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: May 9, 2023

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board April 19, 2023 meeting for the following:**
Manual review criteria for: KEVZARA® (sarilumab), ALS medications, KRAZATI™ (adagrasib), SUNLENCA® (lenacapavir sodium), JAYPIRCA™ (pirtobrutinib), ORSERDU™ (elacestrant), DARTISLA ODT® 1.7 mg and GLYCATE® 1.5 mg (glycopyrrolate), FILSPARI™ (sparsentan)

Point-of-Sale edits for: Pituitary suppressive agents, cystic fibrosis transmembrane conductance regulator (CFTR) agents

Preferred Drug List (PDL) therapeutic classes: Anaphylaxis agents, hypoglycemic agents and pituitary suppressive agents

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I. ANNOUNCEMENTS

A. BENEFICIARY MEDICAID COVERAGE UPDATE

With the national COVID Public Health Emergency (PHE) officially coming to an end on May 11th, 2023, Arkansas DHS is moving back to normal operations in Medicaid. This means that for the first time in three years, DHS can close Medicaid cases for all reasons, which may include closing due to a member being over income for example. During the PHE, Medicaid could only close cases due to death, incarceration, if the beneficiary moved out of state, or if the beneficiary requested closure.

Because of this change, DHS expects that there will be concerns and lots of phone calls when the first round of closures hit at the end of the month and through September. Below are the best ways to help any impacted beneficiaries get assistance.

1. DHS is asking to not suggest or send the beneficiary to a county office. Instead, please provide the beneficiary with the Arkansas DHS Access Arkansas Call Center number: **1-855-372-1084.**
2. If a beneficiary finds that there is a long wait on hold to the Access Arkansas Call Center, encourage them to visit the new DHS online system, Access Anywhere on the DHS website Access Anywhere - Arkansas Department of Human Services**.** This is also a great way to submit Medicaid, ARKids, SNAP and TEA questions.
3. Please share the DHS renew information with your beneficiaries ar.gov/renew**.** That site is compatible to provide information in English, Spanish, and Marshallese.

B. UPDATE TO SHORT-ACTING BETA AGONISTS ON PDL

Effective April 6, 2023, Sandoz has discontinued manufacturing Proventil HFA®. The supply is expected to be exhausted by the end of April 2023. Therefore, the SABA PDL list has been updated to accommodate the removal of Proventil HFA and ProAir HFA. In addition to Ventolin HFA, the generic albuterol HFA inhalers are available until the DUR Board can review the class during the next meeting.

C. SPRAVATO UPDATE

Spravato® (esketamine hydrochloride) solution is indicated in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, and depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. Due to the risks of serious adverse outcomes resulting from sedation, dissociations, and abuse and misuse, Spravato® is restricted under the SPRAVATO REMS program. When initially reviewed by the DUR Board for criteria development, the Board approved criteria limited the prescribing of this medication to psychiatrists. This has caused some patients to be unable to get this medication due to limited appointments available with psychiatrists. Given the strict monitoring required with the REMS program that would apply to any prescriber, the criteria has been changed to include any willing prescriber and not just limited to psychiatrists.

D. CHANGES TO MEDICAID RELATED TO UNWINDING OF PUBLIC HEALTH EMERGENCY

The federal COVID-19 Public Health Emergency ends May 11, 2023, but Arkansas Medicaid is allowed and/or required to continue some flexibilities beyond that date. See the Arkansas Medicaid website for the most up-to-date notices.
https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/changes-to-medicaid-ending-effective-december-31-2022/

II. PREFERRED DRUG LIST

ADDITIONAL UPDATES:
The following changes will be effective July 1, 2023.

- Brand name Lamictal® will no longer be preferred.

The following changes will be effective May 15, 2023.

- Lamotrigine tablets can be dispensed as a preferred option in the anticonvulsant class. This change does not apply to the extended release or ODT formulations.
- Insulin aspart mix pen/vial (generic for Novolog® Mix) and Insulin aspart cartridge/vial/FlexPen (generic for Novolog®) are added as preferred options on the preferred drug list in the Preferred-Rapid/Intermediate Acting Combinations and Preferred-Rapid Acting Insulin classes respectively.

EFFECTIVE JULY 1, 2023
NOTE: Bolded medications indicate a change from the previous preferred drug list or PA status.

1. ANAPHYLAXIS AGENTS

SELF INJECTED EPINEPHRINE

PREFERRED AGENTS

- **EpiPen®--BRAND ONLY**
- **EpiPen Jr®--BRAND ONLY**

NON-PREFERRED AGENTS

- Auvi-Q® 0.1 mg, 0.15 mg, and 0.3 mg
- Epinephrine 0.15 mg and 0.3 mg (generic for Adrenaclick®)
- **Epinephrine 0.15 mg and 0.3 mg (generic for EpiPen Jr® and EpiPen®)**
- Symjepi® 0.15 mg and 0.3 mg

2. HYPOGLYCEMICS

PREFERRED AGENTS

- **Baqsimi® (glucagon intranasal powder)**
- GlucaGen® (glucagon) Hypokit 1 mg injection
- **Gvoke® (glucagon pre-filled syringe and autoinjector)**
- Proglycem® suspension (diazoxide)—**BRAND ONLY**

NON-PREFERRED AGENTS

- Diazoxide suspension (generic for Proglycem®)
- **Glucagon 1 mg emergency kit**
- Gvoke® (glucagon) vial
- Zegalogue® (dasiglucagon pre-filled syringe and autoinjector)

*****The previous manual review PA criteria for Gvoke®, Baqsimi®, and Zegalogue® has been removed. Gvoke® and Baqsimi® are now available without a PA, and Zegalogue® along with the other non-preferred agents require documentation of the medical necessity over preferred agents.*** Quantity limits still apply, and age edits based on FDA approved minimum requirements apply.**

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.

3. PITUITARY SUPPRESSIVE AGENTS (new PDL class)

NOTE: All medications with a prostate cancer indication will be available as a medical bill option only. The medications available as medical bill for prostate cancer include:

- Camcevi® (leuprolide)42 mg
- Eligard® (leuprolide) 7.5 mg, 22.5 mg-3 month, 30 mg-4 month, and 45 mg-6 month
- Lupron® (leuprolide) 1 mg
- Lupron Depot® (leuprolide) 7.5 mg, 22.5 mg-3 month, 30 mg-4 month, 45mg-6 month, and Lupron 2 week Kit
- Trelstar® (triptorelin) 3.75 mg, 11.25 mg, 22.5 mg

A. ENDOMETRIOSIS OR UTERINE LEIOMYOMA

PREFERRED AGENTS

- Lupaneta® (leuprolide inj and norethindrone tablets) 3.75 mg for monthly admin up to 6 months
- Lupron Depot® (leuprolide) 3.75 mg and 11.25 mg-3 month

NON-PREFERRED AGENTS

- None

POINT-OF-SALE APPROVAL CRITERIA (no change from current POS criteria)

- Billed diagnosis of endometriosis or uterine leiomyoma (fibroids), AND
  - <12 billed claims of 3.75mg leuprolide injection (which would include Lupaneta®) in the previous 3 year Medicaid history, OR
  - <4 billed claims of 11.25mg leuprolide injection (which would include Lupaneta®) in the previous 3 year Medicaid history, AND
- No Therapeutic Duplication with other leuprolide products

Denial Criteria

- Diagnosis of infertility in Medicaid history (3 year look back)
- Thrombophlebitis
- Thromboembolic disorders
- Cerebral apoplexy in Medicaid history
- Carcinoma of the breast in Medicaid history

B. BREAST CANCER OR OVARIAN CANCER

PREFERRED AGENTS

- Lupron-Depot® (leuprolide) 3.75 mg, 7.5 mg, and 11.25 mg-3 month

NON-PREFERRED AGENTS

- None

POINT-OF-SALE APPROVAL CRITERIA (no change from current POS criteria)

- Billed diagnosis in Medicaid history of breast cancer or ovarian cancer in the last 2 years
- No Therapeutic Duplication with other leuprolide products

C. CENTRAL PRECOCIOUS PUBERTY (manual review)

PREFERRED AGENTS

- Fensolvi® (leuprolide) 45 mg
- Lupron Depot-Ped® (leuprolide) 7.5 mg, 11.25 mg, 15 mg, 11.25 3-month kit, 30mg 3-month kit, and 45 mg 6-month kit
- Synarel® (nafarelin) spray

NON-PREFERRED AGENTS

- Triptodur® (triptorelin) 22.5 mg-6 month

APPROVAL CRITERIA

Requests for LUPRON-DEPOT PED®, SYNAREL® Nasal Spray, Fensolvi®, Triptodur® or other gonadotropin-releasing hormone (GnRH) agonist drugs, for treating CPP, will require manual review prior authorization on a case-by-case basis.

- Beneficiary is diagnosed with Central Precocious Puberty (CPP)
- Beneficiary must demonstrate full activation of the hypothalamus-pituitary-gonadal (HPG) axis before 8 years of age in females and before 9 years of age in males
- Females shall be less than 8 years of age and males shall be less than 9 years of age when initiating treatment with a GnRH agonists for treatment of CPP
- Beneficiary should not be approved or continue on this therapy with any of the following:
    - When the goal is for the treatment of premature adrenarche (PA) associated with normal rate of growth and no evidence of clitoromegaly, penile growth or testicular enlargement
    - When the goal is for the treatment of premature menarche in the young girl with vaginal bleeding but no or little breast development and no evidence of endocrinopathy on the basis of pelvic ultrasonography or concentrations of LH, FSH and estradiol
    - There is no activation of the HPG axis, and FSH, LH and estradiol or testosterone concentrations are at prepubertal levels.
    - When the goal is for the treatment of premature thelarche (PT) in the very young females (e.g., age < 2 years) without additional indicators for CPP
    - If the only signs of sexual development are pubic and/or axillary hair and/or axillary odor
    - When the child's predicted adult height is within the normal range
    - When pubertal suppression is being used for increasing linear growth
    - When initial age for female ≥11 years and male ≥12 years
- Prescriber must submit the following:

- Current chart notes
- Letter of medical necessity
- Documentation of growth rate acceleration above normal growth rate for age
- All testing and documentation used to determine CPP (e.g., notes on Tanner stage of development, progressive female breast development confirmed by palpation before 8 years of age, progressive penis and testicular enlargement, etc.)
- Bone age determination and predicted adult height
- Baseline labs tests for luteinizing hormone (LH), and either estradiol or testosterone, and follicle stimulating hormone (FSH) (e.g., LH of >0.3 IU/L is the most reliable screening test for CPP on a random blood sample. If LH is <0.3 and CPP is suspected, a stimulation test with a gonadotrophin-releasing hormone (GnRH) analog may be necessary.)
- TSH test for hypothyroidism if the growth velocity is slow instead of rapid (to exclude hypothyroidism as the cause of CPP)
- If requesting a non-preferred medication, provide the medical necessity over the preferred option(s)

RENEWAL REQUIREMENTS:

- Female < 11 years of age or male < 12 years of age for continuation of GnRH therapy previously initiated for treatment of CPP
- Prescriber to provide data that child shows positive response to the drug therapy (e.g., slowing of the growth velocity to <7cm/year, shrinkage or softening of the glandular breast tissue or the testes, or documentation of suppression of the HPG axis

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

EFFECTIVE JULY 1, 2023

1) POINT-OF-SALE (POS) EDITS FOR CF TRANSMEMBRANE CONDUCTANCE REGULATOR AGENTS (CFTR)

****This includes Kalydeco®, Orkambi®, Symdeko®, and Trikafta®.**

Criterion 1:

- Beneficiary has a billed diagnosis of Cystic Fibrosis in the last 2 years
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for the specific requested medication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert

OR

Criterion 2:

- Beneficiary Medicaid profile includes a claim for either Kalydeco®, Orkambi®, Symdeko®, or Trikafta® in the last 90 days

Beneficiaries not meeting the POS edits will require a prior authorization. The prescriber must submit a request with current chart notes documenting a Cystic Fibrosis diagnosis.

EFFECTIVE IMMEDIATELY

2) APPROVAL CRITERIA FOR PRODUCTS WITH THE INDICATION OF POLYMYALGIA RHEUMATICA

***This includes Kevzara®**

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or official Compendia
- Beneficiary has no therapeutic duplication with any other cytokine & CAM antagonists
- Beneficiary must be diagnosed with polymyalgia rheumatica based on clinical symptoms and supporting lab findings with the following:
  - Elevated ESR and/or CRP
  - Pain and morning stiffness about the shoulders, hip girdle, and neck
  - Limited range of motion in shoulders, cervical spine, or hips causing difficulties with activities of daily living (such as pulling on a shirt, putting on socks/shoes, or transfer from lying to seated position)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms
  - Current labs including ESR and CRP
  - Medical necessity over corticosteroids at maximum tolerated doses

EFFECTIVE IMMEDIATELY

3) ALS MEDICATIONS

APPROVAL CRITERIA:

Riluzole tablets

- No PA required
- Quantity limit applies

Exservan® and Tiglutik®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert or official Compendia
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous and current therapies
  - Baseline ALS Functional Rating Scale-Revised score
  - Baseline PFTs
  - Medical necessity over riluzole tablets

Radicava® ORS (edaravone)

- 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 have a diagnosis of amyotrophic lateral sclerosis (ALS) **OR** a diagnosis consistent with any updated FDA approved indications
- Beneficiary should meet the following at baseline:
  - Beneficiary has a disease duration < 2 years

    - Beneficiary has FVC ≥ 80% at baseline
    - Baseline ALSFRS-R score documents the retention of functionality for most activities of daily living (defined as scores of 2 points or better on each individual item)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous and current therapies
    - Baseline ALS Functional Rating Scale-Revised score
    - Current PFTs
    - Duration of symptoms
    - Documentation of concomitant meds for ALS (are they planning on riluzole and/or Relyvrio® as well)

Relyvrio™ (sodium phenylbutyrate/taurursodiol powder) for suspension

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert or official Compendia
- Beneficiary must have a diagnosis of sporadic or familial amyotrophic lateral sclerosis (ALS) **OR** a diagnosis consistent with any updated FDA approved indications
- Beneficiary must not have any of the following:
    - Require bile acid sequestrants, probenecid, or cyclosporine
    - Have moderate to severe renal or hepatic impairment
- Beneficiary should meet the following at baseline:
    - Beneficiary has initial symptoms no longer than 18 months prior to starting medications
    - Beneficiary has a slow vital capacity (SVC) > 60% at baseline
- Prescriber must submit
    - Current chart notes
    - Documentation of previous and current therapies
    - Baseline ALS Functional Rating Scale-Revised score
    - Current PFTs (including SVC)
    - Duration of symptoms
    - Documentation of concomitant meds for ALS (are they planning on riluzole and/or Radicava® ORS as well)

RENEWAL REQUIREMENTS: (pertains to Exservan®, Tiglutik®, Radicava® ORS, or Relyvrio™):

- Beneficiary remains compliant on therapy (defined as 75% utilization)
- Beneficiary does not become dependent on invasive ventilation or tracheostomy
- Prescriber must submit the following:
    - Current chart notes
    - Current PFTs
    - Current ALSFRS-R score

QUANTITY EDITS:

Riluzole
#62 per 31 days
Exservan
#62 per 31 days
Tiglutik
#620 mL per 31 day

Radicava ORS
50 mL bottle--#1 per 28 days
70 mL bottle--#1 per 28 days
Relyvrio
#62 per 31 days

EFFECTIVE IMMEDIATELY

4) KRAZATI™ (adagrasib) 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 KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) and has received at least one prior systemic therapy **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must have tried and failed at least one prior systemic therapy
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Requires concomitant use with strong CYP3A inducers
  - Requires concomitant use with strong CYP3A4 inhibitors and has not reached steady state adagrasib concentrations
  - Requires concomitant use with other products that may prolong the QTc interval. If concomitant use cannot be avoided, monitor electrocardiogram and electrolytes
  - Cannot tolerate the minimum dose of 600 mg once daily
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current labs including CBCs and LFTs
  - Baseline ECG if at risk for QT prolongation or diagnosed with congestive heart failure, bradyarrhythmias, or electrolyte abnormalities
  - Test results verifying the KRAS G12C mutation in tumor or plasma specimens
  - Documentation of previous therapies tried including an immune checkpoint inhibitor (anti-PD-1/PD-L1) (e.g., pembrolizumab, atezolizumab) and/or platinum-based chemotherapy (e.g., cisplatin, carboplatin)

RENEWAL REQUIREMENT:

- Prescriber must submit current chart notes and labs
- Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
- Beneficiary continues to meet approval criteria

QUANTITY EDITS:

#180/30 days

EFFECTIVE IMMEDIATELY

5) SUNLENCA® (lenacapavir sodium) 300 mg tablet and 463.5 mg/1.5 mL

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 HIV-1 infection and heavily treatment-experienced with multidrug resistant disease failing their current antiretroviral regimen due to

resistance, intolerance, or safety considerations **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
    - Multidrug resistance is defined as resistance to ≥2 agents from ≥3 of the 4 main classes of ARV
    - ARV classes include nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI) and integrase strand transfer inhibitor (INSTI)
- Beneficiary should not be approved with any of the following:
    - Concomitant administration of strong CYP3A inducers is required
    - Baseline HIV-1 RNA levels < 400 copies/mL
    - Prior to starting SUNLENCA, there is no current antiretroviral therapy
    - Not prescribed a concomitant optimized background regimen
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Documentation of previous therapies tried
    - Current labs including viral load
    - Documentation of which regimen prescribed
    - Documentation of concomitant antiretrovirals prescribed
- PA will be approved for 1 year

RENEWAL REQUIREMENTS:
- Beneficiary remains compliant on all antiretroviral medications
- Beneficiary has a demonstrated improvement in viral load
- Prescriber must submit the following:
    - Current chart notes
    - Current labs including viral load

QUANTITY EDITS:
- #1 oral tablet pack per year (qty 4 or 5 depending on regimen chosen)
- 1 injection kit (2 vials) every 6 months

EFFECTIVE IMMEDIATELY

6) JAYPIRCA™ (pirtobrutinib) 50 mg and 100 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 relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary with severe renal impairment requires a dose adjustment
- Beneficiary should not be approved with any of the following:
    - Cannot tolerate the minimum daily dose of 50 mg
    - Pregnancy
    - Avoid strong CYP3A inhibitors if possible. If unavoidable, JAYPIRCA dose should be decreased
    - Avoid strong or moderate CYP3A inducers if possible. If unavoidable, JAYPIRCA dose should be increased.
- Prescriber must submit **ALL** of the following:

- Current chart notes
- Documentation of previous therapies tried
- Current labs including CBC with differential, renal function

RENEWAL REQUIREMENTS:

- Prescriber must submit current chart notes and labs
- Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
- Beneficiary continues to meet approval criteria

QUANTITY EDITS:
50 mg—#31/31 days
100 mg—#62/31 days

EFFECTIVE IMMEDIATELY

7) ORSERDU™ (elacestrant) 86 mg and 345 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 estrogen receptor (ER)+/ human epidermal growth factor receptor (HER2)-, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must be a postmenopausal female or an adult male
- Beneficiary should not be approved with any of the following:
  - Not diagnosed with ER+/HER2- breast cancer
  - Does not have the ESR1 mutation
  - Cannot tolerate the minimum dose of 172 mg once daily
  - Pregnancy
  - Requires concomitant strong or moderate CYP3A4 inducers or inhibitors
  - Severe hepatic impairment
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies tried with response
  - Test results documenting ESR1 mutation
  - Current labs including lipid panel (must be monitored periodically)

RENEWAL REQUIREMENTS:

- Beneficiary continues to meet approval criteria
- Beneficiary does not demonstrate disease progression or unacceptable toxicity
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including lipid panel

QUANTITY EDITS:
86 mg tablets--#93/31 days
345 mg tablets--#31/31 days

EFFECTIVE IMMEDIATELY

8) DARTISLA ODT® 1.7 mg and GLYCATE® 1.5 mg (glycopyrrolate) 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 peptic ulcer disease and used as an adjunct to other treatment to reduce symptoms **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary should not be approved if at risk for anticholinergic toxicity (e.g., glaucoma, obstructive uropathies, mechanical obstructive diseases of GI tract, GI motility disorders, active inflammatory or infectious colitis, history of or current toxic megacolon, myasthenia gravis)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous and current therapies
  - Medical necessity of DARTISLA ODT or GLYCATE over regular glycopyrrolate tablets which are available without a PA

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy (if asymptomatic, provider rationale for continued use)
  - Continued medical necessity of DARTISLA ODT or GLYCATE (over glycopyrrolate tablets)

QUANTITY EDITS:
#124/31 days

EFFECTIVE IMMEDIATELY

9) FILSPARI™ (sparsentan) 200 mg and 400 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 is diagnosed with proteinuria associated with primary immunoglobulin A nephropathy (IgAN) **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must discontinue any prescriptions of renin-angiotensin, aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren
- Beneficiary's urine protein-to-creatinine ratio (UPCR) must be ≥ 1.5 g/g or total urine protein must be ≥ 1 g/day at baseline while on RAAS inhibitor treatment
- Beneficiary, prescriber, and pharmacy must all be certified with the FILSPARI REMS program

- Beneficiary should have tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) at maximally tolerated doses unless contraindicated
- Beneficiary should not be approved with any of the following:
  - Baseline elevated aminotransferases > 3x ULN
  - Pregnancy (should be tested monthly)
  - eGFR < 30 mL/min/1.73m^2
  - Prescribed concomitant ACEI or ARB (cannot be on an ACEI or ARB with this med)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Confirmation of the IgAN diagnosis with renal biopsy results and labs
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

RENEWAL REQUIREMENTS:

- Beneficiary has been compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Beneficiary has documented improvement in proteinuria with a reduction in UPCR or urine protein from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

QUANTITY EDITS:

200 mg—#31/31 days
400 mg—#31/31 days

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

If assistance is needed with a Medicaid vaccine or immunization billing issue, the MMIS outreach specialists are available to help. Please refer to this website to find the outreach/provider rep for your pharmacy: **https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach- specialists/**

4. **INCARCERATED PERSONS:**
The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid clients who, on the date the prescription is filled, is incarcerated in a correctional or holding facility, including juvenile correctional facilities, and are detained pending disposition of charges or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid clients, including clients in a juvenile correctional facility, **the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment if billed to Medicaid**. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

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

6. **REGARDING EMERGENCY OVERRIDE**: In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires prior authorization (e.g., a drug that requires a clinical PA or requires a PA

for a non-preferred drug). **This provision applies only <u>in an emergency</u> when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC clients and once per 60 days per drug class for LTC clients.

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, **https://arkansas.magellanrx.com/provider/documents/.**

7. **<u>HARD EDIT ON EARLY REFILL</u>:**

<u>Non-controlled drugs:</u>
The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits or an approved PA must be in the system for the client for the higher dose or an early refill PA will not be approved.

<u>Controlled drugs:</u>
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.

<u>Non-controlled drugs</u>:
Once the client 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 client cannot accumulate more than an *<u>extra</u>* 12 days' supply early during a 180-day period for non-controlled drugs.

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

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

10. **<u>ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:</u>**

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

For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form may be found at the following link.
https://arkansas.magellanrx.com/client/docs/rxinfo/MedInformedConsent.pdf

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

11. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID CLIENTS WITH PRESCRIPTION DRUG BENEFITS:** Only medications prescribed to that client can be billed using the client's Medicaid ID. If medications are needed to treat remaining family members, each prescription must be billed accordingly to each family member's Medicaid ID number. Sanctions may be imposed against a provider for engaging in conduct that defrauds or abuses the Medicaid program. This could include billing a child's medication to a parent's Medicaid ID number and vice-versa.

12. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to $9 for Brand Drugs and $10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website:
https://arkansas.magellanrx.com/provider/documents/ A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website:
https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

13. **OPIOID INFORMATION ON THE MAGELLAN WEBSITE:** To provide educational materials to prescribers and pharmacists on opioid dosing, opioid use disorder, medication assisted treatment and polypharmacy, an opioid information tab has been added to the Magellan Health website.
https://arkansas.magellanrx.com/client/documents

14. **HEPATITIS C TREATMENT INFORMATION**

Educational information on treating Hepatitis C along with treatment consultations may be obtained through the Clinician Consultation Center.

1) Link for the Clinician Consultation Center—**http://www.hepcap.org/hepatitis-c-consultation-warmline/**
2) Hepatitis C Warmline for phone consultation—(844) HEP-INFO or (844) 437-4636

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

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

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

This advance notice is to provide you the opportunity to contact, counsel, and change patients' prescriptions. If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at 501-320-6429.

If you have questions regarding this transmittal, or you need this material in an alternative format such as large print, please contact the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.