are classified as benign or likely benign
  - Clinical symptoms do not support the BBS diagnosis
  - Doesn't meet obesity requirements
  - Obesity is not determined to be related to POMC, PCSK1 or LEPR deficiency or BBS
  - End stage renal disease (eGFR < 15 mL/min/1.73m^2)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current weight and BMI
  - Genetic testing confirming a diagnosis of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **OR** clinical symptoms suggesting a BBS diagnosis
  - Current estimated glomerular filtration rate (eGFR)
- Initial PA for 4 months

RENEWAL REQUIREMENTS:

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

QUANTITY EDITS:

9 vials per month

EFFECTIVE IMMEDIATELY

3) VYJUVEK™ (beremagene geperpavec) 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have one or more chronic or recurrent open wounds with all of the following:
  - Adequate granulation tissue
  - Excellent vascularization
  - No evidence of active wound infection
  - No evidence or history of squamous cell carcinoma
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB

- Vyjuvek gel must be prepared by a pharmacy and delivered directly to the provider for application in the clinic or home setting by a healthcare professional, and it should be used within 8 hours if left unrefrigerated. If immediate use is not possible, Vyjuvek gel can be refrigerated for up to 48 hours.
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation reporting the presence of the COL7A1 gene mutation
  - Plan for acquiring the medication and timeframe for application (application no more than 8 hours after prepared by the pharmacy if left unrefrigerated; administration syringes can be stored for up to 48 hours in the refrigerator)
    - Provide the name of specialty pharmacy/distributer
    - Provide expected delivery date
    - Provide date of Vyjuvek™ application
    - Attestation that medication will be delivered directly to prescriber's clinic or home health professional and not available for patient delivery
  - Baseline description of wound(s)
- Initial PA will be for a maximum of 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 6 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

QUANTITY EDITS:

1 kit per week

EFFECTIVE IMMEDIATELY

4) TARGETED IMMUNOMODULATOR CRITERIA FOR GOUT FLARES

APPROVAL CRITERIA:

- Prescribed by or in consultation with a rheumatologist or other specialist.
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication.
- Maximum dose based on support in manufacturer's package insert or official Compendia.
- Beneficiary has no therapeutic duplication with any other cytokine & CAM antagonists.
- Beneficiary must be diagnosed with gout flares
- Beneficiary must have tried and failed non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and colchicine (unless contraindicated or not tolerated). (Repeated courses of corticosteroids are not appropriate).
- Beneficiary with frequent gout flares (defined as 3 or more gout flares in the previous year) must be on a urate-lowering medication (e.g., allopurinol, febuxostat, probenecid)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of symptoms
  - Current labs including serum urate concentration and documentation of urate crystals in the synovial fluid (if available)
- PA will be approved for 1 dose.
- Renewal requires prescriber to submit updated notes with documentation of continued gout flare. Ilaris® requires at least 12 weeks between doses.

EFFECTIVE IMMEDIATELY

5) SOHONOS™ (palovarotene) 1 mg, 1.5 mg, 2.5 mg, 5 mg, 10 mg capsule

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication (As of 1/3/2024, minimum age is 8 years for females and 10 years for males.)
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with fibrodysplasia ossificans progressive (FOP) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with a specialist knowledgeable in FOP
- Growing pediatric patients should have baseline assessment of skeletal maturity via hand/wrist and knee x-rays, standard growth curves and pubertal staging. Continued monitoring is recommended every 6-12 months until skeletal maturity. Palovarotene can cause premature epiphyseal closure and risk vs. benefit may need to be determined.
- Female beneficiaries of reproductive potential should have highly effective contraception.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnancy
  - Moderate to severe hepatic impairment or severe renal impairment
  - Vertebral fractures (consider the benefit vs. risk)
  - Require strong CYP3A inhibitors (e.g., ritonavir, ketoconazole) and moderate or strong CYP3A inducers (e.g., carbamazepine, phenytoin)
  - Requires tetracycline derivatives
  - Requires high dose Vitamin A
- Prescriber must submit **ALL** of the following:
  - Current chart notes with previous therapies tried.
  - Description of this beneficiary's symptoms and disease progression (volume of heterotopic ossification if available as a baseline)
  - Negative pregnancy test within 1 week of initiating therapy
  - Baseline assessment of bone maturity
  - Dose requested (PA is specific to NDC)

RENEWAL REQUIREMENTS:

- Beneficiary continues to meet approval criteria.
- Provider has considered the benefit versus risk on epiphyseal closure.
- Prescriber must submit the following:
  - Current chart notes
  - Negative pregnancy test results
  - Skeletal maturity test results at least once a year
  - Dose requested (PA is specific to NDC)

QUANTITY EDITS:

Nothing specific as multiple doses must be available depending on need of patient.

EFFECTIVE IMMEDIATELY

6) OJJAARA (momelotinib) 100 mg, 150 mg, and 200 mg tablet

APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in

adults with anemia **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Beneficiary must have hemoglobin <10 g/dL
- Beneficiary with severe hepatic impairment (Child-Pugh C) should start with a reduced dose of 150 mg once daily
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Delay starting therapy if beneficiary has active infection
  - Beneficiaries with HBsAg and/or anti-HBc antibody positivity should consult with a hepatologist to monitor for Hep B reactivation
  - Classified as low-risk MF
- Prescriber must submit **ALL** the following:
  - Current chart notes with documented
  - Previous therapies tried
  - Current labs including CBC with platelets and neutrophils as well as hepatic panel
  - Baseline spleen volume
  - Baseline symptoms attributed to MF
  - Medical necessity over other agents (e.g., ruxolitinib + ESA)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy
- Beneficiary must demonstrate an improvement of documented symptoms compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC with platelets & neutrophils and hepatic panel
  - Updated spleen volume
  - Updated symptoms attributed to MF

QUANTITY EDITS:

#30 per 30 days for each strength

EFFECTIVE IMMEDIATELY

7) XDEMVY™ (lotilaner) 0.25% drops

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 has been diagnosed with *Demodex* blepharitis verified by presence of collarettes through a slit lamp exam **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Xdemvy must be prescribed by or in consultation with an optometrist or ophthalmologist
- Prescriber must submit **ALL** the following:
  - Documentation of results seen with slit lamp examination
  - Other therapies tried
  - Medical necessity over topical tea tree oil/shampoo and oral ivermectin

RENEWAL REQUIREMENTS:

- Beneficiary had a previous positive response with a reduction in collarettes and mites.
- Maximum of 2 treatments per year

QUANTITY EDITS:

1 bottle per 6 weeks

EFFECTIVE IMMEDIATELY

8) OPFOLDA™ (miglustat) 65 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 an adult diagnosed with late-onset Pompe disease (LOPD) based on documentation of one of the following:
  - Deficiency of GAA enzyme
  - GAA genotyping
- Beneficiary must have tried enzyme replacement therapy (ERT) for at least 24 months without improvement (e.g., improved FVC or 6MWT) with one of the following:
  - Lumizyme (alglucosidase alfa) intravenous infusion; OR
  - Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion
- Must be prescribed by or in consultation with a geneticist, neurologist, or provider that specializes in the treatment of lysosomal storage disorders
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnant
  - Not prescribed concomitant Pombiliti infusions (medical billing will be verified)
  - End stage renal disease (moderate-severe impairment requires dose decrease)
  - <40 kg
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Generic testing to confirm LOPD
  - Attestation that both female subjects of childbearing potential and male subjects are using contraception
  - Baseline pulmonary function tests (specifically FVC %predicted) and labs for renal function
  - Baseline 6 minute walk test (6MWT)
- Initial PA for 6 months

RENEWAL REQUIREMENTS:

- Beneficiary must continue to receive Pombiliti infusions every 2 weeks and receiving therapy compliantly
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Attestation that both female subjects of childbearing potential and male subjects continue to use contraception
  - Updated PFTs and renal function labs
  - Updated 6MWT

QUANTITY EDITS:

8 capsules/ 28 days

EFFECTIVE IMMEDIATELY

9) LIKMEZ™ (metronidazole) 500 mg/5mL suspension

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 trichomoniasis, amebiasis, or anaerobic bacterial infection with one of the following specific bacteria:

- Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess, caused by *Bacteroides* species including the *B. fragilis* group (*B. fragilis, B. ovatus, B. thetaiotaomicron, B. vulgatus*), *Parabacteroides distasonis, Clostridium* species, *Eubacterium* species, *Peptococcus* species, and *Peptostreptococcus* species.
- Skin and skin structure infections caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
- Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
- Bacterial septicemia caused by *Bacteroides* species including the *B. fragilis* group and *Clostridium* species.
- Bone and joint infections, (as adjunctive therapy), caused by *Bacteroides* species including the *B. fragilis* group.
- Central nervous system (CNS) infections, including meningitis and brain abscess, caused by *Bacteroides* species including the *B. fragilis* group.
- Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by *Bacteroides* species including the *B. fragilis* group.
- Endocarditis caused by *Bacteroides* species including the *B. fragilis* group.

- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Report indicating diagnosis/bacteria requiring treatment
  - Culture and sensitivity if available
  - Medical necessity over other antibiotics available without a PA including metronidazole tablets
  - Dose requested

RENEWAL REQUIREMENTS:

- Continuation requires a report that documents continued bacteria positivity

QUANTITY EDITS:

- No set maximum quantity since based on dose required

10) 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 beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only. If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211. Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website:
https://humanservices.arkansas.gov/divisions-shared-services/medical-services/

If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy: **https://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 beneficiaries who, on the date the prescription is filled, is incarcerated in a correctional or holding facility, including juvenile correctional facilities, and are detained pending disposition of charges or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid beneficiaries, including beneficiaries in a juvenile correctional facility, **the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment if billed to Medicaid**. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

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

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

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website,
https://ar.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 beneficiary for the higher dose or an early refill PA will not be approved.

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

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

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

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

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

10. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:**

< 18 YEARS OF AGE:
Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Beneficiaries have an ongoing requirement for labs for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs for the antipsychotic agents, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.

For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form may be found at the following link. **https://ar.magellanrx.com/forms-documents**

< 10 YEARS OF AGE:
Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent. All documentation, chart notes, signed informed consent, and required lab work must be submitted, and the manual review will be performed by the Medicaid Pharmacy Program psychiatrist.

11. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID BENEFICIARIES WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that beneficiary can be billed using the beneficiary's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed 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 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://ar.magellanrx.com/provider-documents**

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

The clinical consultation staff may give advice on any of the following topics:

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

The Clinician Consultation Center is not affiliated with Arkansas Medicaid, but the information may be useful for providers in our state and provided only as an educational tool.

This advance notice 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.