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: August 19, 2022

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board July 20, 2022 meeting for the following:**
Manual review criteria for: Acute and prophylaxis migraine treatment, Hemophilia A treatment (Hemlibra®, NovoSeven RT, Sevenfact, FEIBA), Camzyos™ (mavacamten), Vijoice® (alpelisib), Radicava ORS (edaravone), Dupixent (dupilumab) for Eosinophilic Esophagitis

Point-of-Sale edits for: SGLT-2 inhibitors for heart failure (Farxiga® and Jardiance®), Budesonide Respules for Eosinophilic Esophagitis, age edits for benzo and non-benzo sedative hypnotics, maximum dose for targeted immunomodulators

Preferred Drug List (PDL) therapeutic classes: (August 10, 2022 Drug Review Committee meeting) Meeting was cancelled.

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I. ANNOUNCEMENTS

A. Pharmacist enrollment for provider type (PT) 95

Effective April 1, 2022, Arkansas Medicaid began accepting applications for individual pharmacist enrollment. This enrollment will allow pharmacists to have their own Medicaid ID and be an ordering, rendering, and prescribing provider (ORP).

- Pharmacists that intend to use their own NPI and be an ORP provider for pharmacy and medical claim billing must enroll with Arkansas Medicaid.
- The new enrollment type is atypical, provider type 95 – registered, non-credentialed with specialty code RX – Pharmacist.
- Submitting applications for this new individual pharmacist enrollment is via the Provider Application Portal, which is the most efficient way to submit applications. Paper applications may be submitted; however, those will take longer to process. The link to this new enrollment is the following: https://portal.mmis.arkansas.gov/armedicaid/provider/Home/tabid/135/Default.aspx, which would be the Provider Application Portal (Gainwell).
- Portal application requirements will be the online application, the pharmacist license, NPI, Taxonomy, and optional CLIA. See more below for additional details.
- If paper application must be used, the Practitioner Identification Form (PIN) must be filled out and submitted by faxing or mailing to the Provider Enrollment team. The Provider Enrollment team can be reached at 1-800-457-4454, or locally at 501-376-2211.
- **All pharmacies that intend to submit medical claims (including vaccine and immunization claims) on or after June 1, 2022 will require that an individual PT 95 RX NPI be submitted as the renderer for any medical claims. The PT 07 pharmacy NPI may not be submitted as the renderer.**

Additional application submission and overall tips:

- For the pharmacy license submitted, the pharmacy state license should match the state listed on the service location. The license should reflect pharmacist and should match the enrolling provider. Providers can submit a copy of their license card or a web verification from the state licensing board.
- The effective date for a pharmacist using their own NPI as an ORP provider will be the same day as the pharmacist was officially enrolled.
- For submitting CLIA, which is optional – the enrolling pharmacist provider must match either the laboratory name or the lab director's name. If the name on the application doesn't match either lab name or lab directors name, then the pharmacist provider has to submit a signed letter from the lab director giving permission for the pharmacist provider to use the CLIA. CLIA end date should always be 12-31-2299. As an optional requirement if all required items have been met, you can proceed to process the application without the CLIA if there is an issue with the CLIA submitted. Ensure the CLIA # is removed in this case.

II. PREFERRED DRUG LIST (PDL):

The Drug Review Committee meeting scheduled for August 10, 2022 was cancelled. The PDL had no updates for this quarter.

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

EFFECTIVE IMMEDIATELY

1. **ACUTE AND PROPHYLAXIS MIGRAINE TREATMENT**

INDICATIONS: Medications/drug classes in green will not be discussed in the following criteria.

Medications for acute treatment	Medications for prevention
Migranal (dihydroergotamine)	Aimovig (erenumab-aooe)
Trudhesa (dihydroergotamine)	Ajovy (fremanezumab-vfrm)
Nurtec ODT (rimegepant)	Emgality (galcanezumab-gnlm)
Reyvow (lasmiditan)	Nurtec ODT (rimegepant)
Ubrelvy (ubrogepant)	Qulipta (atogepant)
Elyxyb (celecoxib)	Vyepti (eptinezumab-jjmr)—Medical claim only
Triptans	Botox—Medical claim only
NSAIDS	Beta blockers, tricyclic antidepressants, topiramate, divalproex

ACUTE MIGRAINE TREATMENT
(MIGRANAL/TRUDHESA, ELYXYB, NURTEC ODT, REYVOW, UBRELVY)
APPROVAL CRITERIA: (highlighted denotes changes)
Any new medications for acute migraine treatment released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.

- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; **AND**
- Recipient must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient must have a failure of at least TWO (2) preferred 5HT1B/1D receptor agonists (triptans) using two (2) different chemical agents not just different dosage forms at maximally tolerated doses **AND** one of those trials should include a non-steroidal anti-inflammatory steroid (NSAID) unless recipient has one of the following contraindications:
  - For triptans
    - Ischemic coronary artery disease; **OR**
    - Arrhythmias; **OR**
    - History of stroke or transient ischemic attack (TIA); **OR**
    - Peripheral vascular disease; **OR**
    - Ischemic bowel disease; **OR**
    - Uncontrolled hypertension
  - NSAID allergy
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of migraine frequency and severity/duration; **AND**
  - List of all therapies trialed with timeframes; **AND**
  - Attestation that medication overuse headaches have been ruled out.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has any of the following:
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – UBRELVY and NURTEC ODT
  - Requires continued use of a strong CYP3A inducer (rifampin) – UBRELVY and NURTEC ODT
  - Requires continued use of P-gp or BCRP substrates – REYVOW
  - End stage renal disease (CrCl <15 mL/min) – UBRELVY, NURTEC ODT, and ELYXYB
  - Severe hepatic impairment (Child-Pugh Class C) – REYVOW, NURTEC ODT, and ELYXYB
  - NSAID allergy or recent coronary artery bypass graft (CABG) surgery -- ELYXYB

- UBRELVY recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CrCl 15-29 mL/min)

CONTINUATION CRITERIA:

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

MIGRAINE PROPHYLAXIS
(NURTEC ODT, QULIPTA, AIMOVIG, EMGALITY, AJOVY)
APPROVAL CRITERIA:

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

- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; **AND**
- Recipient must have a diagnosis of either:
  - Chronic migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) with ≥ 15 headache days per month with ≥ 8 migraine days per month (EMGALITY, AJOVY, or AIMOVIG); **OR**
  - Episodic migraine or episodic cluster headache (EMGALITY, NURTEC ODT, or QULIPTA); **OR**
  - Diagnosis consistent with FDA indication; **AND**
- Recipient has documented failure of a **3-month** trial of at least **ONE** agent from **TWO** of the following preventative classes:
  - Anticonvulsants (e.g., valproate, topiramate)
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Beta blockers (e.g., propranolol, metoprolol, atenolol)
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of migraine frequency and severity/duration; **AND**
  - List of all therapies trialed with timeframes; **AND**
  - Attestation that medication overuse headaches have been ruled out.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- If approved, recipient does not have a reduction from baseline in monthly migraine days or migraine severity; **OR**
- Recipient is not adherent to prescribed dose; **OR**
- Recipient has medication overuse headache caused by opiate overuse or other headache medication overuse as identified by the prescriber; **OR**
- Beneficiary is <18 years of age or >65 years of age; **OR**
- Recipient has any of the following:
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
  - Requires continued use of a strong CYP3A inducer (rifampin) – NURTEC ODT
  - End stage renal disease (CrCl <15 mL/min) –NURTEC ODT
  - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA

CONTINUATION CRITERIA:

- Recipient must have a reduction from baseline in monthly migraine days and migraine severity after 3rd month of treatment; **AND**
- Prescriber must submit the following:
  - Chart notes since previous PA approval; **AND**
  - Documentation of current migraine frequency and severity; **AND**
- Recipient is adherent to therapy; **AND**
- Recipient has decreased claims of acute migraine treatment

EFFECTIVE IMMEDIATELY:

2. HEMOPHILIA A REVIEW (not including Factor VIII products)

NOVOSEVEN RT, Coagulation Factor VIIa (Recombinant), works by activating coagulation Factor X to Factor Xa as well as coagulation Factor IX to Factor IXa and is indicated for:

- Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets.
- Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.

SEVENFACT [coagulation factor VIIa (recombinant)-jncw] works by activating Factor X to Factor Xa directly bypassing the reactions that require Factor VIII or Factor IX and is indicated for:

- Treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors.
- Limitation of Use: SEVENFACT is not indicated for the treatment of patients with congenital Factor VII deficiency.

FEIBA, an Anti-Inhibitor Coagulant Complex, works by interacting with plasma coagulation factors and platelets to increase the impaired thrombin generation of hemophilia patients with inhibitors and indicated for use in hemophilia A and B patients with inhibitors for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

FEIBA is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.

HEMLIBRA, a bispecific factor IXa- and factor X-directed antibody, works by bridging activated Factor IX and Factor X to restore the function of missing activated Factor VIII and is indicated for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

EFFECTIVE IMMEDIATELY

APPROVAL CRITERIA FOR HEMLIBRA:

APPROVAL CRITERIA for Hemophilia A WITH Inhibitors:

- Recipient must have a diagnosis of congenital hemophilia A WITH inhibitors **AND** ONE of the following:
  - High factor VIII inhibitor titer (≥5 Bethesda units per mL (BU)); **OR**
  - Factor VIII inhibitor titer <5 BU/mL with inadequate response to high dose factor;
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Prescriber must submit the following:
  - Chart notes for the last 24 weeks; **AND**
  - Current labs including CBCs and LFTs; **AND**
  - Documentation that Hemlibra® is prescribed for the prevention of bleeding episodes (not acute treatment); **AND**
  - Documentation of any previous treatment with episodic and prophylactic bypassing agents (FEIBA®, NovoSeven RT®, or Sevenfact®); **AND**
  - Documentation of one of the following:

        - Inadequate response to Immune Tolerance Induction (ITI); **OR**
        - Rationale why the recipient is not a candidate for ITI;
    - Attestation that recipient will NOT be receiving concurrent prophylactic treatment with bypassing agents or has possibility of receiving ITI while taking Hemlibra®; **AND**
    - Attestation that the recipient has been counseled on proper technique on episodic treatment with bypassing agents as needed for breakthrough bleeding episodes; **AND**
    - Current weight; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

APPROVAL CRITERIA for Hemophilia A WITHOUT Inhibitors:

- Recipient must have a diagnosis of congenital hemophilia A WITHOUT inhibitors **AND** ONE of the following:
    - Severe disease with <1% of factor VIII in blood while on factor VIII products; **OR**
    - Moderate disease with 1-5% of factor VIII in blood while on factor VIII products with ONE of the following (prescriber must submit letter of medical necessity and chart notes to support):
        - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; **OR**
        - At least two (2) joint bleeds causing hemophilia-related joint damage; **OR**
        - Poor venous access; **OR**
        - High Factor VIII dose
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Prescriber must submit the following:
    - Chart notes for the last 24 weeks; **AND**
    - Current labs including CBCs and LFTs; **AND**
    - Documentation that Hemlibra® is prescribed for the prevention of bleeding episodes (not acute treatment); **AND**
    - Documentation of any previous prophylactic and/or episodic FVIII infusions; **AND**
    - Attestation that recipient will NOT be receiving concurrent prophylaxis factor VIII; **AND**
    - Attestation that recipient has been counseled on proper technique on episodic treatment with factor VIII products as needed for breakthrough bleeding episodes; **AND**
    - Current weight; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

DENIAL CRITERIA:

- Recipient does not have a diagnosis of congenital hemophilia A; **OR**
- Recipient continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents); **OR**
- If approved and the recipient is not compliant on prescribed Hemlibra® dose; **OR**
- Prescriber requests dose above FDA-approved dose or prescribes the use of Hemlibra® for PRN dosing; **OR**
- If approved and the recipient has no positive response with the decrease of bleeding episodes and/or decrease of episodic agent use

EFFECTIVE IMMEDIATELY

APPROVAL CRITERIA FOR NOVOSEVEN RT/SEVENFACT

Hemophilia A and B with Inhibitors (NovoSeven RT® or Sevenfact®)

- Recipient must have a diagnosis of congenital or acquired hemophilia A or B with inhibitors confirmed by blood coagulation testing that requires treatment of bleeding episodes or peri-operative management; **AND**
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Recipient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (Hemlibra®) (NovoSeven® or Sevenfact® may be taken as breakthrough for patients taking emicizumab) – **Hemophilia A only**
- Recipient has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – **Hemophilia B only**
- Prescriber must submit the following:
    - Chart notes with history of bleeds and treatment for the last 24 weeks; **AND**
    - Current labs; **AND**
    - Current weight for dosing; **AND**
    - Provide requested dose as PA will be entered for specific dosing requirements Hemophilia A or B with Inhibitors

Congenital Factor VII Deficiency (NovoSeven RT®)

- Recipient has a diagnosis of congenital factor VII deficiency confirmed by blood coagulation testing requiring treatment of bleeding episodes or peri-operative management; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of prothrombin time and factor VII coagulant activity prior to administration as baseline

Glanzmann's Thrombasthenia (NovoSeven RT®)

- Recipient has a diagnosis of Glanzmann's thrombasthenia and condition is refractory to platelet transfusions; **AND**
- Used for the treatment of one of the following:
    - Control of bleeding episodes; **OR**
    - Peri-operative management

Acquired Hemophilia (NovoSeven RT®)

- Recipient has a diagnosis of Acquired Hemophilia; **AND**
- Used for the treatment of one of the following:
    - Control of bleeding episodes; **OR**
    - Peri-operative management

EFFECTIVE IMMEDIATELY

APPROVAL CRITERIA FOR FEIBA

- Recipient must have a diagnosis of hemophilia A or B with high factor VIII or factor IX titer inhibitors (≥ 5 Bethesda Units) requiring treatment for ONE of the following:
    - Control and prevention of bleeding episodes; **OR**
    - Peri-operative management; **OR**
    - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Recipient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (Hemlibra®) (FEIBA® may be taken as breakthrough for patients taking emicizumab) – **Hemophilia A only**
- Recipient has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – **Hemophilia B only**
- Prescriber must submit the following:
    - If doses above 100 units/kg or daily doses of 200 units/kg are required, provide the treatment plan to monitor for Disseminated Intravascular Coagulation (DIC) or signs of ischemia and thromboembolic events; **AND**
    - Chart notes with history of bleeds and treatment for the last 24 weeks; **AND**
    - Current labs; **AND**
    - Current weight for dosing; **AND**
    - Provide requested dose as PA will be entered for specific dosing requirements

EFFECTIVE OCTOBER 3, 2022

3. TREATMENT OF COPD WITH INHALED STEROIDS

Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines 2020

- Regular and as-needed use of SABA or SAMA improves FEV_1 and symptoms
- Combinations of SABA and SAMA are superior to either medication alone
- LABAs and LAMAs significantly improve lung function and reduce exacerbation
- LAMAs have a greater effect on exacerbation reduction compared with LABAs
- Combination with LABA and LAMA increased lung function over monotherapy
- ICS combined with LABA is more effective than individual components for moderate to severe COPD
- Triple inhaled therapy of ICS/LAMA/LABA improves function compared to ICS/LABA, LABA/LAMA or LAMA monotherapy

FLOVENT® HFA (fluticasone) and ASMANEX® TWISTHALER (mometasone)—

- All point-of-sale criteria will be removed for these preferred medications on the PDL.
- Non-preferred inhaled corticosteroids will continue to require a prior authorization submission with documentation of the medical necessity over the preferred options.

BUDESONIDE RESPULES

- **Criteria 1:** Recipient < 4 years of age (maximum dose is 2 mg/day)
  OR
- **Criteria 2:** Regardless of age, recipient 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

UPDATE TO PDL:
Oral inhaled corticosteroids
Preferred agents

- Fluticasone propionate HFA inhaler (Flovent HFA Inhaler)
- Mometasone furoate (Asmanex Twisthaler)

Preferred agents with criteria

- Budesonide ampules for nebulizer -**GENERIC ONLY**

NOTE: Preferred triple therapy treatment options (as of the date of this memo)—

- Symbicort or Dulera or Advair Diskus combined with Spiriva
- Bevespi Aerosphere combined with Flovent HFA or Asmanex Twisthaler

EFFECTIVE OCTOBER 19, 2022

4. POS CRITERIA FOR SGLT-2 INHIBITORS AND GLP-1 RECEPTOR AGONISTS

INDICATIONS (for preferred SGLT-2 inhibitor medications):

JARDIANCE is indicated for:

- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.
- To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease.
- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

FARXIGA is indicated for:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors.
- To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

INDICATIONS (for preferred GLP-1 receptor agonist medications):

BYETTA is indicated for:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

VICTOZA is indicated for:

- As an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus,
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

POS APPROVAL CRITERIA FOR PREFERRED SGLT-2 INHIBITORS
(recipient must meet one of the following)

- Diagnosis of type 2 diabetes mellitus; **AND**
  - Metformin claim in the last 90 days **OR**
  - Diagnosis of ASCVD
- Diagnosis of heart failure
- Diagnosis of CKD (Farxiga® only)
- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a SGLT-2 inhibitor

NOTE: Non-preferred products will continue to require a prior authorization.

POS APPROVAL CRITERIA FOR PREFERRED GLP-1 RECEPTOR AGONISTS
(recipient must meet one of the following)

- Diagnosis of type 2 diabetes mellitus; **AND**
  - Metformin claim in the last 90 days; **OR**
  - Diagnosis of ASCVD
- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a GLP-1 receptor agonist

NOTE: Non-preferred products will continue to require a prior authorization.

If doesn't meet POS criteria, a prior authorization will be required.

MANUAL REVIEW APPROVAL CRITERIA FOR SGLT-2 INHIBITORS:

- Recipient must have a diagnosis consistent with FDA approved indications, support in MicroMedex® or support in treatment guidelines; **AND**
- Recipient prescribed a SGLT-2 inhibitor for heart failure with one of the following; **AND**
    - With reduced ejection fraction (HFrEF) must have New York Heart Association (NYHA) class II-IV heart failure with low left ventricular ejection fraction (LVEF) ≤ 40% and elevated NT-proBNP or BNP; **OR**
    - With symptomatic heart failure with preserved ejection fraction (HFpEF) with LVEF ≥ 50% and elevated NT-proBNP or BNP
    - Recipient must be prescribed the following therapy titrated to the maximum tolerated or target doses;
        - Angiotensin Receptor-Neprilysin Inhibitor (ARNI)/ Angiotensin-Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB); **AND**
        - Beta blocker; **AND**
        - Diuretic (as needed); **AND**
        - If not on standard of care therapy listed above, explain the reason; **AND**
    - Prescriber must submit the following:
        - Current chart notes with documentation of previous therapy; **AND**
        - Baseline LVEF; **AND**
        - Baseline N-terminal pro–B-type natriuretic peptide (NT-proBNP) or BNP
- Recipient prescribed a SGLT-2 inhibitor for type 2 diabetes
    - Recipient must have tried metformin with continued elevated HbA1c or have a diagnosis of ASCVD; **AND**
    - Provider must submit the following:
        - Documentation of previous metformin use or contraindication to the use; **AND**
        - Current HbA1c; **AND**
        - Documentation of comorbidities
- Recipient prescribed a SGLT-2 inhibitor for chronic kidney disease (CKD)
    - Recipient must have tried and failed maximally tolerated doses of ACE inhibitors or ARBs; **AND**
    - Provider must submit the following:
        - Documentation of previous ACEi/ARB use or contraindication to the use; **AND**
        - Current labs including eGFR

MANUAL REVIEW APPROVAL CRITERIA FOR GLP-1 INHIBITORS:

- Recipient must have a diagnosis consistent with FDA approved indications, support in MicroMedex® or support in treatment guidelines; **AND**
- Recipient with diabetes must have tried metformin with continued elevated HbA1c or have a diagnosis of ASCVD; **AND**
- Provider must submit the following:
    - Documentation of previous metformin use or contraindication to the use; **AND**
    - Current HbA1c; **AND**
    - Documentation of comorbidities

EFFECTIVE IMMEDIATELY

5. CAMZYOS™ (mavacamten)

INDICATION:

CAMZYOS™ is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

APPROVAL CRITERIA:

- Recipient must be at least 18 years of age; **AND**
- Recipient must have a diagnosis of NYHA Class II-III obstructive hypertrophic cardiomyopathy **OR** a diagnosis consistent with any updated FDA indications; **AND**
- Prescribers, patients, and pharmacies must be enrolled in the Camzyos™ REMS program due to risk of heart failure due to systolic dysfunction; **AND**
- Recipient must have tried and failed beta blockers and calcium channel blockers unless contraindicated; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Previous treatment; **AND**
    - Confirmation for absence of pregnancy and attestation that females of reproductive potential will use effective contraception; **AND**
    - Baseline LVEF, Valsalva LVOT peak gradient, and mixed peak oxygen consumption

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has a baseline LVEF <55% or Valsalva LVOT peak gradient < 50 mmHg; **OR**
- Recipient requires moderate to strong CYP2C19 inhibitors or inducers, **OR** strong CYP3A4 inhibitors, **OR** moderate to strong CYP3A4 inducers; **OR**
- Recipient is pregnant

CONTINUATION CRITERIA:

- Recipient must have LVEF ≥50% to continue; **AND**
- After 30 weeks, the recipient must have at a minimum an improvement of mixed peak oxygen consumption and no worsening in NYHA class; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Echocardiogram reports at weeks 4,8,12 and every 12 weeks; **AND**
    - Documentation of response to treatment

QUANTITY EDITS:

#31/ 31 days

EFFECTIVE IMMEDIATELY

6. VIJOICE® (alpelisib)

INDICATION:

VIJOICE is indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

APPROVAL CRITERIA:

- Recipient must be ≥2 years of age; **AND**
- Recipient must have a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) requiring systemic therapy **OR** a diagnosis consistent with any updated FDA approved indications; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Genetic testing results identifying a PIK3CA mutation and/or the clinical presentation confirming the diagnosis; **AND**
    - Identify which PROS disease has been confirmed; **AND**
    - Current labs including fasting plasma glucose and HbA1c; **AND**
    - Previous treatment including surgery (provide explanation if surgery is not an option); **AND**
    - Baseline size/volume of target lesion(s); **AND**
    - Attestation that both males and females of reproductive potential have been counseled on the importance of contraception; **AND**
    - Current dose requested (Patients unable to swallow tablets can use any dose to make a suspension based on preparation guidance from the packet insert.)
        - Recipient <6 years—max of 50 mg daily
        - Recipient 6-17 years of age—50 mg daily for at least 24 weeks before increasing to 125 mg daily
        - Recipient ≥18 years of age—max of 250 mg daily

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient has been diagnosed with severe cutaneous adverse reactions (SCARs) including Stevens-Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis or pneumonitis; **OR**
- Recipient cannot tolerate the minimum dose of 50 mg daily; **OR**
- Recipient requires a concomitant strong CYP3A4 inducer or BCRP inhibitor; **OR**
- Recipient has Type 1 or uncontrolled Type 2 diabetes

CONTINUATION CRITERIA:

- Recipient does not demonstrate disease progression, had at least at 20% reduction in lesion volume by week 24, and has no unacceptable toxicity; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of response to therapy; **AND**
    - Current dose requested

QUANTITY EDITS:
50 mg--#31/ month
125 mg--#31/ month
250 mg pack--#62/ month

AGE EDITS:
50 mg—2-17 years
125 mg—18+ (if child needs this dose, another PA can be entered)
250 mg pack—18+

7. **ZTALMY® (ganaxolone)—Postponed until rebate eligible**
8. **VIVJOA™ (oteseconazole)—Postponed until rebate eligible**

9. **RADICAVA ORS® (edaravone)**

INDICATION:
RADICAVA ORS is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Discussion tabled until the October 19, 2022 DUR Board meeting.

10. **TREATMENT OF EOSINOPHILIC ESOPHAGITIS**

EFFECTIVE OCTOBER 3, 2022
POS APPROVAL CRITERIA FOR CORTICOSTEROIDS:
Flovent (fluticasone)—no point-of-sale criteria required for EoE

Pulmicort Respules (budesonide)

- **Criteria 1:** Recipient < 4 years of age (maximum dose is 2 mg/day)
  OR
- **Criteria 2:** Regardless of age, recipient has a billed diagnosis of EOE in the last 2 years
  - Age < 10 years—maximum dose is 2 mg/day
  - Age ≥ 10 years—maximum dose is 4 mg/day

Dose recommendations for budesonide slurry

- 1-2 mg once daily for patients < 10
- 2 mg once daily for patients ≥ 10; may titrate to 4 mg daily
- Documentation suggests the use of 0.5 mg/2 mL to ensure enough liquid volume to coat the esophagus.

Example directions for compounding the slurry
Budesonide can be administered as an oral viscous slurry (1 mg daily for children under the age of 10 years, and up to 2 mg twice daily for older children and adults; the total daily dose is often divided into twice daily). In some studies, the total daily dose for adolescents and adults was 4 mg per day divided into two doses. Viscous budesonide can be compounded by mixing two or four 0.5 mg/2 mL Pulmicort Respules with sucralose (Splenda; 10 1-gram packets per 1 mg of budesonide, creating a volume of approximately 8 mL) or another carrier vehicle that is not liquid.

EFFECTIVE IMMEDIATELY

APPROVAL CRITERIA FOR DUPIXENT® (manually reviewed):

- Recipient must be ≥ 12 years of age and at least 40 kg; **AND**
- Recipient must have a confirmed diagnosis of eosinophilic esophagitis (EOE) with an esophageal biopsy that indicates ≥15 eosinophils per high-power field (eos/hpf) and 1 of the following:
  - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain); **OR**
  - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows); **AND**
- Recipient must have at least a 12 week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide) and proton pump inhibitors (e.g., pantoprazole or omeprazole); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Previous therapies including dietary restrictions, procedures, or pharmacological treatment; **AND**
  - Baseline eos/hpf after corticosteroid and PPI trials; **AND**
  - Baseline recipient determined Dysphagia Symptom Questionnaire (DSQ) score

CONTINUATION CRITERIA FOR DUPIXENT®:

- Recipient demonstrates a positive response with one of the following after 6 months of treatment:
  - Achieved remission with ≤ 6 eos/hpf; **OR**
  - Decrease in DSQ score from baseline
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current recipient determined DSQ score; **AND**
  - Current eos/hpf

11. MAXIMUM DOSE FOR TARGETED IMMUNOMODULATORS

Maximum dose and frequency for each product will be consistent with the FDA approved dosing found in the individual product's package insert. Dose or frequency requests that exceed FDA approved dosing will be considered on a case-by-case basis and be considered if there is support in MicroMedex®.

The discussion about proactive therapeutic drug monitoring has been tabled for further review.

EFFECTIVE SEPTEMBER 1, 2022

12. AGE EDITS FOR SEDATIVE HYPNOTICS

PRODUCT	MINIMUM AGE	PRODUCT	MINIMUM AGE
TEMAZEPAM (RESTORIL®)	18	~~TRIAZOLAM (HALCION®)~~	~~18~~
ESTAZOLAM (PROSOM®)	18	FLURAZEPAM (DALMANE®)	18
ESZOPICLONE (LUNESTA®)	18	ZALEPLON (SONATA®)	18
ZOLPIDEM (AMBIEN®)	18	SUVOREXANT (BELSOMRA®)	18
LEMBOREXANT (DAYVIGO®)	18	DOXEPIN (SILENOR®)	18
ZOLPIDEM SL (EDLUAR®)	18	DARIDOREXANT (QUVIVIQ®)	18
RAMELTEON (ROZEREM®)	18	ZOLPIDEM ER (AMBIEN CR®)	18

Sedative hypnotic prescriptions for children will require a prior authorization approval. The prescriber must submit the following to the State Pharmacy Unit via fax (800-424-5851):

- Current chart notes; **AND**
- Medical necessity for the use since not FDA approved for children; **AND**
- Describe the necessity if intended to be used long-term

NOTE: Triazolam will not be limited to adults.

13. FRIENDLY REMINDERS

1. Any questions concerning various Medicaid topics (e.g., Medicaid enrollment, prescription coverage, provider manuals, and billing policies) may be researched using one of the following links.
   - **https://humanservices.arkansas.gov/divisions-shared-services/medical-services**
   - **https://humanservices.arkansas.gov/**
   - **https://arkansas.magellanrx.com/**

   Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member. For more information about PASSE, please refer to the website:
   https://humanservices.arkansas.gov/about-dhs/dms/passe/

2. **MAT (Medication Assisted Treatment) with buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: "Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care. As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities."

   http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

3. **For vaccine billing and updates, visit the Welcome to Arkansas webpage.**
   https://humanservices.arkansas.gov/
   https://humanservices.arkansas.gov/covid-19/dhs-response-to-covid-19/updates-for-providers/
   For adult vaccines (ages 18 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:
   G0008 – Influenza immunization
   90471 – First vaccine administered
   90472 – Subsequent vaccines administered
   The **Injection administration code, T1502** will continue to be payable for clients of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only.
   If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211.
   Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website:
   https://humanservices.arkansas.gov/divisions-shared-services/medical-services/

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

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

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

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

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

7. **HARD EDIT ON EARLY REFILL:**

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

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

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

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

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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 CLIENT:** Pharmacies are required to reverse and credit back to Medicaid original prescriptions and refills if the medication was not provided to the client. Pharmacies should reverse and credit Medicaid within 14 days of the date of service for any prescription that was not provided to the client. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.

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

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

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

< 10 YEARS OF AGE:
Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) for all new starts on an antipsychotic agent, including a change in the chemical entity for children

currently on an antipsychotic agent. All documentation, chart notes, signed informed consent, and required lab work must be submitted, and the manual review will be performed by the Medicaid Pharmacy Program psychiatrist.

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

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

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

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

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

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

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

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