ARKANSAS DEPARTMENT OF HUMAN SERVICES

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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: May 26, 2021

SUBJ: **AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR Board April 21, 2021 meeting for the following:**
Manual review criteria for: Ukoniq™ (umbralisib); Nexletol™ (bempedoic acid); Cabenuva (cabotegravir and rilpivirine); Bronchitol® (mannitol); Tepmetko® (tepotinib); Lupkynis™ (voclosporin); Benlysta® (belimumab); Orgovyx™ (relugolix); Orladeyo™ (berotralstat); SGLT-2 inhibitors for heart failure (Farxiga® and Jardiance®);
Updated point-of-sale edit (effective July 14, 2021): Otezla® (apremilast); GI motility (Amitiza®, Linzess®, and Movantik®);
Updated PA form: Informed consent form for children on antipsychotics
Preferred Drug List (PDL) therapeutic classes from the May 12, 2021 Drug Review Committee meeting for the following: Colony Stimulating Factors; Lipotropic Agents (statins); Narcolepsy Agents (Provigil/Nuvigil only); Phosphate Binders; and Platelet Aggregation Inhibitors

Table of Contents

I. ANNOUNCEMENTS 3
- **A. PLACE OF SERVICE 3**
- **B. COVID-19 VACCINATION UPDATED RATES AND BILLING CODES 3**
- **C. ADHD UPDATE REMINDER 4**
- **D. HEPATITIS C TREATMENT INFORMATION 4**

II. PREFERRED DRUG LIST (PDL): 4
- **1) COLONY STIMULATING FACTORS 4**
- **2) LIPOTROPIC AGENTS ("Statins") 5**
- **3) NARCOLEPSY AGENTS (Provigil/Nuvigil only) 5**
- **4) PHOSPHATE BINDERS 5**
- **5) PLATELET AGGREGATION INHIBITORS 6**

III. PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED): 6
- **1) OTEZLA® (apremilast) 30 mg tablets 6**
- **2) GI MOTILITY POS EDIT (lubiprostone, linaclotide, and naloxegol) 8**
- **3) SGLT-2 INHIBITORS FOR HEART FAILURE (dapagliflozin and empagliflozin) 10**
- **4) ANTIPSYCHOTICS INFORMED CONSENT FORM FOR CHILDREN 13**
- **5) UKONIQ™ (umbralisib) 200 mg tablets 15**

6) NEXLETOL™ (bempedoic acid) 180 mg tablets....16
7) CABENUVA (cabotegravir and rilpivirine) injection....18
8) BRONCHITOL® (mannitol) 40 mg inhalation powder capsule....20
9) TEPMETKO® (tepotinib) 225 mg tablets....21
10) LUPKYNIS™ (voclosporin) 7.9 mg capsule....23
11) BENLYSTA® (belimumab) 200 mg/mL SQ injection....24
12) ORGOVYX™ (relugolix) 120 mg tablets....26
13) ORLADEYO™ (berotralstat) 110 mg and 150 mg capsules....27
14) FRIENDLY REMINDERS....29

I. ANNOUNCEMENTS

A. PLACE OF SERVICE

Arkansas Medicaid is adding the correct National Place of Service Code to the Pharmacy manual to comply with national standards and ensure pharmacies are billing with consistency. The current code of "99" is being replaced with Place of Service Code "01". "99" will be effective for the Place of Service Code until 7/31/2021. Effective 8/1/2021 and after, the "01" will be the only acceptable Place of Service Code.

B. COVID-19 VACCINATION UPDATED RATES AND BILLING CODES

In response to the COVID-19 outbreak in Arkansas and consistent with CMS's anticipated coverage of vaccination administration, DMS is covering COVID-19 Vaccination provided by:

- Physicians
- Nurse Practitioners
- Nurse Midwives
- FQHCs
- RHCs
- Pharmacies who are enrolled to provide vaccines
- ADH
- Hospitals (outpatient)

Initially, the vaccine is being provided at no cost to the providers who can administer the vaccine, but administration of the vaccine will be compensated. The following codes and rates will be available for billing once that vaccine is distributed. **These rates and codes will be available through the public health emergency.**

CODE	SHORT DESCRIPTION	LABELER NAME	FEE
91300	SARSCOV2 VAC 30MCG/0.3ML IM	PFIZER-BIONTECH	$0.01
0001A	ADM SARSCOV2 30MCG/0.3ML 1ST	PFIZER-BIONTECH	$40.00
0002A	ADM SARSCOV2 30MCG/0.3ML 2ND	PFIZER-BIONTECH	$40.00
91301	SARSCOV2 VAC 100MCG/0.5ML IM	MODERNA	$0.01
0011A	ADM SARSCOV2 100MCG/0.5ML1ST	MODERNA	$40.00
0012A	ADM SARSCOV2 100MCG/0.5ML2ND	MODERNA	$40.00
91303	SARSCOV2 VAC AD26 .5ML IM **(START DATE 02/04/2021)**	JANSSEN	$0.01
0031A	ADM SARSCOV2 VAC AD26 .5ML **(START DATE 02/04/2021)**	JANSSEN	$40.00

***These new rates will be effective as of 3/15/2021 for 0001A, 0002A, 0011A, and 0012A.**

*Per CDC guidelines DMS has put a temporary hold on the administration and payment of the Janssen COVID Vaccine as of 4/13/2021. This will be in effect until further recommendations are forthcoming from the CDC.

*As of 4/25/21, the temporary hold on the administration for the Janssen vaccine has been lifted per the CDC recommendation and DMS has authorized the administration of the vaccine for payment using the previously provided codes and rates.

C. ADHD UPDATE REMINDER

As of 2/10/2021, the point-of-sale (POS) edits for ADHD medications have changed.

1) Recipients ≥ 19 years of age require a prior authorization request and a completed CII stimulant form. https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_SMN_Adult_C-II_Stimulant.pdf
2) Recipients < 6 years of age require a prior authorization request for all CII stimulants and atomoxetine.
3) A billed diagnosis of ADHD in the last 2 years is required for children 6-18 years of age. If no ADHD diagnosis is billed, a prior authorization request is required.
4) Atomoxetine will require a billed diagnosis of ADHD for children and adults in the last 2 years.

D. 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.

EFFECTIVE JULY 1, 2021:

II. PREFERRED DRUG LIST (PDL):

****Bolded medications have had a change in status.****

1) COLONY STIMULATING FACTORS

PREFERRED AGENTS:

- Neupogen® (filgrastim) vial and syringe
- **Nyvepria® (pegfilgrastim-apgf)**

NONPREFERRED AGENTS:

- Fulphila® (pegfilgrastim-jmbd)
- **Granix® (tbo-filgrastim) syringe**
- Leukine® (sargramostim) vial
- Neulasta® Onpro® Kit (pegfilgrastim)
- **Neulasta® (pegfilgrastim) syringe**
- Nivestym® (filgrastim-aafi) vial and syringe
- Udenyca® (pegfilgrastim-cbqv)
- Zarxio® (filgrastim-sndz) syringe

- Ziextenzo® (pegfilgrastim-bmez) syringe

2) LIPOTROPIC AGENTS ("Statins")

PREFERRED AGENTS:

- Atorvastatin calcium (generic for Lipitor®)
- **Lovastatin (generic for Mevacor®)**
- Pravastatin sodium (generic for Pravachol®)
- **Rosuvastatin calcium (generic for Crestor®)**
- Simvastatin (generic for Zocor®)

NONPREFERRED AGENTS:

- Altoprev® (lovastatin ER)
- Atorvastatin/Amlodipine (generic for Caduet®)
- Caduet® (Atorvastatin/Amlodpine)
- Crestor® (rosuvastatin)
- Fluvastatin sodium (generic for Lescol®)
- Lescol® XL (Fluvastatin)
- Livalo® (Pitavastatin calcium)
- Simvastatin/Ezetimibe (generic for Vytorin®)
- Vytorin® (Simvastatin/Ezetimibe)
- Zocor® (Simvastatin)

3) NARCOLEPSY AGENTS (Provigil/Nuvigil only)

PREFERRED AGENTS THAT REQUIRE MANUAL REVIEW FOR PRIOR AUTHORIZATION:

- Nuvigil® (armodafinil) (BRAND ONLY)

NONPREFERRED AGENTS:

- Provigil® (modafinil)
- Modafinil (generic for Provigil®)
- Armodafinil (generic for Nuvigil®)

4) PHOSPHATE BINDERS

PREFERRED AGENTS:

- Calcium Acetate capsule
- Calcium Acetate tablet
- **Renagel® tablet (sevelamer HCL)-** BRAND ONLY
- Renvela® tablet (sevelamer carbonate)- BRAND ONLY

NONPREFERRED AGENTS:

- Auryxia® tablet (ferric citrate)
- Fosrenol® Chew tablet and powder pack (lanthanum carbonate)
- Lanthanum Carbonate Chew tablets (generic for Fosrenol®)
- Phoslyra® Solution (calcium acetate)
- Renvela® Powder packet (sevelamer carbonate)
- Sevelamer Carbonate powder packet (generic for Renvela®)
- Sevelamer Carbonate tablet (generic for Renvela®)
- **Sevelamer HCL tablets (generic for Renagel®)**
- Velphoro® chew tablet (sucroferric oxyhydroxide)

5) PLATELET AGGREGATION INHIBITORS

PREFERRED AGENTS:

- Aspirin/dipyridamole (generic for Aggrenox®)
- Brilinta® (ticagrelor)
- Clopidogrel (generic for Plavix®)
- Dipyridamole
- Prasugrel (generic for Effient®)

NONPREFERRED AGENTS:

- Effient® (prasugrel)
- Plavix® (clopidogrel bisulfate)
- Zontivity® (vorapaxar sulfate)

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

EFFECTIVE JULY 14, 2021

1) OTEZLA® (apremilast) 30 mg tablets

INDICATION:

- Treatment of adult patients with active psoriatic arthritis
- Treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Treatment of adult patients with oral ulcers associated with Behçet's Disease

DOSING:

- Day 1-5 titration:
- Starting Day 6, maintenance dose is 30 mg twice daily

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

Table 1: Dosage Titration Schedule

DOSING MODIFICATION:

- Reduced to 30 mg once daily in patients with severe renal impairment (creatinine clearance (CLcr) of less than 30 mL per minute)

APPROVAL CRITERIA FOR OTEZLA:

Must meet one of the following criteria:

Criterion 1:

- Recipient has a submitted diagnosis of psoriasis in the past two years; **AND**
- Recipient is ≥ 18 years of age; **AND**
- During days 180 to 395 days ago, a total of >180 days of topical drug therapy with:

  - Calcipotriene; **OR**
  - Corticosteroids; **OR**
  - Tazarotene; **AND**
- During days 1 to 210 ago, a total of >180 days of systemic drug therapy with:
  - Cyclosporine; **OR**
  - Methotrexate; **OR**
  - Acitretin; **AND**
- Topical drug therapy trial occurred before systemic drug therapy

Criterion 2:

- Recipient has a submitted diagnosis of psoriatic arthritis in the past two years; **AND**
- Recipient is ≥ 18 years of age; **AND**
- ≥ Six (6) claims for any of the following in the past 365 days:
  - Methotrexate; **OR**
  - Hydroxychloroquine; **OR**
  - Sulfasalazine; **OR**
  - Leflunomide

Criterion 3:

- Recipient has a submitted diagnosis of psoriasis or psoriatic arthritis in the past two years; **AND**
- Recipient is ≥ 18 years of age; **AND**
- Paid drug claim for apremilast (OTEZLA) in the past 45 days

NOTE: Before moving to a non-preferred option, the patient must have a documented trial and failure of at least adalimumab (HUMIRA) and/or etanercept (ENBREL) AND apremilast (OTEZLA) for patients with psoriasis and psoriatic arthritis.

Manual Review for Behçet's Disease with manifestation of oral ulcers:
(Manual Review for any new FDA approved indications)

APPROVAL CRITERIA:

- Recipient must be ≥ 18 of age; **AND**
- Recipient must have a diagnosis of Behçet's Disease **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient with oral ulcers has tried and failed topical corticosteroids (i.e., triamcinolone acetonide cream 0.1% in Orabase); **AND**
- Recipient has tried and failed at least 3 months of treatment with colchicine or immunosuppressant; **AND**
- Prescriber must submit current chart notes; **AND**
- Disease manifestation besides oral ulcers will be reviewed on a case-by-case basis; **AND**
- Initial PA approved for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia

CONTINUATION CRITERIA:

- Recipient demonstrates ulcer improvement after 3 months of therapy; **AND**
- Prescriber must submit current chart notes with documentation of response.

QUANTITY EDITS:
#62/31 days

EFFECTIVE JULY 14, 2021

2) GI MOTILITY POS EDIT (lubiprostone, linaclotide, and naloxegol)

PREFERRED DRUG LIST WITH INDICATIONS FOR PREFERRED AGENTS:

PREFERRED AGENTS with criteria	INDICATIONS
• **AMITIZA® tablet (lubiprostone)**	• Treatment of chronic idiopathic constipation (CIC) • Treatment of irritable bowel syndrome with constipation (IBS-C) in females ≥ 18 years old • Treatment of opioid-induced constipation (OIC) in adults with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
• **LINZESS® capsule (linaclotide)**	• Treatment of chronic idiopathic constipation (CIC) • Treatment of irritable bowel syndrome with constipation (IBS-C)
• **MOVANTIK® tablet (naloxegol)**	• Treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

NONPREFERRED AGENTS
• **ALOSETRON tablet (generic for Lotronex®)**
• **LOTRONEX® tablet (alosetron)**
• **LUBIPROSTONE tablet (generic for Amitiza®)**
• **MOTEGRITY® tablet (prucalopride)**
• **RELISTOR® tablet and injection (methylnaltrexone)**
• **SYMPROIC® tablet (naldemedine)**
• **TRULANCE® tablet (plecanatide)**
• **VIBERZI® tablet (eluxadoline)**
• **ZELNORM® tablet (tegaserod)**

APPROVAL CRITERIA for AMITIZA:

Criterion 1:

- Recipient must be ≥ 18 years old
- Recipient's Medicaid profile must include a paid drug claim for AMITIZA within the past 60 days

Criterion 2:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule of different strengths, or new agents to market.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age

APPROVAL CRITERIA FOR LINZESS:

Criterion 1:

- Recipient must be ≥ 18 years old
- Recipient's Medicaid profile must include a paid drug claim for LINZESS within the past 60 days

Criterion 2

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule, or new agents to market.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age; **OR**
- Recipient has a paid claim for an opioid in the last 60 days.

APPROVAL CRITERIA FOR MOVANTIK:

Criterion 1:

- Recipient must be ≥ 18 years old

- Recipient's Medicaid profile must include a paid drug claim for MOVANTIK within the past 60 days

Criterion 2:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule of different strengths, or new agents to market; **AND**
- Recipient has a paid claim for an opioid (includes buprenorphine) in the last 60 days.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age; **OR**
- Recipient does not have a paid claim for an opioid in the last 60 days.

EFFECTIVE IMMEDIATELY:

3) SGLT-2 INHIBITORS FOR HEART FAILURE (dapagliflozin and empagliflozin)

FARXIGA® (dapagliflozin) 5 mg and 10 mg tablets

INDICATION:

1.1 Type 2 Diabetes Mellitus

FARXIGA (dapagliflozin) is indicated:

- 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 established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

1.2 Heart Failure

FARXIGA is indicated 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.

1.3 Limitations of Use

FARXIGA is not recommended for patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

JARDIANCE® (empagliflozin) 10 mg and 25 mg tablets

JARDIANCE is indicated:

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

- to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

APPROVAL CRITERIA:

- Based on current treatment guidelines for treating heart failure without a diabetes diagnosis (includes empagliflozin and dapagliflozin); **AND**
- Recipient 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; **AND**
- Recipient must be prescribed first-line standard of care therapy titrated to the maximum tolerated or target doses; **AND**
    - Angiotensin Receptor-Neprilysin Inhibitor (ARNI)/ Angiotensin-Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB); **AND**
    - Beta blocker; **AND**
    - Diuretic (as needed)
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapy; **AND**
    - Baseline LVEF; **AND**
    - Current estimated glomerular filtration rate (eGFR)
    - Baseline N-terminal pro–B-type natriuretic peptide (NT-proBNP) or BNP

DENIAL CRITERIA:

- Recipient does not meet approval criteria; **OR**
- Recipient has type 1 diabetes; **OR**
- Recipient is on dialysis; **OR**
- Recipient has eGFR below the following recommendations:
    - JARDIANCE—eGFR <20 mL/min/1.73 m^2
    - FARXIGA—eGFR <30 mL/min/1.73 m^2

CONTINUATION CRITERIA:
If the recipient remains “stable and compliant”, the claim will continue to process at point-of-sale without an additional prior authorization. “Stable and compliant” is defined as at least 90 days of medication therapy out of the previous 120 days based on the recipient’s Medicaid drug profile.

EFFECTIVE JULY 1, 2021

4) ANTIPSYCHOTICS INFORMED CONSENT FORM FOR CHILDREN

Medication Informed Consent Document
For Behavioral or Psychiatric Conditions
Clients < 18 years of age
A newly signed and dated form by all parties is required for changes in antipsychotic chemical entity or delivery system.

After completing the information below please fax to the Arkansas Medicaid Pharmacy Program. Fax: 1-800-424-6861. For questions call: 501-683-4120.

Client Information

LAST NAME: | FIRST NAME:

MEDICAID ID NUMBER: | DATE OF BIRTH: – –

Prescriber Information

LAST NAME: | FIRST NAME:

NPI NUMBER: | DEA NUMBER:

PHONE NUMBER: – – | FAX NUMBER: – –

PARENTAL/GUARDIAN CONSENT STATEMENT - I understand:

- ☐ With or without medicine, counseling is important to help change behavior.
- ☐ Medicine may help manage some symptoms.
- ☐ What to expect without treatment, with counseling only, with medicine only, and with both counseling and medicine.
- ☐ I can refuse the use of this or any other medicine at any time.
- ☐ Medicines may sometimes cause behavior or health problems. Sometimes these effects may be permanent.
- ☐ I was given an information sheet about the recommended medicine. The sheet tells about:
  - FDA approval (if any) for using the medicine in children
  - Any safety concerns
  - How to stop taking the medicine
  - What to do about missing a dose
  - How to keep track of the effects of the medicine
- ☐ The effects and risks of this medicine may change over time. My child will need regular visits with the doctor to make sure it is safe to keep using the medicine.

PRESCRIBER SECTION

☐ **Patient's diagnosis** (e.g. Bipolar II):

☐ **ICD-10 Code for diagnosis** (e.g. F31.81): ☐ **DSM-5 Code for diagnosis** (e.g. 296.89)

☐ **Specific targeted symptoms to be addressed by antipsychotic medication:**

☐ **A comprehensive mental health or developmental/behavioral evaluation has been performed (CHECK ONE):**

☐ More than 12 months ☐ In the past 12 months ☐ Current referral ☐ No evaluation planned

☐ **Patient and/or family counseling or behavioral intervention?**

☐ Past ☐ Current ☐ Referred ☐ No

Provider comments:

DHS 07/01/21 Page 1 of 2

Medication Informed Consent Document
For Behavioral or Psychiatric Conditions
Clients < 18 years of age
A newly signed and dated form by all parties is required for changes in antipsychotic chemical entity or delivery system.

PRESCRIBER MUST SUBMIT THE FOLLOWING DOCUMENTATION:

- ☐ Progress/chart notes
- ☐ Psychiatric evaluation
- ☐ Psycho-social history
- ☐ After care plan (for inpatient)
- ☐ Labs every 6 months
- ☐ Completed informed consent form

☐ **Medication Recommendation:** _____

Dose: _____

Dosing Instructions (please write clearly): _____

Medicines previously used: _____

Other medicines continued or started: _____

I have explained to the parent/guardian of patient the risks and benefits of this medication via: ☐ PHONE ☐ FACE-TO-FACE

(Mark which method was used for education consultation)

_____ ☐☐ - ☐☐ - ☐☐☐☐
Prescriber Signature (Required) *Date*

Prescriber's original signature required; copied, stamped, or e-signature are not allowed.
(By signature, the Prescriber confirms the above information is accurate and verifiable by patient records.)

PRESCRIBER LAST NAME: **PRESCRIBER FIRST NAME:**

As the parent/guardian of the patient named, I understand the risks and benefits of this medication as they have been explained to me and I consent to the use of the named medication. *Relationship:* _____

_____ ☐☐ - ☐☐ - ☐☐☐☐
Parent/Guardian Signature (Required) *Date*

PARENT/GUARDIAN LAST NAME: **PARENT/GUARDIAN FIRST NAME**

_____ ☐☐ - ☐☐ - ☐☐☐☐
Witness Signature *Date*

WITNESS LAST NAME: **WITNESS FIRST NAME:**

DHS 07/01/21

Page 2 of 2

EFFECTIVE IMMEDIATELY:

5) UKONIQ™ (umbralisib) 200 mg tablets

INDICATION:

- Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen (accelerated approval)
- Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy (accelerated approval)

DOSING:

- Recommended dosage of UKONIQ is 800 mg taken orally once daily with food until disease progression or unacceptable toxicity.

DOSE MODIFICATION:

- Recurring neutropenia with ANC less than 0.5×10^9/L
- Recurring thrombocytopenia with platelets $< 25 \times 10^9$/L or 25 to $< 50 \times 10^9$/L with bleeding
- Recurrent moderate diarrhea or asymptomatic colitis

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen **OR** relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must take concomitant prophylaxis for *Pneumocystis jirovecii* pneumonia (PJP) and consider prophylactic antivirals to prevent cytomegalovirus (CMV) infection; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of diagnosis; **AND**
  - Current labs including CBC with differential and liver function tests; **AND**
  - Documentation of previous therapies

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a confirmed diagnosis of PJP; **OR**
- Recipient is pregnant; **OR**
- MZL recipient has not received at least one prior therapy; **OR**
- MZL or FL recipient has prior exposure to a PI3K inhibitor; **OR**
- FL recipient has not received at least three prior systemic therapies; **OR**
- FL recipient has Grade 3b FL, large cell transformation, prior allogeneic transplant, or history of CNS lymphoma; **OR**
- Recipient cannot tolerate the dose of minimum dose of 400 mg per day; **OR**
- Recipient has severe renal impairment or moderate/severe hepatic impairment.

CONTINUATION CRITERIA:

- Recipient has a positive response without disease progression (submitting PA request implies no disease progression); **AND**
- Recipient must continue PJP prophylaxis; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to treatment; **AND**
  - Current labs including CBC with differential and liver function tests

QUANTITY EDITS:
#120/ 30 days

EFFECTIVE IMMEDIATELY:

6) NEXLETOL™ (bempedoic acid) 180 mg tablets

INDICATION:

- Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.
- Limitation: effect on cardiovascular morbidity and mortality has not been determined.

Treatment recommendations per ICER:
Treatment of patients with FH and established ASCVD includes risk factor modification such as dietary and lifestyle changes and smoking cessation, medical therapy, and when necessary, percutaneous or surgical revascularization. Because of the association between lipid levels and MACE, medical therapy should include intensive lipid-lowering therapy, with a goal LDL-C reduction of at least 50%. Ideally this should be accomplished with a high dose or maximally tolerated statin, but for patients who continue to have LDL-C levels at or above 70 mg/dL, the addition of ezetimibe is recommended as second-line therapy. Finally, for those patients who continue to have LDL-C levels above 70 mg/dL on statin and ezetimibe, a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor can be considered. For patients who have statin-associated side effects (SASE) (also known as statin intolerance) -- defined as not able to tolerate moderate to high intensity statin therapy due to side effects -- therapy with ezetimibe, PCSK9 inhibitors, and other lipid-lowering therapies may be considered to reach treatment goals.

DOSING:

- The recommended dosage of NEXLETOL, in combination with maximally tolerated statin therapy, is 180 mg administered orally once daily. NEXLETOL can be taken with or without food.
- After initiation of NEXLETOL, analyze lipid levels within 8 to 12 weeks.

DOSE MODIFICATION:

- Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
- Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia **or** atherosclerotic cardiovascular disease **OR** a diagnosis consistent with FDA indications; **AND**
- Provider must submit the following:
    - Current chart notes
    - Chart notes during trials of statins **AND** ezetimibe; **AND**
    - Current labs including lipids and LFTs as well as labs corresponding with previous trials of statins **AND** ezetimibe taken concomitantly; **AND**
    - Uric acid levels for patients with a gout diagnosis; **AND**
    - Medical necessity over the use of medications outlined in current treatment guidelines; **AND**
- Compliance on previous lipid therapy is required unless contraindicated (see definition). Recipient's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance; **AND**
- Recipient must be prescribed concomitant statin therapy unless contraindicated or patient demonstrated statin intolerance (see definition); **AND**
- Recipient should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after trials of moderate-high intensity statins and ezetimibe per current treatment guidelines unless the recipient has a contraindication; **AND**
- Provider must submit diet plan for lowering cholesterol; **AND**
- If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; **AND**
- Initial approval for 2 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a ruptured tendon; **OR**
- Provider orders concomitant statin therapy with simvastatin dose > 20 mg or pravastatin dose > 40 mg; **OR**
- Recipient has end-stage renal disease (ESRD) receiving dialysis **OR** severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is taking PCSK9 inhibitors; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe per treatment guidelines (For patients that do not have a contraindication or intolerance to statins).

CONTINUATION CRITERIA:

- Provider should submit current chart notes; **AND**
- Provider should submit current labs; **AND**
- Recipient must have a decline in LDL-C or non-HDL-C; **AND**
- Renewal reviews may be approved for up to 6 months.

DEFINTIONS:
Contraindication to statins—may include but not limited to a significant increase in LFTs or myositis which has been confirmed with a biopsy. Ezetimibe use would still be expected.

Statin intolerance—patient has inability to tolerate at least two different statins at moderate or high doses **AND** decreasing statin dose and/or frequency to avoid side effects does not lower LDL-C to desired level when taken with ezetimibe. Ezetimibe use would still be expected.

QUANTITY EDITS:
#31/ 31 days

EFFECTIVE IMMEDIATELY:

7) CABENUVA (cabotegravir and rilpivirine) injection

INDICATION:
CABENUVA is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

DOSING:
2.1 Adherence to CABENUVA
CABENUVA must be administered by a healthcare professional. Prior to starting CABENUVA, healthcare professionals should carefully select patients who agree to the required monthly injection dosing schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses.

2.2 Oral Lead-in Dosing to Assess Tolerability of CABENUVA
Oral lead-in should be used for approximately 1 month (at least 28 days) prior to the initiation of CABENUVA to assess the tolerability of cabotegravir and rilpivirine. The recommended oral lead-in daily dose is one 30-mg tablet of VOCABRIA (cabotegravir) and one 25-mg tablet of EDURANT (rilpivirine).

Drug	Oral Lead-In (at Least 28 Days)	Intramuscular (Gluteal) Initiation Injections (One-Time Dosing)	Intramuscular (Gluteal) Continuation Injections (Once-Monthly Dosing)
	Month 1	At Month 2 (On the Last Day of Oral Lead-In Dosing)	Month 3 Onwards

Cabotegravir	30 mg once daily with a meal	600 mg (3 mL)	400 mg (2 mL)
Rilpivirine	25 mg once daily with a meal	900 mg (3 mL)	600 mg (2 mL)

DOSE MODIFICATION:
If a patient plans to miss a scheduled injection visit by more than 7 days, take daily oral therapy to replace up to 2 consecutive monthly injection visits. The recommended oral daily dose is one 30-mg tablet of VOCABRIA (cabotegravir) and one 25-mg tablet of EDURANT (rilpivirine). The first dose of oral therapy should be taken approximately 1 month after the last injection dose of CABENUVA and continued until the day injection dosing is restarted.

APPROVAL CRITERIA:
- Recipient must be ≥ 18 years of age; **AND**
- Recipient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**
- Recipient must be virologically suppressed (HIV-1 RNA less than 50 copies per mL); **AND**
- Recipient must be on a stable antiretroviral regimen with no history of treatment failure; **AND**
- Recipient must have taken Vocabria (cabotegravir) and Edurant® (rilpivirine) for at least a month to assess tolerability; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Labs including current RNA documenting viral suppression; **AND**
    - Attestation that recipient has been counseled on the importance of compliance; **AND**
    - PA request must be submitted after trial of oral therapy has begun; **AND**
    - Medical necessity over current oral therapy; **AND**
- Prior authorization will be approved for 12 months.

DENIAL CRITERIA:
- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires coadministration with any of the following:
    - Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin; **OR**
    - Antimycobacterials: Rifabutin, rifampin, rifapentine; **OR**
    - Glucocorticoid (systemic): Dexamethasone (more than a single-dose treatment); **OR**
    - Herbal product: St John's wort (Hypericum perforatum)

CONTINUATION CRITERIA:
- Recipient has been compliant on injections; **AND**
- Recipient remains virologically suppressed; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including RNA documenting viral suppression; **AND**
- Renew PA for an additional 12 months.

QUANTITY EDITS:
600 mg/ 900 mg kit—1 per year
400 / 600 mg kit—1 per 30 days

EFFECTIVE IMMEDIATELY:

8) BRONCHITOL® (mannitol) 40 mg inhalation powder capsule

INDICATION:

- Add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with Cystic Fibrosis. Use BRONCHITOL only for adults who have passed the BRONCHITOL Tolerance Test.

DOSING:

- For patients who have passed the BTT, the recommended dosage of BRONCHITOL is 400 mg twice a day by oral inhalation (the contents of 10 capsules administered individually) via the inhaler.
- A short-acting bronchodilator should be administered by oral inhalation, 5-15 minutes before every dose of BRONCHITOL.
- BRONCHITOL should be taken once in the morning and once in the evening, with the later dose taken at least 2-3 hours before bedtime.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Cystic Fibrosis **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have passed a BRONCHITOL Tolerance Test (BTT). Chiesi provides the 10 capsules requested for the BTT free of charge (NDC# 10122-216-01 – WAC Price $0.00). However, if a facility cannot accept "samples" then the work around is the BTT with NDC# 10122-212-04 – WAC Price $62.18. Both NDCs come with 10 capsules. Failure would include bronchospasms, a decrease in FEV_1, or a decrease in oxygen saturation with administration of BRONCHITOL; **AND**
- Recipient must have a recent claim for a short-acting bronchodilator; **AND**
- Recipient must continue other standard of care treatments; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous and current medications; **AND**
  - Current pulmonary function tests results with baseline FEV_1 > 40% and < 90% predicted; **AND**
  - Results from a recent BTT; **AND**
  - Medical necessity over hypertonic saline and Dornase alfa

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**

- Recipient failed the BTT; **OR**
- Recipient has an episode of hemoptysis (>60 mL) in the previous 3 months or develops hemoptysis during treatment; **OR**
- Recipient does not remain compliant on therapy with PA renewal request.

CONTINUATION CRITERIA:

- Recipient demonstrated an improvement in their FEV_1 from baseline; **AND**
- Recipient remains compliant on the medication; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current pulmonary function tests

QUANTITY EDITS:

One (1) four week treatment pack per 28 days (#560/ 28 days)

EFFECTIVE IMMEDIATELY:

9) TEPMETKO® (tepotinib) 225 mg tablets

INDICATION:

- Treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations (accelerated approval).

DOSING:

- Select patients for treatment with TEPMETKO based on the presence of MET exon 14 skipping alterations in plasma or tumor specimens.
- Recommended dosage of TEPMETKO is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

DOSE MODIFICATION:

- The recommended dose reduction of TEPMETKO for the management of adverse reactions is 225 mg orally once daily.
- Permanently discontinue TEPMETKO in patients who are unable to tolerate 225 mg orally once daily.
- Adverse reactions:
  - Discontinue with confirmed Interstitial Lung Disease
  - Discontinue if Grade 4 increase in ALT and/or AST without increased total bilirubin
  - Discontinue if ALT and/or AST >3X ULN with total bilirubin >2X ULN
  - Discontinue if Grade 4 increase in total bilirubin without increased ALT and/or AST

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of metastatic non-small lunch cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapies; **AND**
    - Documentation of the presence of MET exon 14 skipping alterations; **AND**
    - Current labs including liver function tests and CBCs; **AND**
    - Attestation that patient has been counseled on contraception (both male and female); **AND**
- Recipient should not take concomitant dual strong CYP3A inhibitors and P-gp inhibitors (e.g., clarithromycin, itraconazole, verapamil) **OR** strong CYP3A inducers (e.g., phenytoin, rifampin); **AND**
- Recipient must have a negative status for epidermal growth factor receptor(EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; **AND**
- Initial PA may be approved for 3 month

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is diagnosed with interstitial lung disease/pneumonitis; **OR**
- Recipient cannot tolerate the minimum dose of 225 mg daily; **OR**
- Recipient is pregnant; **OR**
- Recipient has severe renal impairment; **OR**
- Recipient has Grade 4 increase in ALT and/or AST without increased total bilirubin **OR** ALT and/or AST >3X ULN with total bilirubin >2X ULN **OR** Grade 4 increase in total bilirubin without increased ALT and/or AST; **OR**
- Recipient requires coadministration with dual strong CYP3A inhibitors and P-gp inhibitors **OR** strong CYP3A inducers.

CONTINUATION CRITERIA:

- Recipient does not demonstrate disease progression or unacceptable toxicity; **AND**
- Prescriber should submit the following:
    - Current chart notes with response to therapy; **AND**
    - Current labs including LFTs and CBCs

QUANTITY EDITS:

#62/ 31 days

EFFECTIVE IMMEDIATELY:

10) LUPKYNIS™ (voclosporin) 7.9 mg capsule

INDICATION:

- In combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

DOSING:

- The recommended starting dose of LUPKYNIS is 23.7 mg twice a day.
- Use LUPKYNIS in combination with mycophenolate mofetil (MMF) and corticosteroids

DOSE MODIFICATION:

Based on recipient's eGFR:

- If eGFR <60 mL/min/1.73 m^2 and reduced from baseline by >20% and <30%, reduce the dose by 7.9 mg twice a day. Re-assess eGFR within two weeks; if eGFR is still reduced from baseline by >20%, reduce the dose again by 7.9 mg twice a day.
- If eGFR <60 mL/min/1.73 m^2 and reduced from baseline by ≥30%, discontinue LUPKYNIS. Re-assess eGFR within two weeks; consider re-initiating LUPKYNIS at a lower dose (7.9 mg twice a day) only if eGFR has returned to ≥80% of baseline.
- For patients that had a decrease in dose due to eGFR, consider increasing the dose by 7.9 mg twice a day for each eGFR measurement that is ≥80% of baseline; do not exceed the starting dose.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of biopsy-proven active lupus nephritis (Class III, IV or V) **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must also take mycophenolate mofetil (MMF) and corticosteroids concomitantly with Lupkynis; **AND**
- Recipient must have an elevated urine protein to creatinine (UPCR) ratio; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including liver function tests, urine protein to creatinine (UPCR) ratio, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR). eGFR must be assessed every two weeks for the first month, and every four weeks thereafter; **AND**
    - Current blood pressure; **AND**

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient has a baseline eGFR ≤ 45 mL/min/1.73m^2; **OR**
- Recipient has a baseline blood pressure >165/105 mmHg or with hypertensive emergency; **OR**

- Recipient is not taking concomitant mycophenolate mofetil and corticosteroids; **OR**
- Recipient is taking cyclophosphamide; **OR**
- Recipient requires concomitant strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin); **OR**
- Prescriber orders a dose > 23.7 mg twice daily **OR** < 7.9 mg twice daily; **OR**
- Recipient has severe hepatic impairment; **OR**
- If approved, recipient has not experienced therapeutic benefit by 24 weeks.

CONTINUATION CRITERIA:

- Recipient must be a responder with a decrease in corticosteroid usage/dosage **AND/OR** improved UPCR **AND/OR** improved eGFR; **AND**
- Recipient must be compliant on therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including eGFR and UPCR; **AND**
  - Current blood pressure

QUANTITY EDITS:
#180/ 30 days

EFFECTIVE IMMEDIATELY:

11) BENLYSTA® (belimumab) 200 mg/mL SQ injection

INDICATION:

- Patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy
- Adult patients with active lupus nephritis who are receiving standard therapy (NEW)

LIMITATIONS:

- Patients with severe active central nervous system lupus
- Use in combination with other biologics

DOSING:
BENLYSTA may be administered as an intravenous infusion in patients aged 5 years and older or as a subcutaneous injection in patients aged 18 years and older. Vials are intended for intravenous use only (not for subcutaneous use) and autoinjectors and prefilled syringes are intended for subcutaneous use only (not for intravenous use).
Vials would be excluded from pharmacy benefits since used for intravenous infusion.

Recommended Subcutaneous Dosage Regimen — Adult Patients with SLE

- The recommended dosage is 200 mg once weekly given as a subcutaneous injection in the abdomen or thigh. Subcutaneous dosing is not based on weight.

Recommended Subcutaneous Dosage Regimen — Adult Patients with Lupus Nephritis

- In patients initiating therapy with BENLYSTA for active lupus nephritis, the recommended dosage regimen is a 400 mg dose (two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter.
- In lupus nephritis patients transitioning from intravenous therapy, the first SQ dose of 200 mg should be given 1-2 weeks after last IV dose.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age (for subcutaneous injection); **AND**
- Recipient must have a diagnosis of either active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy **OR** active lupus nephritis (LN) who are receiving standard therapy **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient with SLE must have:
    - Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of ≥ 8; **AND**
    - Positive autoantibody test (anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA)); **AND**
- Recipient with LN must have:
    - Clinical diagnosis of SLE; **AND**
    - Biopsy confirmed active lupus nephritis
- Recipient must take concomitant standard therapy which could include corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), NSAIDs, and immunosuppressives (e.g., azathioprine, methotrexate, mycophenolate); **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including CBC with differential, urine protein to creatinine (UPCR) ratio for LN recipient, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR) for LN recipient. eGFR must be assessed every two weeks for the first month, and every four weeks thereafter; **AND**
    - Current blood pressure; **AND**
    - Medical necessity over supported immunosuppressive therapy alone for SLE patients (i.e., mycophenolate mofetil or azathioprine).

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has progressive multifocal leukoencephalopathy (PML); **OR**
- Recipient has a SELENA-SLEDAI score of < 8 and does not have a positive autoantibody test; **OR**
- Recipient has been prescribed biologic therapies, anti-tumor necrosis factor therapy, interleukin-1 receptor antagonist, IVIG, or plasmapheresis in the previous 3 months; **OR**
- Recipient has severe active CNS lupus; **OR**
- Recipient is pregnant; **OR**
- Recipient is not taking concomitant standard therapy.

CONTINUATION CRITERIA:

- Recipient must be a responder with a decrease in corticosteroid usage/dosage **AND/OR** improved SELEMA-SLEDAI score (for SLE) **AND/OR** improvement in UPCR or eGFR (for LN); **AND**
- Recipient must be compliant on therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including eGFR and UPCR; **AND**
  - Current blood pressure

QUANTITY EDITS:

4 syringes/ 28 days

EFFECTIVE IMMEDIATELY:

12) ORGOVYX™ (relugolix) 120 mg tablets

INDICATION:

- Gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer

DOSING:

- Initiate treatment of ORGOVYX with a loading dose of 360 mg on the first day and continue treatment with a 120 mg dose taken orally once daily at approximately the same time each day.
- If treatment with ORGOVYX is interrupted for greater than 7 days, restart ORGOVYX with a loading dose of 360 mg on the first day and continue with a dose of 120 mg once daily.

DOSE MODIFICATION:

- Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first and separate dosing by at least 6 hours. Treatment with ORGOVYX may be interrupted for up to two weeks if a short course of treatment with a P-gp inhibitor is required.
- Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg once daily

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be a male; **AND**
- Recipient must have a diagnosis of advanced prostate cancer **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient requires at least a year of Androgen Deprivation Therapy (ADT); **AND**
- Recipient has a baseline testosterone level > 50 ng/dL; **AND**
- Prescriber must submit the following:

- Chart notes; **AND**
- Current labs including baseline prostate-specific antigen (PSA) and testosterone; **AND**
- Previous therapies; **AND**
- Medical necessity over other options for ADT including degarelix and leuprolide; **AND**
- Baseline ECG if patient is a risk for QT prolongation

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is a female; **OR**
- Recipient has end-stage renal disease with or without hemodialysis or severe hepatic impairment (Child-Pugh C); **OR**
- Recipient requires a P-gp inhibitor or combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, separate dosing for those requiring P-gp inhibitors and increase the ORGOVYX dose for those requiring combined P-gp and strong CYP3A inducers; **OR**
- Baseline testosterone level (without ADT) is <50 ng/dL; **OR**
- Testosterone level does not remain at castration level on renewal request (<50 ng/dL).

CONTINUATION CRITERIA:

- Recipient has not developed castrate-resistant or hormone-refractory prostate cancer; **AND**
- Recipient remains compliant on ORGOVYX; **AND**
- Recipient's PSA remains low (if increases, additional therapy may be needed); **AND**
- Recipient's serum testosterone level remains at castrate level; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including PSA and testosterone; **AND**
  - Response to current chemotherapy or radiation

QUANTITY EDITS:
#31/ 31 days

EFFECTIVE IMMEDIATELY:

13) ORLADEYO™ (berotralstat) 110 mg and 150 mg capsules

INDICATION:

- Plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.
- ORLADEYO should not be used for treatment of acute HAE attacks.

DOSING:

- The recommended dosage of ORLADEYO is one 150 mg capsule taken orally once daily with food.

DOSE MODIFICATION:

- Hepatic impairment: dose for moderate or severe hepatic impairment is 110 mg once daily
- Concomitant P-gp or BCRP inhibitors: dose is 110 mg once daily
- Persistent GI reactions: consider dose of 110 mg once daily

APPROVAL CRITERIA:

- Recipient must be ≥12 years of age; **AND**
- Recipient must have a laboratory diagnosis of Type 1 or Type 2 hereditary angioedema **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks; **AND**
- Provider (allergist/immunologist/hematologist) must submit the following:
    - Current chart notes with documentation of previous therapies tried with disease history and description of typical angioedema attack; **AND**
    - Proposed treatment plan for both acute attacks and prophylaxis treatment; **AND**
    - Documentation of attack frequency, comorbidities, and access to emergency care for the previous 12 months on the initial request; **AND**
    - Documentation of expected angioedema triggers (Trigger avoidance is crucial); **AND**
    - IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation; **AND**
      • 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
      • Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
    - Provide the following labs:
        - Complement C1 esterase inhibitor level; **AND**
        - Complement C4 level; **AND**
        - Functional C1 inhibitor activity; **AND**
- Initial PA maximum 3-month trial if approved

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Prescriber intends for recipient to use for the treatment of acute attacks of HAE; **OR**
- Prescriber requests a dose of >150 mg per day; **OR**
- Recipient is prescribed an ACEi, estrogen, or other drugs that can possibly be angioedema triggers; **OR**
- Prescriber requests a therapeutic duplication with 2 or more preventative agents

``CONTINUATION CRITERIA:

- Recipient must provide updated diary of events documenting any angioedema events; **AND**
- Recipient must be compliant on maintenance medication; **AND**
- If there is no response from prophylaxis in severity and frequency, considering changing the medication and/or question diagnosis of Type I or Type II. It may be Type III. Question triggers or accuracy of diagnosis; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of response to therapy with attack frequency and severity

QUANTITY EDITS:
#31/ 31 days for each strength

14) 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://medicaid.mmis.arkansas.gov/**
- **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/
For questions about each PASSE organization, please refer to this website for contact information:
https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us

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://medicaid.mmis.arkansas.gov/Provider/Docs/Docs.aspx/

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. **Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the FDA approved dose for treating opioid addiction is prescribing the total daily dose as one single daily dose. "After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. **The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose**. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage."

6. **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.**

7. **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/.

8. **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.

9. **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.

10. **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.

11. **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.

12. **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.

13. **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

14. **ELECTRONIC PROVIDER MEMO:** To reduce paper waste beginning April 2019, Arkansas Medicaid will no longer mail Pharmacy Program Provider Memos. An electronic message will be sent to all Medicaid enrolled prescribing providers and pharmacy providers as an alert message when the complete Provider Memo is posted on the Arkansas Medicaid Pharmacy Program website.

    NOTE: To ensure you receive the notification email, please verify that your email is correct in the Arkansas Medicaid provider portal. Department of Human Services correspondence would also be included in this effort to reduce paper waste. To ensure that all correspondence is received, we ask that each provider verify that the provider portal has the correct email address used for your business communications.

    The Arkansas Medicaid Pharmacy Program Provider Memos can be found at https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx. To access the memos, select the OTHER LINKS drop-down menu in the upper-left corner of the screen, click MAGELLAN MEDICAID ADMINISTRATION, select the ADMINISTRATOR box, select the RESOURCES drop-down menu in the upper-right corner, click DOCUMENTS, select the PHARMACY tab in the top row of tabs, and then click MEMORANDUMS. The Memo can also be found at: https://arkansas.magellanrx.com/provider/documents/. To access the memos, select the PHARMACY tab and then click MEMORANDUMS.

    An added benefit of viewing the Medicaid Pharmacy Program Provider Memo online is the search feature, which will allow a more accessible and efficient user experience. To use this feature, use the shortcut by pressing the Ctrl + F keys, enabling a keyword search. Starting with the January 2018 memo, the online versions of the Provider Memos will also contain active hyperlinks in the Table of Contents. To activate these hyperlinks, open the Provider Memo, hover the mouse over the Table of Contents, press the Ctrl key until the mouse cursor (“hand”) appears, then place the cursor on the item desired and click the mouse. The hyperlink in the Table of Content will then redirect to the corresponding chapter of the Provider Memo.

15. **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

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.