ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

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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: November 25, 2020

SUBJ: **AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board October 21, 2020 meeting for the following:** **Manual review criteria for:** Palforzia™ (peanut allergy), Fasenra® (benralizumab) injection, Qinlock™ (ripretinib) tablet, Kynmobi™ (apomorphine hydrochloride) SL films, Fintepla® (fenfluramine) oral solution, Evyrsdi™ (risdiplam) powder, Enspryng™ (satralizumab) injection, Inqovi® (cedazuridine and decitabine) tablet, Oral CGRP antagonists (Ubrelvy™ and Nurtec™ ODT), and Dojolvi® (triheptanoin) liquid; **Point-of-sale and claim edit updates:** CII stimulant update and controlled drug early refill threshold update

Preferred Drug List (PDL) therapeutic classes from the November 12, 2020 Drug Review Committee Meeting for the following: Angiotensin modulators (ACE inhibitors, ARBs, renin inhibitors, and combination products), calcium channel blockers, cytokine and CAM antagonists (targeted immune modulators), immunomodulators for asthma, stimulants and related agents, and thrombopoiesis stimulating proteins.

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I. ANNOUNCEMENTS

A. EARLY REFILL EDIT AND REFILL TOO SOON LOGIC

Reinstatement of EARLY REFILL (ER) EDIT and REFILL TOO SOON (RTS) LOGIC for all non-controlled drugs:
Beginning March 23, 2020, due to the COVID-19 emergency, Arkansas Medicaid POS pharmacy providers have been allowed to bypass the early refill ProDUR alert for non-controlled prescriptions. Currently, this change allows the pharmacy provider to enter an override for an early refill DUE alert. The claim will then pay at Point-of-Sale (POS) as long as all additional criteria for that drug is met. In addition, on March 23, 2020, the update to the POS system also included the removal of the "Refill Too Soon" Accumulation Logic from all non-controlled medications. The Refill Too Soon Accumulation Logic removed the requirement to allow an accumulation of up to 12 days of non-controlled medications per 186 days.

Once the Governor's declaration of public health emergency ends for the COVID-19 outbreak, the early refill and accumulation logic edits will be reinstated.

To ensure quality and consistency of care to Medicaid beneficiaries, DMS will coordinate with the Office of the Medicaid Inspector General (OMIG) to conduct retrospective reviews and audits of early refills dispensed during this time. Please keep all records of services as required by Medicaid physician billing and telemedicine rules.

B. VACCINE/IMMUNIZATION BILLING

Effective July 1, 2020, Arkansas Medicaid will pay $15.45 for the administration of an influenza immunization. A rate of $13.14 will be paid for the administration of other Medicaid payable vaccines. The existing rates for Vaccines For Children (VFC) and SCHIP vaccines will be adjusted to account for this rate increase.

For adult vaccines (ages 18 and above), the following HCPCS and CPT codes are to be used in conjunction with the vaccine being administered:

G0008 – Influenza immunization

90471 – First vaccine administered

90472 – Subsequent vaccines administered

The **Injection administration code, T1502** will continue to be payable for beneficiaries of all ages. **T1502** may be used for billing the administration of subcutaneous and/or intramuscular injections only.

If you have questions regarding this notice, please contact the Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at (501) 376-2211.

Arkansas Medicaid provider manuals (including update transmittals), official notices, notices of rulemaking, and remittance advice (RA) messages are available for download from the Arkansas Medicaid website: https://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/

C. STATE SUPPORTED PLAN PREFERS BRAND (PPB)

State Supported PPB
Afinitor (effective 1/1/2021)
Atripla
Apriso
Banzel Suspension
Cuprimine capsules
Depen tablets
Emtriva
Exjade
Sabril Powder Pkts
Sabril Tablets
Symfi/Symfi Lo
Taclonex Suspension
Truvada

EFFECTIVE JANUARY 1, 2021:

II. PREFERRED DRUG LIST (PDL):

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

A. ANGIOTENSIN MODULATORS

ANGIOTENSIN-CONVERTING ENZYME INHIBITORS and COMBINATION PRODUCTS

Preferred agents

- BENAZEPRIL (generic for Lotensin)
- **BENAZEPRIL/AMLODIPINE** (generic for Lotrel)
- BENAZEPRIL/HCTZ (generic for Lotensin HCT)
- ENALAPRIL (generic for Vasotec)
- ENALAPRIL/HCTZ (generic for Vaseretic)
- **FOSINOPRIL** (generic for Monopril)
- **FOSINOPRIL/HCTZ** (generic for Monopril HCT)
- LISINOPRIL (generic for Zestril)
- LISINOPRIL/HCTZ (generic for Zestoretic)
- QUINAPRIL (generic for Accupril)
- QUINAPRIL/HCTZ (generic for Accuretic)
- RAMIPRIL (generic for Altace)

Non-preferred agents

- ACCUPRIL (quinapril)
- ACCURETIC (quinapril/HCTZ)
- ALTACE (ramipril)
- CAPTOPRIL/HCTZ (generic for Capozide)
- EPANED (enalapril solution)
- LOTREL (benazepril/amlodipine)
- MOEXIPRIL (generic for Univasc)
- MOEXIPRIL/HCTZ (generic for Uniretic)
- PERINDOPRIL (generic for Aceon)
- QBRELIS (lisinopril solution)
- TARKA (trandolapril/verapamil)
- TRANDOLAPRIL (generic for Mavik)
- TRANDOLAPRIL/VERAPAMIL (generic for Tarka)
- ZESTORETIC (lisinopril/HCTZ)
- ZESTRIL (lisinopril)

Non-preferred agent with criteria

- CAPTOPRIL (generic for Capoten)
    - Point-of-sale approval for children ≤ 12years of age

DIRECT RENIN INHIBITORS (Non-preferred agents)

- ALISKIREN (generic for Tekturna)
- TEKTURNA (aliskiren)
- TEKTURNA HCT (aliskiren/HCTZ)

ANGIOTENSIN II RECEPTOR BLOCKERS

Preferred agents

• IRBESARTAN (generic for Avapro)
• IRBESARTAN/HCTZ (generic for Avalide)
• LOSARTAN (generic for Cozaar)
• LOSARTAN/HCTZ (generic for Hyzaar)
• **OLMESARTAN** (generic for Benicar)
• **OLMESARTAN/AMLODIPINE** (generic for Azor)
• VALSARTAN (generic for Diovan)
• VALSARTAN/HCTZ (generic for Diovan HCT)
• VALSARTAN/AMLODIPINE (generic for Exforge)
• **VALSARTAN/AMLODIPINE/HCTZ** (generic for Exforge HCT)

Preferred agent with criteria:

• ENTRESTO (valsartan/sacubitril)
  - Point-of-sale approval for diagnosis in Medicaid medical history in previous 2 years of congestive heart failure
  - Point-of-sale denial if female recipient is currently pregnant

Non-preferred agents

• ATACAND (candesartan)
• ATACAND HCT (candesartan HCTZ)
• AVALIDE (irbesartan/HCTZ)
• AVAPRO (irbesartan)
• AZOR (olmesartan/amlodipine)
• BENICAR (olmesartan)
• BENICAR HCT (olmesartan/HCTZ)
• CANDESARTAN (generic for Atacand)
• CANDESARTAN/HCTZ (generic for Atacand HCT)
• COZAAR (losartan)
• DIOVAN (valsartan)
• DIOVAN HCT (valsartan/HCTZ)
• EDARBI (azilsartan)
• EDARBYCLOR (azilsartan/chlorthalidone)
• EPROSARTAN (generic for Teveten)
• EXFORGE (valsartan/amlodipine)
• **EXFORGE HCT** (valsartan/amlodipine/HCTZ)
• HYZAAR (losartan/HCTZ)
• MICARDIS (telmisartan)
• MICARDIS HCT (telmisartan/HCTZ)
• OLMESARTAN/AMLODIPINE/HCTZ (generic for Tribenzor)
• OLMESARTAN/HCTZ (generic for Benicar HCT)
• TELMISARTAN (generic for Micardis)
• TELMISARTAN/AMLODIPINE (generic for Twynsta)
• TELMISARTAN/HCTZ (generic for Micardis HCT)
• TRIBENZOR (amlodipine/olmesartan/HCTZ)

B. CALCIUM CHANNEL BLOCKERS

Dihydropyridine preferred agents

- AMLODIPINE BESYLATE (generic for Norvasc)
- AMLODIPINE/VALSARTAN (generic for Exforge)
- **AMLODIPINE/BENAZEPRIL** (generic for Lotrel)
- **AMLODIPINE/OLMESARTAN** (generic for Azor)
- **AMLODIPINE/VALSARTAN/HCTZ** (generic for Exforge HCT)
- NIFEDIPINE IR (generic for Procardia)
- NIFEDIPINE ER (generic for Adalat CC, Procardia XL)

Non-dihydropyridine preferred agents

- DILTIAZEM ER CAPSULE (generic for Dilacor XR, Tiazac)
- DILTIAZEM TABLET (generic for Cardizem)
- VERAPAMIL TABLET (generic for Calan)
- VERAPAMIL ER TABLET (generic for Calan SR)

Dihydropyridine non-preferred agents

- AMLODIPINE/ATORVASTATIN (generic for Caduet)
- AMLODIPINE/OLMESARTAN/HCTZ (generic for Tribenzor)
- EXFORGE (amlodipine/valsartan)
- **EXFORGE HCT** (amlodipine/valsartan/HCTZ)
- FELODIPINE ER (generic for Plendil)
- ISRADIPINE (generic for Dynacirc)
- ISRADIPINE ER (generic for Dynacirc CR)
- KATERZIA suspension (amlodipine)
- NICARDIPINE (generic for Cardene)
- **NIMODIPINE** (generic for Nymalize)
- NISOLDIPINE ER (generic for Sular)
- NORVASC (amlodipine)
- NYMALIZE SOLUTION (nimodipine)
- PROCARDIA XL (nifedipine ER)

Non-dihydropyridine non-preferred agents

- CALAN SR (verapamil ER)
- CARDIZEM, CARDIZEM CD, LA (diltiazem)
- DILTIAZEM CD, LA, XR, XT (generic for Cardizem, Matzim LA)
- MATZIM LA (diltiazem)
- TIAZAC (diltiazem)
- VERAPAMIL ER CAPSULES (generic for Verelan, Verelan PM)
- VERELAN, VERELAN PM (verapamil)

C. CYTOKINE AND CAM ANTAGONISTS (TARGETED IMMUNE MODULATORS)

Preferred agents with criteria

- ENBREL (etanercept)
- HUMIRA (adalimumab)
- **OTEZLA (apremilast)**

Non-preferred agents

- ACTEMRA (tocilizumab)
- ARCALYST (rilonacept)
- CIMZIA (certolizumab)
- COSENTYX (secukinumab)
- ENTYVIO (vedolizumab)
- ILARIS (canakinumab)
- **ILUMYA (tildrakizumab-asmm)**
- KEVZARA (sarilumab)
- KINERET (anakinra)
- OLUMIANT (baricitinib)
- ORENCIA CLICKJECT AND SYRINGE (abatacept)
- **RINVOQ (upadacitinib)**
- SILIQ (brodalumab)
- SIMPONI (golimumab)
- SKYRIZI (risankizumab-rzaa)
- STELARA (ustekinumab)
- TALTZ (ixekizumab)
- TREMFYA (guselkumab)
- XELJANZ, XELJANZ XR (tofacitinib)

D. IMMUNOMODULATORS, ASTHMA

Preferred agents with criteria

FASENRA SYRINGE AND PEN (benralizumab)

Non-preferred agents

DUPIXENT SYRINGE AND PEN (dupilumab)
NUCALA VIAL, AUTO-INJECT, SYRINGE (mepolizumab)
XOLAIR VIAL AND SYRINGE (omalizumab)

E. STIMULANTS AND RELATED AGENTS

Preferred agents with criteria

- ADDERALL XR **brand only** (amphetamine salts ER)
- AMPHETAMINE SALTS TABLET (generic for Adderall IR)
- ATOMOXETINE (generic for Strattera)
- CLONIDINE IR (generic for Catapres)
- **CONCERTA brand only** (methylphenidate ER)
- DEXTROAMPHETAMINE TABLET (generic for Zenzedi)
- FOCALIN IR **brand only** (dexmethylphenidate)
- FOCALIN XR **brand only** (dexmethylphenidate ER)
- GUANFACINE ER (generic for Intuniv ER)
- GUANFACINE IR (generic for Intuniv)
- METHYLPHENIDATE TABLET (generic for Ritalin)
- VYVANSE CAPSULES (lisdexamfetamine)
- **VYVANSE CHEWABLE TABS** (lisdexamfetamine chew)

Non-preferred agents

- ADHANSIA XR CAPSULE (methylphenidate)
- ADZENYS ER SUSPENSION (amphetamine)
- ADZENYS XR-ODT (amphetamine)
- AMPHETAMINE SUSPENSION (generic for Adzenys ER)
- APTENSIO XR CAPSULE (methylphenidate)
- CLONIDINE ER SUSPENSION (generic for Nexiclon XR)
- CLONIDINE ER TABLET (generic for Kapvay ER, Nexiclon XR)
- COTEMPLA XR-ODT (methylphenidate)
- DAYTRANA PATCH (methylphenidate ER patch)
- DESOXYN TABLET (methamphetamine)
- DEXEDRINE SPANSULE (dextroamphetamine)
- DEXMETHYLPHENIDATE ER CAPSULE (generic for Focalin XR)
- DEXMETHYLPHENIDATE TABLET (generic for Focalin)
- DEXTROAMPHETAMINE /AMPHETAMINE SALTS ER CAPSULE (generic for Adderall XR)
- DEXTROAMPHETAMINE CAPSULE (generic for Dexedrine Spansule)
- DEXTROAMPHETAMINE SOLUTION (generic for Procentra)
- DYANAVEL XR SUSPENSION (amphetamine)
- EVEKEO and EVEKEO ODT (amphetamine)
- INTUNIV IR and INTUNIV ER (guanfacine)
- JORNAY PM CAPSULE (methylphenidate)
- METHAMPHETAMINE TABLET (generic for Desoxyn)
- METHYLPHENIDATE CHEWABLE TABLET (generic for Methylin)
- METHYLPHENIDATE ER 72 MG TABLETS
- METHYLPHENIDATE ER CAPSULE (generic for Metadate CD, Ritalin LA, Aptensio XR)
- METHYLPHENIDATE ER TABLET (generic for Concerta)
- METHYLPHENIDATE ER TABLET (generic for Metadate ER, Ritalin SR)
- METHYLPHENIDATE SOLUTION (generic for Methylin)
- MYDAYIS ER CAPSULE (dextroamphetamine/amphetamine)
- PROCENTRA SOLUTION (dextroamphetamine)
- QUILLICHEW ER CHEWABLE TABLETS (methylphenidate)
- QUILLIVANT XR SUSPENSION (methylphenidate)
- RITALIN and RITALIN LA CAPSULE (methylphenidate)
- STRATTERA (atomoxetine)
- ZENZEDI TABLET (dextroamphetamine)

F. THROMBOPOIESIS STIMULATING PROTEINS

Preferred agents with criteria

- PROMACTA TABLETS (eltrombopag olamine)

Non-preferred agents

- DOPTELET TABLETS (avatrombopag maleate)
- MULPLETA TABLETS (lusutrombopag)
- PROMACTA SUSPENSION (eltrombopag olamine)
- TAVALISSE TABLETS (fostamatinib disodium)

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

EFFECTIVE FEBRUARY 10, 2021

1. ATTENTION DEFICIT HYPERACTIVITY DISORDER UPDATE

a. For children--increase minimum age and expand maximum age

- Recommendation is to change minimum age for all CII stimulants and atomoxetine from ≥ 5 years to ≥ 6 years of age to better correlate with the manufacturer's package insert.
  - Recipients ≤ 5 years of age will require a PA.
- Recommendation is to change the maximum age to be considered a "child" when prescribed a CII stimulant. Currently, recipients ≥ 18 years of age require a PA for every request.
  - Recipients ≥ 19 years of age are now considered an adult in the treatment of ADHD. The change would allow recipients 6-18 years of age to receive a preferred medication without a PA if they meet current therapeutic duplication, quantity requirements, and swallow criteria.
- These changes would apply to preferred and nonpreferred medications.

b. Require a billed diagnosis of ADHD

- Recommendation is to require a billed diagnosis of ADHD in the last 2 years to allow POS claims for children 6-18 years of age.
- If the ADHD diagnosis is not billed, a PA will be required.
  - Prescriber would need to submit documentation of an ADHD diagnosis with current chart notes.
  - If recipient does not have ADHD, a letter of medical necessity would need to be provided
- The goal is to prevent off-label use of CII stimulants in children.
- Atomoxetine (Strattera®) will also require a billed diagnosis of ADHD for children **AND** adults. If the recipient does not have a billed diagnosis of ADHD in the last 2 years, atomoxetine will require a prior authorization.

c. New Adult CII Stimulant form (see below)

Statement of Medical Necessity for ADULT use of a C-II stimulant

For patients ≥ 19 years of age being treated with a C-II stimulant for ADD/ADHD

Fax completed form to Magellan Medicaid Administration PDL Help Desk at 800-424-7976.

Beneficiary 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: ___ – ___ – ____

REQUESTED MEDICATION: _____

STRENGTH AND DOSAGE FORM: _____

DIRECTIONS: _____

PLEASE NOTE:

As an alternative to using a C-II stimulant, Strattera, Clonidine IR, and Guanfacine IR do not require prior approval for treating adult ADD.

1. Please state the diagnosis requiring the requested C-II stimulant:

   _____

   _____

2. Please provide the goals of drug therapy:

   _____

   _____

3. What methods have been used to evaluate ADD/ADHD for this adult patient?

   _____

   _____

   Date of most recent evaluation: _____

4. Please list current behavioral therapies for ADHD:

   _____

   _____

5. As an **adult**, does your patient attend school? ☐ YES ☐ NO

   If **YES**, does your patient have **clinically significant impairment** due to ADD/ADHD symptoms present in the academic/school setting? ☐ YES ☐ NO

   If **YES**, Name of school: _____ High school grade/college level _____

   If attending college or vocational school, number of hours per semester: _____

6. As an **adult**, is your patient employed? ☐ YES ☐ NO

   If **YES**, name of employer: _____

   If **YES**, does you patient have **clinically significant impairment** due to ADD/ADHD symptoms present in occupational/work setting? ☐ YES ☐ NO

   If **NO**, describe reason this patient is not employed:

   _____

   _____

   _____

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Statement of Medical Necessity for ADULT use of a C-II stimulant

For patients ≥ 19 years of age who are being treated with a C-II stimulant for ADD/ADHD

7. If your patient has any of the following conditions, please address as follows:

a. Hypertension	☐ TREATED	☐ CONTROLLED
b. Cardiovascular disease, chest pain, Arrhythmias or congestive heart failure	☐ TREATED	☐ CONTROLLED
c. Diabetes	☐ TREATED	☐ CONTROLLED
d. Bipolar Disease	☐ TREATED	☐ CONTROLLED
e. Schizophrenia	☐ TREATED	☐ CONTROLLED
f. Drug abuse	☐ TREATED	☐ CONTROLLED
g. Alcohol abuse	☐ TREATED	☐ CONTROLLED
h. Anorexia/Bulimia	☐ TREATED	☐ CONTROLLED

Please provide additional information regarding any conditions marked in question #7.

8. If patient has a history of drug abuse or alcohol abuse, is the patient currently receiving counseling? ☐ Yes ☐ No

IF YES on question 8 above, fax written documentation of substance abuse counseling. Documentation should include date, time, type of therapy or counseling and location. If the counseling is done offsite, please provide the phone number and name of person providing the counseling. If counseling is done onsite, please provide the chart notes correlating to the visits.

If NO on question 8 above, has the patient had counseling in the past? If YES to this, describe when and where

9. Please list the patient's specific DSM-IV or DSM-V ADD/ADHD symptoms:

****To expedite the prior authorization review, please provide this completed form, current chart notes, and a letter of medical necessity if the above patient is not in school or working.****

_____ _____

Prescriber Signature (Required) ***Date***

Prescriber's original signature required; copied, stamped, or e-signature are not allowed.

This signature certifies that the information provided in the Statement of Medical Necessity is accurate and substantiated by the patient's medical records. The prescriber also agrees that Medicaid may review this patient's medical records to ascertain the medical necessity for accuracy of data submitted for this request for a C-II stimulant for treatment of adult ADD/ADHD.

Fax This Form to: Magellan Medicaid Administration (MMA) PDL Help Desk at 800-424-7976.
If additional information is needed, please call 800-424-7895 and press PDL option

EFFECTIVE JANUARY 20, 2021

2. CONTROLLED DRUG EARY REFILL THRESHOLD UPDATE

- Early refill hard edit threshold will change from 75% to 90% of the days' supply expended for controlled drugs (schedule II-V). This edit change would allow a refill at point-of-sale 2-3 days early on a 30 or 31-day supply.
- Benzodiazepines will remain the same at 90% of the days' supply expended before a refill is allowed.
- Early refill hard edit threshold for sedative hypnotics will change from 100% to 90% of the days' supply expended to allow consistency between all controlled drugs.

EFFECTIVE IMMEDIATELY:

3. PALFORZIA™ (peanut allergy) 0.5 mg, 1 mg, 10 mg, 20 mg, 100 mg, and 300 mg

INDICATION:

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitation of Use:

- Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Prescriber, pharmacy and patient must be enrolled int eh PALFORZIA REMS program.

APPROVAL CRITERIA:

- Recipient must be ≥ 4 years of age and ≤ 17 years of age to initiate treatment; **AND**
- Recipient must have a confirmed diagnosis of a peanut allergy; **AND**
- Prescriber must be an Allergy and Immunology specialist; **AND**
- Prescriber, clinic, pharmacy and recipient must be enrolled in the Risk Evaluation and Mitigation Strategy (REMS) program and remain compliant with program requirements; **AND**
- Prescriber must attest that the recipient has been counseled to continue a peanut-avoiding diet as this medication is for accidental exposure to peanuts; **AND**
- Recipient must continue to have injectable epinephrine on hand with a pharmacy claim within the last year; **AND**
- Prescriber must require Initial Dose Escalation and first dose of each up-dosing stage to occur in the office to monitor for anaphylaxis for at least 60 minutes and provide a plan on how to manage potential anaphylaxis reactions while in the office; **AND**
- Prescriber should provide the following:
  - Current chart notes; **AND**
  - Documentation of a systemic reaction to peanuts **AND** at least one of the following:
    - Positive serum immunoglobulin E (IgE) to peanuts within the past 12 months; **OR**

  - Skin prick test (SPT) to peanut with a mean wheal diameter of ≥ 8 mm compared to control; **OR**
  - Documented reaction to peanut upon supervised oral food challenge at a dose of ≤ 100 mg peanut protein (≤ 200 mg peanut flour).
- PAs will be approved for 2 months at a time with correct dosages per the taper. Compliance, response to therapy, and tolerance will be reviewed on renewal request; **OR**

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has uncontrolled asthma, markedly compromised lung function, severe mast cell disorder or cardiovascular disease (decreased ability to survive anaphylaxis); **OR**
  - Uncontrolled asthma is defined per the 2007 NHLBI, and involves: asthma symptoms throughout the day, nighttime awakenings often (7x/week), poor lung function (FEV1 < 60% predicted; FEV1/FVC reduced > 5%), extreme limitation on normal activity, and the need to use a short-acting beta agonist (rescue inhaler) several times a day.
- Recipient has suspected eosinophilic esophagitis and/or other eosinophilic gastrointestinal disease; **OR**
- Recipient cannot tolerate doses up to and including the 3 mg dose during Initial Dose Escalation; **OR**
- Recipient had a severe or life-threatening anaphylaxis within the previous 60 days.

CONTINUATION CRITERIA:

- Recipient's Medicaid profile will be reviewed for compliance for PA renewal; **AND**
- Prescriber should submit current chart notes with response/tolerance to medication; **AND**
- PA renewals for maintenance dosing may be approved for 3-6 months depending on length of proven tolerance.

QUANTITY EDITS:
Initial Dose Escalation blister pack— 1 pack per 365 days
Each up-dosing pack— #1 pack/15 days
Maintenance pack of 300 mg daily— #1 pack (30 powder packs)/ 30 days

EFFECTIVE IMMEDIATELY:

4. FASENRA® (benralizumab) injection

INDICATION:
FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitations of use:

- FASENRA is not indicated for treatment of other eosinophilic conditions.
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus.

DOSING:
The recommended dose of FASENRA is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

- The prefilled syringe is for administration by a healthcare provider.
- FASENRA PEN is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate.

APPROVAL CRITERIA:

- Recipient must be ≥ 12 years of age (If the indicated ages change, the criteria will reflect the change); **AND**
- Recipient must have a diagnosis of severe asthma, eosinophilic phenotype with a history of 2 or more exacerbations in the previous year **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be compliant on at least two (2) asthma maintenance medications for at least one (1) year (one must be an inhaled corticosteroid); **AND**
- Recipient has a morning lung function pre-bronchodilator FEV1 < 90% in adolescents and < 80% in adults despite treatment with medium or high dose ICS plus LABA; **AND**
- Recipient must have a baseline blood eosinophil count ≥ 300 cells/µL; **AND**
- Recipient must be ordered FASENRA PEN as prefilled syringes are excluded from the pharmacy program; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current pulmonary function tests (PFTs); **AND**
    - Current labs including baseline blood eosinophil count; **AND**
    - Baseline Asthma Control Questionnaire-6 (ACQ-6) for all patients **OR** Standardized Asthma Quality of Life Questionnaire (AQLQ(S)+12) for adults only; **AND**
    - Documentation of all previous therapies tried with response; **AND**
    - Letter of medical necessity for the use over other therapies outlined in treatment guidelines.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has helminth infections. Pre-existing helminth infections should be treated prior to beginning FASENRA; **OR**
- Recipient has approval for other interleukins (daclizumab, mepolizumab, or others new to the market) or omalizumab; **OR**
- Recipient is not compliant on asthma controller medication for at least 1 year including inhaled corticosteroid; **OR**
- Recipient is a current smoker; **OR**
- Recipient must remain compliant on asthma controller medications (inhaled corticosteroids) if medication is approved.

CONTINUATION CRITERIA:

- Recipient is compliant on asthma controller medication (ICS or ICS/LABA) and benralizumab injections; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy after 6 months; **AND**
  - Current PFTs with improvement over baseline; **AND**
  - Current labs indicating a decrease in blood eosinophil count; **AND**
- Recipient demonstrates improved control of asthma with fewer exacerbations, improved PFTs and improved asthma questionnaire scores.

QUANTITY EDITS:
#1 FASENRA pen every 8 weeks (will need quantity override for first 3 months)

EFFECTIVE IMMEDIATELY:

5. QINLOCK™ (ripretinib) 50 mg tablet

INDICATION:
QINLOCK is indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

DOSING:
The recommended dosage of QINLOCK is 150 mg orally once daily with or without food until disease progression or unacceptable toxicity.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and previously treated with 3 or more TKIs including imatinib **OR** a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBC and LFTs; **AND**
  - Baseline echocardiogram or MUGA scan to monitor ejection fraction; **AND**
  - Current blood pressure; **AND**
  - Documentation of dermatologic evaluations as baseline due to possible cutaneous squamous cell carcinoma; **AND**
  - Pregnancy test for women of childbearing potential.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires strong CYP3A inducers; **OR**

- Recipient is unable to tolerate 100 mg once daily dose; **OR**
- Recipient has Grade 4 uncontrolled hypertension or Grade 3 or 4 left ventricular systolic dysfunction
  LVEF < 50%; **OR**
- Recipient has moderate or severe hepatic impairment; **OR**
- Recipient has documented disease progression or unacceptable toxicity.

CONTINUATION CRITERIA:

- Recipient has no documented disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including liver function tests; **AND**
  - Current blood pressure; **AND**
  - Documentation of tumor response assessments every 28 days for the first 4 months then every 56 days thereafter.

QUANTITY EDITS:
#90/ 30 days

EFFECTIVE IMMEDIATELY:

6. KYNMOBI™ (apomorphine HCl) 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg SL films

INDICATION:
KYNMOBI is indicated for the acute, intermittent treatment of “off” episodes in patients with Parkinson's disease (PD).

DOSING:
The dose range for KYNMOBI is 10 mg to 30 mg per dose, administered sublingually, as needed, for the acute, intermittent treatment of “off” episodes. Doses should be separated by at least 2 hours, not to exceed 30 mg per dose or 5 doses per day.

Titration doses must be given in a healthcare setting to allow for monitoring of blood pressure and pulse. Patients are instructed to not take their morning doses of carbidopa/levodopa or any other Parkinson’s disease medications. If the dose is tolerated but the response is insufficient, the patient's usual Parkinson's disease medications should be resumed and up-titration with KYNMOBI continued generally within 3 days. Increase dosage by increments of 5 mg and assess response.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Parkinson’s disease with acute, intermittent “OFF” episodes **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be compliant on current therapy of levodopa/carbidopa (immediate or CR) at maximally tolerated doses for at least 4 weeks before adding KYNMOBI; **AND**
- At baseline, recipient must experience at least one well defined "OFF" episode per day with a total daily "OFF" time duration of ≥ 2 hours during the waking day, based on patient self-assessment; **AND**

- Recipient is Hoehn and Yahr Stage III or less in the "ON" state; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current vital signs including blood pressure and heart rate and documentation that recipient has been evaluated for potential hypotension/orthostatic hypotension; **AND**
  - Current labs including CBC, BMP and LFTs; **AND**
  - Documentation that the recipient has an antiemetic (e.g. trimethobenzamide) beginning 3 days prior to initial dose; **AND**
  - Medical necessity of adding this medication over increasing the current levodopa/carbidopa dosage or adding another PD medication that does not require a PA; **AND**
  - Baseline Unified Parkinson's Disease Rating Scale (UPDRS) Part III Motor Examination score.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires concomitant use of 5HT3 antagonists (i.e., ondansetron, granisetron, dolasetron, palonosetron, alosetron), dopamine antagonists (excluding quetiapine or clozapine) or dopamine depleting agents due to risk for profound hypotension or loss of consciousness; **OR**
- Recipient has a documented history of hypotension; **OR**
- Recipient has drug or alcohol dependency issues noted in the past 12 months; **OR**
- Recipient has major psychiatric disorder including, but not limited to, dementia, bipolar disorder, psychosis OR suicidal ideation/attempt in the last year; **OR**
- Recipient has ≤ 2 hours per day of "OFF" time; OR
- Recipient has Hoehn and Yahr stage > 3 in an "ON" state; **OR**
- Recipient cannot tolerate the 10 mg dose; **OR**
- Recipient reports significant daytime sleepiness or episodes of falling asleep during activities that require active participation.

CONTINUATION CRITERIA:

- Recipient has an improvement in the UPDRS Part III motor examination score when measured pre-dose and 30 minutes post dose after 12 weeks of therapy; **AND**
- Recipient is tolerating the medication and compliant on maintenance PD medications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current UPDRS Part III motor examination score; **AND**
  - Current vital signs.

QUANTITY EDITS:
#1 Titration kit per 365 days
All strengths--#150/ 30 days

EFFECTIVE IMMEDIATELY:

7. FINTEPLA® (fenfluramine) 2.2 mg/mL oral solution

BLACK BOXED WARNING:
VALVULAR HEART DISEASE AND PULMONARY ARTERIAL HYPERTENSION

FINTEPLA is only available through a REMS program.

INDICATION:
FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

DOSING:
The initial starting and maintenance dosage is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability. TABLE 1 provides the recommended titration schedule, if needed.

Table 1: FINTEPLA Recommended Titration Schedule*

	Without concomitant stiripentol*		With concomitant stiripentol and clobazam	
	Weight-based Dosage	Maximum Total Daily Dosage	Weight-based Dosage	Maximum Total Daily Dosage
Initial Dosage	0.1 mg/kg twice daily	26 mg	0.1 mg/kg twice daily	17 mg
Day 7	0.2 mg/kg twice daily	26 mg	0.15 mg/kg twice daily	17 mg
Day 14	0.35 mg/kg twice daily	26 mg	0.2 mg/kg twice daily	17 mg

**For patients not on concomitant stiripentol in whom a more rapid titration is warranted, the dose may be increased every 4 days*

APPROVAL CRITERIA:

- Recipient must be ≥ 2 and ≤ 18 years of age; **AND**
- Recipient has a diagnosis of seizures associated with Dravet syndrome **OR** a diagnosis consistent with FDA indications; **AND**
- Provider must submit written documentation showing convulsive status epilepticus, alternating hemiconvulsions, OR myoclonic seizures and include genetic testing results for Dravet Syndrome that shows mutations within SCN1A gene.
- Prescriber, pharmacy and recipient must all be enrolled in the FINTEPLA REMS program; **AND**
- Recipient must have inadequately controlled seizures while on at least one anti-epileptic drug (Trials required a minimum of 6 convulsive seizures in a 6-week baseline period while stable on current AEDs.); **AND**
- Maximum dose for recipients **NOT** taking stiripentol is 0.35 mg/kg twice daily (26 mg per day), and maximum dose for recipients taking stiripentol is 0.2 mg/kg twice daily (17 mg per day); **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of weight and blood pressure; **AND**
  - Current list of medications with doses and all other therapies tried; **AND**
  - Current baseline seizure activity; **AND**

- Current labs including CBC, BMP and LFTs; **AND**
- Results from echocardiogram (must evaluate for valvular heart disease and pulmonary arterial hypertension); **AND**
- Current dose needed based on weight and stiripentol usage.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has moderate or severe renal impairment; **OR**
- Recipient has hepatic impairment; **OR**
- Recipient has valvular heart disease or pulmonary arterial hypertension; **OR**
- Recipient requires concomitant monoamine oxidase inhibitors; **OR**
- Recipient develops acute decrease in visual acuity or ocular pain; **OR**
- Prescriber orders dosing not consistent with FDA approved labeling.

CONTINUATION CRITERIA:

- Recipient demonstrates a reduction in convulsive seizure frequency compared to baseline; **AND**
- Recipient must remain compliant on FINTEPLA; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Update on seizure frequency compared to baseline; **AND**
  - Repeated echocardiogram every 6 months per FINTEPLA REMS.

QUANTITY EDITS:
360mL bottle: 1 bottle/ 30 days—gives maximum dose of 26 mg per day.

EFFECTIVE IMMEDIATELY:

8. EVRYSDI™ (risdiplam) 0.75 mg/mL powder

INDICATION:
EVRYSDI is indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.

DOSING:
EVRYSDI must be taken immediately after it is drawn up into the oral syringe. If EVRYSDI is not taken within 5 minutes, EVRYSDI should be discarded from the oral syringe, and a new dose should be prepared.
EVRYSDI is administered orally once daily. The recommended dosage is determined by age and body weight.

Table 1 Adult and Pediatric Dosing Regimen by Age and Body Weight

Age and Body Weight	Recommended Daily Dosage
2 months to less than 2 years of age	0.2 mg/kg
2 years of age and older weighing less than 20 kg	0.25 mg/kg
2 years of age and older weighing 20 kg or more	5 mg

APPROVAL CRITERIA:

- Recipient must be ≥ 2 months of age; **AND**
- Recipient has a diagnosis of Type 1 spinal muscular atrophy (SMA)—all other SMA types will be reviewed on a case-by-case basis. (At the time of this memo, available trial data was insufficient in demonstrating clinically significant efficacy for Type 2 and Type 3 patients.); **AND**
- Prescriber must be a neurologist with expertise in treating SMA; **AND**
- Recipient is non-ambulatory; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current weight; **AND**
  - Genetic testing results documenting the SMA diagnosis and SMA type; **AND**
    - Documentation of SMN1 gene deletion or mutation
    - Documentation of at least 2 or more copies of SMN2 gene
  - Current labs including liver function tests; **AND**
  - Female recipients of childbearing potential must have a negative pregnancy test prior to beginning EVRYSDI therapy **OR** has documentation of contraception usage; **AND**
  - Documentation that female members of childbearing potential have been counseled about contraception; **AND**
  - Documentation that male members have been counseled about potential infertility with EVRYSDI therapy; **AND**
  - Documentation of physical therapy; **AND**
  - Documentation of all previous therapies tried; **AND**
  - Baseline results of **one** of the following:
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **OR**
    - Motor Function Measure Score (MFM-32); **OR**
    - Revised Upper Limb Module (RULM); **OR**
    - Hammersmith Infant Neurological Examination Module 2 (HINE-2); **OR**
    - Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
    - Bayley Scales of Infant and Toddler Development, Third Addition (BSID-III or Bayley-III)

DENIAL CRITERIA:

- Recipient does not meet approval criteria; **OR**
- Dosing requested is not consistent with recipient's age and weight; **OR**
- Recipient is ambulatory; **OR**
- Recipient is pregnant; **OR**
- Recipient has hepatic impairment; **OR**
- Recipient takes a Multidrug and Toxin Extruder (MATE1) substrate such as metformin, cimetidine or acyclovir; **OR**
- Recipient has concomitant or previous administration of a SMN2-targeting antisense oligonucleotide, SMN2 splicing modifier or gene therapy either in a clinical study or as part of medical care;
    - Recipient has been given Zolgensma® (onasemnogene abeparvovec-xioi); **OR**
    - Recipient has history of taking Spinraza® (nusinersen) unless recipient had an intolerable medically documented adverse reaction; **OR**
- Recipient has the presence of advanced SMA with permanent ventilation dependence which is defined as requiring a tracheostomy **OR** more than 21 consecutive days of either non-invasive ventilation for ≥ 16 hour per day or intubation; **OR**
- Recipient has been hospitalized in the past 60 days with a pulmonary event; **OR**
- Recipient has had surgery for scoliosis or hip fixation in the last year.

CONTINUATION CRITERIA:

- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current weight; **AND**
    - Current labs including liver function tests; **AND**
    - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage; **AND**
    - Documentation of continued physical therapy; **AND**
    - Documentation of response to therapy using the same measuring scale as the baseline score; **AND**
- Recipient must demonstrate a clinical response to EVRYSDI by either an improvement in motor function score or no decline in test score compared to baseline; **AND**
- Recipient has not received therapy with Spinraza® or have received Zolgensma®; **AND**
- Recipient does not have hepatic impairment; **AND**
- Recipient does not have a tracheostomy or require a ventilator.

QUANTITY EDITS:

Based on max dose of 5 mg per day, 3 bottles (240mL total) per 31 days

EFFECTIVE IMMEDIATELY:

9. ENSPRYNG™ (satralizumab) 120 mg/mL injection

INDICATION:

ENSPRYNG is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

DOSING:

The recommended loading dosage of Enspryng™ for the first three administrations is 120 mg by subcutaneous injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every 4 weeks.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of neuromyelitis optica spectrum disorder and anti-aquoporin-4 (AQP4) antibody positive **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have **one** core clinical characteristics from the following:
    - Optic neuritis; **OR**
    - Acute myelitis; **OR**
    - Area postrema syndrome (unexplained hiccups or nausea and vomiting); **OR**
    - Acute brainstem syndrome; **OR**
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; **OR**
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- Recipient has an Expanded Disability Status Scale (EDSS) score between 0-6.5; **AND**
- Recipient has clinical evidence of at least 1 relapse in the previous 12 months; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of symptoms of inflammation; **AND**
    - Current labs including CBCs, lipids, and LFTs; **AND**
    - Current Hepatitis B test results including surface antigen (HBsAg) and anti-HBV tests (HBcAb); **AND**
    - Current tuberculosis test results for active and latent infections; **AND**
    - Documentation of previous therapies trialed (i.e. corticosteroids, immunosuppressants, plasma exchange); **AND**
    - Documentation of AQP4 antibody tests results; **AND**
    - MRI results if needed for confirmation of diagnosis.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has an active Hepatitis B infection; **OR**

- Recipient has active or untreated latent tuberculosis; **OR**
- Recipient has a known active infection (excluding fungal infections of nail beds) within 4 weeks prior to initiation of therapy; **OR**
- Medical necessity over immuno-suppressive therapy has not been established; **OR**
- ALT or AST is > than 5X ULN with an elevation in bilirubin; if no elevation in bilirubin, the recipient may continue ENSPRYNG after AST and ALT return to normal. If that takes longer than 12 weeks, recipient must restart with loading dose.

CONTINUATION CRITERIA:

- Recipient has been compliant on therapy; **AND**
- Recipient must show improvement in symptoms associated with optic nerve, spinal cord, and brainstem inflammation; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBCs, lipids, and LFTs (LFTs should be monitored every 4 weeks for the first 3 months then every 3 months; Neutrophils should be monitored every 4-8 weeks.)

QUANTITY EDITS:
#1/ 28 days (first month will require a quantity override to allow 3 injections)

EFFECTIVE IMMEDIATELY:

10. INQOVI® (cedazuridine and decitabine) 100 mg/35 mg tablet

INDICATION:
INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

DOSING:
The recommended dosage of INQOVI is 1 tablet (containing 35 mg decitabine and 100 mg cedazuridine) orally once daily on Days 1 through 5 of each 28-day cycle for a minimum of 4 cycles until disease progression or unacceptable toxicity. A complete or partial response may take longer than 4 cycles.

APPROVAL CRITERIA:

- Recipient is ≥ 18 years of age; **AND**
- Recipient has a documented diagnosis of myelodysplastic syndrome (MDS) **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:

  - Current chart notes; **AND**
  - Current labs including CBC with differential, BMP, and LFTs; **AND**
  - Female recipients of childbearing potential must have a negative pregnancy test prior to beginning Inqovi® **OR** has documentation of contraception usage; **AND**
  - Documentation of prior therapies with response; **AND**
  - Medical necessity over IV decitabine; **AND**
- Recipient has an absolute neutrophil count (ANC) > 1,000/µL and platelets > 50,0000/µL; **AND**
- Recipient has Total or direct bilirubin ≤2 × upper limit of normal (ULN); AST/SGOT and ALT/SGPT ≤2.5 × ULN; **AND**
- Recipient has serum creatinine ≤1.5 × ULN or calculated creatinine clearance or glomerular filtration rate >50 mL/min/1.73 m^2; **AND**
- Prior authorizations will be approved for only one (1) month at a time.

DENIAL CRITERIA:
- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient does not meet lab approval criteria; **OR**
- Recipient is taking concomitant IV decitabine; **OR**
- Recipient had cytotoxic chemotherapy or prior azacitidine or decitabine within 4 weeks of first dose; **OR**
- Recipient has rapidly progressive or highly proliferative disease (total white blood cell count of >15 × 10^9/L) or other criteria that render the subject at high risk of requiring intensive cytotoxic chemotherapy within the next 3 months; **OR**
- Recipient has a life-threatening illness or severe organ system dysfunction, such as uncontrolled congestive heart failure or chronic obstructive pulmonary disease, or other reasons including laboratory abnormalities, which could compromise the recipient's safety, interfere with absorption or metabolism.

CONTINUATION CRITERIA:
- Recipient has no disease progression or unacceptable toxicity; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy; **AND**
  - Current labs including CBC with differential, BMP, and LFTs (CBCs must be drawn prior to every cycle); **AND**
  - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage.

QUANTITY EDITS:
#5 tablets/ 28 days

EFFECTIVE IMMEDIATELY:

11. ORAL CGRP ANTAGONISTS

INDICATION for UBRELVY AND NURTEC ODT:

Calcitonin gene-related peptide receptor (CGRP) antagonist indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

Not indicated for the preventive treatment of migraine.

DOSING FOR UBRELVY:

The recommended dose of UBRELVY is 50 mg or 100 mg taken orally with or without food.

If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg. The safety of treating more than 8 migraines in a 30-day period has not been established.

DOSING FOR NURTEC ODT:

The recommended dose of NURTEC ODT is 75 mg taken orally.

The maximum dose in a 24-hour period is 75 mg. The safety of treating more than 15 migraines in a 30-day period has not been established.

APPROVAL CRITERIA:
Any new oral CGRP antagonists released will follow this same criterion and follow documentation in the label.

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of acute migraines with or without auras **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient must have a failure of **at least TWO** (2) preferred $5HT_{1B/1D}$ receptor agonists using two (2) different chemical agents not just different dosage forms (sumatriptan tablets, Imitrex nasal spray, rizatriptan tablets, or Zomig nasal spray) 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
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of migraine frequency and severity/duration; **AND**
  - List of all therapies trialed with timeframes; **AND**

- Attestation that the beneficiary has been evaluated for severe hepatic impairment and severe renal impairment and made the appropriate dose adjustment if necessary.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires continued use of a strong CYP3A4 inhibitor (i.e. ketoconazole, itraconazole, clarithromycin, etc.) or a strong CYP3A4 inducer (rifampin) for both UBRELVY and NURTEC ODT; recipient requires concomitant use of P-gp (i.e. amiodarone, carvedilol, macrolides) or BCRP inhibitors (i.e. statins) for NURTEC ODT; **OR**
- Recipient has end stage renal disease (CLcr <15 mL/min); **OR**
- NURTEC ODT recipient has severe hepatic impairment (Child-Pugh Class C); **OR**
- UBRELVY recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CLcr 15-29 mL/min); **OR**
- Recipient does not have improvement while on the oral CGRP agonist.

CONTINUATION CRITERIA:

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

QUANTITY EDITS:
UBRELVY
#10 pills / 30 days (both strengths)—Package size is #10

NURTEC ODT
#8 pills / 30 days—Package size is #8

EFFECTIVE IMMEDIATELY:

12. DOJOLVI™ (triheptanoin) liquid

INDICATION:
DOJOLVI is indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

DOSING:
Assess the metabolic requirements of the patient by determining their daily caloric intake (DCI) prior to calculating the dose of DOJOLVI

The recommended target daily dosage of DOJOLVI is up to 35% of the patient's total prescribed DCI divided into at least four doses and administered at mealtimes or with snacks.

In order to reach a target daily dosage, patients may require an increase in their total fat intake. All patients treated with DOJOLVI should be under the care of a clinical specialist knowledgeable in appropriate disease-related dietary management based upon current nutritional recommendations.

The total daily dosage is converted to a volume of DOJOLVI to be administered in mL using the following calculation:

- Caloric value of DOJOLVI = 8.3 kcal/mL
- Round the total daily dosage to the nearest whole number.
- Divide the total daily dosage into at least four approximately equal individual doses.

$$Total\ Daily\ Dose\ (\_\_\_mL) = \frac{Patients\ DCI\ (\_\_\_kcal)\ x\ Target\ \_\_\_\ \%\ dose\ of\ DCI}{8.3\frac{kcal}{mL}\ of\ DOJOLVI}$$

APPROVAL CRITERIA:

- Recipient has a confirmed diagnosis of long-chain fatty acid oxidation disorder **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient is under the care of a clinical specialist knowledgeable in appropriate disease-related dietary management based upon current nutritional recommendations; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation confirming the diagnosis of LC-FAOD with one of the following:
        - Acylcarnitine profiles from a newborn screen; **OR**
        - Fatty acid oxidation probe studies in cultured fibroblasts (low enzyme activity); **OR**
        - Mutation analysis containing one of the following mutations—CPT2, ACADVL, HADHA, or HADHB;
    - Total daily dose based on required daily caloric intake (DCI) X target % of DCI; **AND**
    - Documentation of symptoms; **AND**
    - Documentation of diet plan; **AND**
    - Baseline echocardiogram with documented left ventricular ejection fraction; **AND**
    - Medical necessity over other available options.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has pancreatic insufficiency; **OR**
- Recipient requires concomitant pancreatic lipase inhibitors (e.g. orlistat); **OR**
- Recipient is receiving another medium-chain triglyceride product; **OR**
- Recipient has a feeding tube manufactured of polyvinyl chloride (PVC).

CONTINUATION CRITERIA:

- Recipient demonstrates an improvement in symptoms; **AND**

- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current total daily dose; **AND**
  - Documentation of current symptoms if applicable.

QUANTITY EDITS:
No edits as volume required is not consistent between recipients.

IV. FRIENDLY REMINDERS:

1. Effective March 1, 2019, Arkansas Medicaid implemented PASSE (Provider-Led Arkansas Shared Savings Entity), a new Medicaid program to address the needs of individuals who have intensive behavioral health and intellectual and developmental disabilities service needs. The PASSE organizations administer all medical needs *and all pharmacy prescription drug needs* for all PASSE members. 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-provider-info

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. In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such patients for appropriate counseling and other nonpharmacological therapies." http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

   Per ASAM National Practice Guideline Update, in Part 7: **"Psychosocial treatment should be considered in conjunction with all pharmacological treatments for opioid use disorder."** https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2

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

4. **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."

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. **CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017:** 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.

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 beneficiaries and once per 60 days per drug class for LTC beneficiaries.

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

   Controlled drugs:
   The hard edit disallowing early refills (ER) for controlled drugs sooner than 90% of days' supply expended will be 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 beneficiary has accumulated an "extra" 12 days' supply for that GSN for *non-controlled drugs*, any incoming claim that is early will reject at point of sale. The accumulation edit is set so that the beneficiary cannot accumulate more than an *extra* 12 days' supply early during a 180-day period for non-controlled drugs.

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

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

11. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN < 18 YEARS OF AGE** 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 can be found: https://arkansas.magellanrx.com/provider/forms
    As the form is updated and posted on the Medicaid website, providers are required to use the most current form.

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

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/ Information on the 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.

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.

For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the Gainwell Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.