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 Cynthia Neuhofel

DATE: February 15, 2023

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board January 18, 2023 meeting for the following:**
Manual review criteria for: Vivjoa™ (oteseconazole), Enspryng® (satralizumab), multiple sclerosis class, Qutenza® (capsaicin), Lytgobi® (futibatinib), Hyftor™ (sirolimus), Rezlidhia™ (olutasedinib), and antimigraine agents (non-triptan)

Point-of-Sale edits for: leukotriene receptor antagonists

Preferred Drug List (PDL) therapeutic classes: cephalosporins, leukotriene receptor antagonists

Table of Contents

I. ANNOUNCEMENTS

A. COST SHARING FOR ADULT MEDICAL CLIENTS AND EXEMPTIONS

Cost sharing or copays began on 1/1/2023 for certain adult Medicaid clients. There are some exemptions, including but not limited to pregnancy-related services. The out-of-pocket costs clients may pay are small but important. The Arkansas Medicaid program covers medical costs, so clients don't have big bills after an emergency or illness.

Components of cost sharing:

- Copay: A small fee clients pay when they receive a medical service or fill a prescription.
- Copay limit: Limits to the total amount clients pay each quarter (3-month period). Once a client meets the limit, he/she will not pay co-pays for the rest of that quarter. The client starts paying co-pays again the next quarter.

Clients with cost share questions should call AFMC at 888-987-1200.

<table>
<tr><th></th><th>Beginning 2023</th></tr>
<tr><td>Adult clients who pay to cost sharing</td><td>Adult clients above 20% of FPL who are in the following programs:
ARHOME: Only Individuals enrolled in a QHP and those awaiting enrollment in a QHP; medically frail clients will NOT have cost sharing
Workers with Disabilities, and
Transitional Medicaid Adult
Exemptions:
Individuals in these Medicaid programs who do NOT have to pay copays include:
Under 20% FPL
Medically frail
19- and 20-year-olds
Individuals in hospice
Pregnant women
American Indian/Alaskan Native</td></tr>
<tr><td>Service-specific copay amounts</td><td>Adults pay $4.70/$9.40, depending on the service. (These copay amounts do not apply to ARKids B.)

Exemptions
Services that are exempt from copays (copays are not charged) include:
Emergency services
Family planning services and supplies
Pregnancy-related services
Preventive services
Inpatient hospitalization
**To override pharmacy copays for a pregnant client, use the Pregnancy Indicator of 2 in the NCPDP field #335-2C. The valid values are Blank=Not Specified, 1=Not Pregnant, or 2=Pregnant. OR, put in the pregnancy diagnosis (ICD-10) of Z33.1 in the NCPDP field #424-DO.</td></tr>
<tr><td>Copay limits</td><td>Quarterly copay limit is based on household federal poverty level<table><tr><th>FPL</th><th>Copay Limit</th></tr><tr><td>0%-20%</td><td>$0</td></tr><tr><td>21%-40%</td><td>$27</td></tr><tr><td>41%-60%</td><td>$54</td></tr><tr><td>61%-80%</td><td>$81</td></tr><tr><td>81%-100%</td><td>$108</td></tr><tr><td>101%-120%</td><td>$135</td></tr><tr><td>121%-138%</td><td>$163</td></tr></table></td></tr>
<tr><td>Clients' copays contributing to copay limit</td><td>The ARHOME clients and all Medicaid clients who pay copays in the individual's family.
Example: two adults in a family in ARHOME at 40% FPL. If they each are charged $15 in copays, their total copays would be limited to $27. (ARKids B copays do not count toward the copay limit, but TEFRA premiums do.)</td></tr>
</table>

B. CLIENT MEDICAID COVERAGE UPDATE

The federal government declared a public health emergency when the COVID-19 pandemic began in March 2020. Since then, state agencies have continued health care coverage for all medical assistance programs, even for people who have not renewed their eligibility or are no longer eligible. Clients have been allowed to keep their Medicaid during the pandemic without renewing, but that will soon end. Clients will have to send in renewal paperwork to see if they are still eligible for health care coverage.

The federal government has set April 1, 2023 as the official start date for this process. However, states are allowed to begin sending out renewal packets earlier. In Arkansas, letters will be mailed out from DHS to Medicaid clients who need to send in renewal paperwork starting in February 2023. It is very important that all Medicaid clients look for these letters from DHS in their mail starting in February and continuing through July.

Clients can go online at **access.arkansas.gov**, create an account if they don't have one already, and see if they need to renew their eligibility. They can even complete the renewal information online. Clients can also submit a question via the Access Anywhere form at **ar.gov/accessanywhere**, or they can call any local DHS county office and ask someone to check their Medicaid to see if they need to renew.

If clients do not respond to their renewal with the requested information, they will be sent a letter explaining that their coverage will end. The letter will give a specific date based on the date when the information was due.

Clients no longer eligible for Medicaid will receive a notice of when their Medicaid coverage will end. It will include information on how to file an appeal if the client thinks the decision was incorrect. Additionally, if clients are ineligible due to income, DHS will automatically send their information to the federal marketplace. Non-Medicaid providers will contact clients and help them find other health coverage. Information about the marketplace is also listed in the notice. DHS is working with providers and community-based organizations to help those who are otherwise no longer eligible to transfer to other potential sources of coverage.

C. UPDATE TO STATE SUPPORTED BRAND LIST

Effective March 1, 2023, the following brand name product will be removed from the State supported brand list. Pharmacies should begin processing claims with generics on that date.

- Afinitor®

Current State Supported Brand List can be found with the following link:
https://arkansas.magellanrx.com/client/docs/rxinfo/State_Supported_Brand_Meds.pdf

II. PREFERRED DRUG LIST

EFFECTIVE APRIL 1, 2023

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

1. CEPHALOSPORINS

PREFERRED AGENTS

- Cefadroxil capsule and suspension (generic for Duricef®)
- Cefdinir capsule and suspension (generic for Omnicef®)
- Cefpodoxime tablet and suspension (generic for Vantin®)
- Cefprozil tablet and suspension (generic for Cefzil®)
- Cefuroxime tablet (generic for Ceftin®)
- Cephalexin capsule and suspension (generic for Keflex®)

NON-PREFERRED AGENTS

- **Cefaclor capsule, ER tablet, and suspension (generic for Ceclor®)**
- **Cefadroxil tablet (generic for Duricef®)**
- Cefixime capsule and suspension (generic for Suprax®)
- **Cephalexin tablet (generic for Keflex®)**
- Suprax® chew tablet, capsule, and suspension (cefixime)

2. LEUKOTRIENE RECEPTOR ANTAGONISTS

PREFERRED AGENT WITH CRITERIA

- Montelukast tablets, chewable tablets, and granules (generic for Singulair®)

NON-PREFERRED AGENTS

- Accolate® tablet (zafirlukast)
- Singulair® tablets, chewable tablets, and granules (montelukast) BRAND
- Zafirlukast tablet (generic for Accolate®)
- Zileuton ER tablet (generic for Zyflo CR®)
- Zyflo® tablet (zileuton)

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

EFFECTIVE MARCH 29, 2023

1. LEUKOTRIENE RECEPTOR ANTAGONISTS

POINT-OF-SALE EDITS

POS EDITS:

- TD edit for other LTRA if >25% of the days' supply of the claim in history remains
- Age edits
  - Montelukast 10 mg tablet— ≥ 15 years
  - Montelukast 4 & 5 mg chew tablets— 24 months to 16 years
  - Montelukast 4 mg granule— ≥ 6 months to < 24 months

Currently, montelukast will deny for a therapeutic duplication with another leukotriene receptor antagonist including other montelukast strengths.

Claims will process at point-of-sale if a recipient meets ANY of the following:

Criterion 1:

- Diagnosis of asthma in the previous 2 years

OR

- AR Medicaid pharmacy claim for any of the following in the previous 186 days:
  - Inhaled corticosteroid (ICS)
  - Inhaled long-acting beta2 agonist (LABA)
  - Inhaled short-acting beta2 agonist (SABA)
  - Inhaled ICS/LABA

Criterion 2:

- Diagnosis of allergic rhinitis in the previous 2 years

OR

- AR Medicaid pharmacy claim for any of the following within the previous 60 days:
  - ≥ 1 claim for an inhaled nasal steroid
  - ≥ 1 claim for a first or second-generation antihistamine
  - ≥ 1 claim for azelastine nasal spray or ipratropium nasal spray

Criterion 3:

- Diagnosis of Chronic Idiopathic Urticaria in the previous 2 years

EFFECTIVE JANUARY 18, 2023

2. NON-TRIPTAN ANTIMIGRAINE AGENTS

ACUTE MIGRAINE TREATMENT: MIGRANAL/TRUDHESA, ELYXYB, NURTEC ODT, REYVOW, UBRELVY

APPROVAL CRITERIA:

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 unless recipient has one of the following contraindications:
  - 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
- A request for a nonpreferred agent requires documentation of the medical necessity over preferred options; AND
- Prescriber must submit **ALL** of 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)

RENEWAL REQUIREMENTS:

- 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, AJOVY, 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)
- Recipient requesting an oral CGRP agent (including preferred medications) must have a documented failure of a 6-month trial with at least ONE injectable CGRP agent or a contraindication to the use; AND
- A request for a nonpreferred agent requires documentation of the medical necessity over preferred options; AND
- Prescriber must submit **ALL** of 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

RENEWAL REQUIREMENTS:

- 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 JANUARY 18, 2023

3. VIVJOA™ (oteseconazole) 150 mg capsule

APPROVAL CRITERIA:

- Recipient is an adult, female with a history of recurrent vulvovaginal candidiasis (RVVC) defined as ≥4 episodes of vulvovaginal candidiasis in a 12 month period **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must have permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy, or post-menopausal)
- Recipient should not be approved with any of the following:
  - Severe renal impairment (eGFR 15-29 mL/min) or ESRD (eGFR <15 mL/min)
  - Moderate to severe hepatic impairment (Child-Pugh B or C)
- For diabetic recipients with HbA1c >9%, prescriber must provide efforts taken to achieve better glycemic control
- Recipient must have continued vulvovaginal candidiasis despite a minimum of fluconazole 150 mg once weekly for 6 months
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - History of symptomatic vulvovaginal candidiasis with previous treatment
  - Vaginal discharge culture or microscopy report
  - Current HbA1c
  - Documentation verifying that the current infection is recurrent and not a non-clearance of a previous infection
  - Medical necessity over fluconazole
  - Note which therapy will be initiated
    - VIVJOA-only; **OR**
    - Fluconazole/VIVJOA
- PA will be approved for a maximum of 12 weeks

RENEWAL REQUIREMENTS:

- Reviewed on a case-by-case basis
- Prescriber should submit the following:
  - Current chart notes with confirmation of RVVC despite previous treatment
  - Diabetic recipients must maintain glycemic control with HbA1c < 9%
  - Rationale for a subsequent treatment when the package insert does not support beyond one 12 week course

QUANTITY EDITS:

#18 for full course over 12 weeks

EFFECTIVE JANUARY 18, 2023

4. ENSPRYNG® (satralizumab-mwge) 120 mg/mL syringe

APPROVAL CRITERIA:

- Prescribed by a specialist experienced with NMOSD
- Recipient is diagnosed with neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 (AQP4) antibody positive and confirmed with the following:
  - Test indicating recipient is seropositive for AQP4-IgG antibodies
  - Recipient has at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions)
  - Exclusion of alternative diagnoses (i.e., Lupus, multiple sclerosis, sarcoidosis, cancer, chronic infection like HIV)

- 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 an official Compendia
- Recipient must have history of at least one documented relapse (including first attack) in the last 12 months
- Recipient must have an Expanded Disability Status Scale (EDSS) score ≤ 6.5
- Recipient is not prescribed medication for the treatment of multiple sclerosis (i.e., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.)
- Recipient is not prescribed other treatment options for NMOSD concomitantly (i.e., eculizumab or inebilizumab)
- Prescribed to prevent future attacks (not meant to treat an acute attack)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Confirmation of NMOSD diagnosis
  - Baseline Expanded Disability Status Scale score
  - Medical necessity over the use of immunotherapy (e.g., rituximab, azathioprine, mycophenolate, or methotrexate)
  - Results for Hepatitis B virus and tuberculosis screens (should be negative for approval)

RENEWAL REQUIREMENTS:

- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy which is defined by any of the following:
  - Decrease in acute relapses
  - Improvement in EDSS
  - Reduced hospitalizations
  - Reduction/discontinuation in plasma exchange treatments or corticosteroids

QUANTITY EDITS:

#1 per 28 days

EFFECTIVE JANUARY 18, 2023

5. MULTIPLE SCLEROSIS DRUGS

APPROVAL CRITERIA:

All non-preferred medications:

- Confirmed diagnosis of a relapsing form of MS including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease
- Initial request must be submitted by or in consultation with a neurologist or other appropriate 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 an official Compendia
- Recipient with moderately active disease must have tried at least 2 preferred agents for a minimum of 6 months each and treatment must be considered a failure as defined by any of the following:
  - At least one relapse during therapy with preferred medications
  - MRI indicates additional lesions compared to baseline
  - Recipient demonstrates an increased disability as measured by the Expanded Disability Status Scale (EDSS) compared to baseline
  - Documented adverse effects to the preferred agents
- Recipient with highly active or rapidly evolving aggressive disease will be reviewed on a case-by-case basis
- Recipient is not prescribed other Disease-Modifying Therapies (DMTs) for the treatment of MS to be used concomitantly
- Prescriber must submit **ALL** of the following:
  - Current chart notes

- Documentation of previous therapies with response
- Letter of medical necessity over the preferred medications
- Baseline MRI with documentation of lesions
- Baseline Expanded Disability Status Scale (EDSS)

- See additional criteria noted below for specific medications

FUMARATES: Bafiertam®, Brand Tecfidera®, Vumerity®

- Recipient does **NOT** have any of the following:
  - Moderate to severe renal impairment
  - Moderate to severe hepatic impairment
  - Previous failure with any fumarate product
  - Prescribed concomitant fumarate therapies
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential

INTERFERONS: Betaseron®, Extavia®, Plegridy®, Rebif®/Rebif Rebidose®

- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including CBC with differential and LFTs
  - Attestation that patient has been counseled about depression
  - Medical necessity over Avonex®

GLATIRAMER: Copaxone® 40 mg, Glatopa® 20 mg or 40 mg

- Prescriber must submit the necessity over Copaxone® 20mg daily (convenience would not be considered medically necessary)

SPHINGOSINE 1-PHOSPHATE RECEPTOR MODULATOR: Gilenya®, Mayzent®, Ponvory®, Tascenso ODT®, Zeposia®

- Recipient does **NOT** have any of the following:
  - Current systemic or clinically significant infection
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Baseline heart rate ≤ 55 bpm
  - Moderate to severe hepatic impairment (Child-Pugh class B or C)
  - MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class II or IV heart failure in the last 6 months
  - Presence of Mobitz type II second-degree, third-degree AV block, sick sinus syndrome, or sino-atrial block, unless have a pacemaker
  - Previous treatment with alemtuzumab
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Documentation of CYP2C9 genotype to determine dose for Mayzent®
  - Documentation of cardiac evaluation with ECG if recipient has preexisting conditions (Contraindicated in recent MI, angina, stroke, TIA, severe HF, baseline QTc interval ≥500 msec, or cardiac arrhythmias requiring therapy).
  - Baseline eye exam report
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential
- Gilenya® recipient must be ≥ 10 years of age
- Mayzent® recipient must NOT have a CYP2C9 *3/*3 genotype (homozygous)

MONOCLONAL ANTIBODIES: Kesimpta® (Lemtrada®, Ocrevus® and Tysabri® are excluded from the pharmacy program.)

- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - ~~Medical necessity over the use of Ocrevus® (convenience would not be considered medically necessary~~) The DUR Board voted to include this bullet. Upon further review of treatment recommendations, this bullet has been removed.
  - Confirmed negative for Hepatitis B
  - Baseline serum immunoglobulin levels (monitor periodically for any decrease)
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential

PYRIMIDINE SYNTHESIS INHIBITOR: Aubagio®

- Recipient does **NOT** have any of the following:
  - Severe hepatic impairment
  - Concomitant leflunomide or antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including LFTs and CBC
  - Documentation of negative tuberculosis test
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential

PURINE ANTIMETABOLITE: Mavenclad®

- Recipient should **NOT** have a diagnosis of clinically isolated syndrome
- Recipient does **NOT** have any of the following:
  - Human immunodeficiency virus (HIV), hep B or C, TB or other current systemic or clinically significant infection
  - Current malignancy
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Moderate to severe renal impairment (CrCl < 60 mL/minute)
  - Moderate to severe hepatic impairment (Child-Pugh score > 6)
- Prescriber must submit **ALL** of the following (in addition to info request above):
  - Medical necessity over all other DMTs
  - Treatment plan after two years of therapy
  - Current labs including a CBC with differential including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential
  - Reports for screening Hepatitis B and C, HIV, and tuberculosis
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative

RENEWAL REQUIREMENTS:

- Prescriber must submit current chart notes with documentation of response to therapy
- Recipient must have a positive response to therapy which may include any of the following:
  - Decrease in the number of relapses
  - Improvement or no decline in Expanded Disability Status Scale (EDSS)
  - Improvement in MRI findings since initiating therapy

EFFECTIVE JANUARY 18, 2023

6. QUTENZA® (capsaicin) 8% kit

APPROVAL CRITERIA:

- Prescriber must be a specialist in treating neuropathic pain
- Recipient must be diagnosed with neuropathic pain associated with postherpetic neuralgia (PHN) or neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- QUTENZA may be purchased through buy and bill from specialty distributor or by prescription from specialty pharmacy. QUTENZA must be delivered to prescriber directly.
- 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 an official Compendia
- Application time must be consistent with the actual diagnosis (60 minutes for postherpetic neuralgia and 30 minutes for diabetic peripheral neuropathy)
- Recipients being treated for PHN pain must have continued pain at least 6 months after healing of herpes zoster rash
- Recipient must have tried and failed at least 3 of the following prior to consideration for this medication:
  - Postherpetic neuralgia (PHN)
    - Topical capsaicin or lidocaine
    - Gabapentin and/or pregabalin
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
    - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
    - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
  - Diabetic peripheral neuropathy (DPN)
    - Topical capsaicin or lidocaine
    - Gabapentin and/or pregabalin
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
    - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
    - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
    - Electrical nerve stimulation
    - Spinal cord stimulation
    - Alpha-lipoic acid
- Prescriber must submit **ALL** of the following:
  - Current chart notes with documentation if treating PHN or DPN
  - Previous therapies tried
  - Medical necessity over other treatment options
  - Size of area to be treated. PA will be entered for a specific package size pertaining to the amount needed based on treatment area size.
  - If received from the specialty pharmacy as an outpatient prescription, prescriber must attest that the patient will not have access to this medication. The prescription must be delivered directly to the prescriber's office.
- If approved, PA will be entered for one (1) treatment at a time. Subsequent treatments will require additional PA review.
- PAs will be entered for one (1) treatment at a time and only one (1) treatment is allowed every 3 months

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Documented improvement in neuropathic pain

QUANTITY EDITS:

1 single use topical system per 90 days (carton can include 1, 2, or 4 systems)

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7. LYTGOBI® (futibatinib) 4 mg tablet

APPROVAL CRITERIA:

- 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 an official Compendia
- Recipient is diagnosed with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must have failed prior platinum-based therapy (e.g., gemcitabine/cisplatin, FOLFOX, FOLFIRI)
- Recipient should not be approved or continue on this therapy with any of the following:
  - Pregnancy
  - Diagnosed with retinal piment epithelial detachment (RPED)
  - Uncontrolled hyperphosphatemia with continued phosphate >7 mg/dL on lowest dose
  - Does not tolerate the minimum dose of 12 mg daily
  - Require concomitant dual P-gp and strong CYP3A inhibitors or inducers (e.g., itraconazole and rifampin)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Test results confirming the presence of FGFR2 gene fusion or other rearrangements
  - Documentation of the previous therapies
  - Current labs including CBC and serum phosphate
  - Baseline comprehensive ophthalmological exam (repeat every 2 months for first 6 months then every 3 months)
  - Attestation that patients of reproductive potential are using contraception
- Initial approval for 1 month, PA renewals may be 3 months if patient tolerates potential toxicities

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)
- Recipient continues to meet approval criteria

QUANTITY EDITS:

#155/31 days

EFFECTIVE JANUARY 18, 2023

8. HYFTOR™ (sirolimus) 0.2% gel

APPROVAL CRITERIA:

- 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 an official Compendia
- Recipient is diagnosed with tuberous sclerosis with facial angiofibromas **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must have at least 3 angiofibromas measuring ≥2 mm in diameter
- Recipient should not be approved or continued on this therapy with any of the following:
  - Pregnancy
  - Requires live vaccine (should be completed prior to therapy initiation)
  - No improvement after 12 weeks of treatment
  - Does not have at least 3 angiofibromas measuring ≥2 mm in diameter
- Prescriber must submit **ALL** of the following:
  - Current chart notes documenting a diagnosis of tuberous sclerosis

- Baseline description of facial angiofibromas
- If approved, PA duration will be 3 months

RENEWAL REQUIREMENTS:
- Prescriber must submit current chart notes with documented change from baseline
- Recipient must have a least a 50% reduction in angiofibroma size and redness by 3 months of use.

QUANTITY EDITS:
2 tubes/ 31 days

EFFECTIVE JANUARY 18, 2023

9. REZLIDHIA™ (olutasidenib) 150 mg capsule

APPROVAL CRITERIA:
- 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 an official Compendia
- Recipient is diagnosed with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient should not be approved or continued on this therapy with any of the following:
  - Continued signs of differentiation syndrome despite dosage modification
  - Require concomitant moderate or strong CYP3A inducers
  - Severe renal or hepatic impairment
  - No previous induction therapy
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies tried
  - Current labs including CBC with differential and LFTs
  - Report confirming the presence of an IDH1 mutation
  - Treatment plan for hematopoietic cell transplant
- Approved PA requests will be entered for 6 months

RENEWAL REQUIREMENTS:
- Current chart notes with response to therapy
- Current labs including CBC and LFTs (labs drawn at least once weekly for first 2 months, once every other week for third month, once in fourth month, and once every other month thereafter)
- Lack of disease progression (trial at least 6 months to assess clinical response) or unacceptable toxicities

QUANTITY EDITS:
#62/31 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 in an emergency when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC clients and once per 60 days per drug class for LTC clients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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