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#### **MEMORANDUM**

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: August 14, 2023

SUBJ: AR Medicaid Prior Authorization Edits approved at the AR Medicaid DUR/DRC Board July 19, 2023

meeting for the following:

Manual review criteria for: Daybue™ (trofinetide), Joenja® (leniolisib), Vowst™ (fecal microbiota spores, live-brpk), Veozah™ (fezolinetant), asthma immunomodulators class, ADD/ADHD agents for adults, narcolepsy agents, certain medications for atopic dermatitis, and certain HIV drugs.

Point-of-Sale edits for: Antidepressants, long-acting injectable antipsychotics

Preferred Drug List (PDL) therapeutic classes without PA criteria: Short-acting beta agonists (SABA)

Preferred Drug List (PDL) therapeutic classes with PA criteria: Antidepressants, long-acting injectable antipsychotics, asthma immunomodulators, ADD/ADHD agents, narcolepsy agents, medications for atopic dermatitis (topical and biologic), and HIV agents

Policy update: General Medication Coverage Policy (formerly known as New-To-Market policy)

## Table of Contents

I.	ANNOUNCEMENTS	3
1)	) BENEFICIARY MEDICAID COVERAGE UPDATE	3
2	PRESCRIBER AND PHARMACY INFORMATION UPDATE	3
3)	) ARKANSAS MEDICAID DUR/DRC BOARD OPEN POSITIONS	3
4)	) RSV SEASON UPDATE	4
II.	PREFERRED DRUG LIST	4
1)	) SHORT-ACTING BETA AGONISTS	4
2	) ANTIDEPRESSANTS (second generation)	5
3)	) LONG-ACTING INJECTABLE ANTIPSYCHOTICS	7
4)	) IMMUNOMODULATORS, ASTHMA	11
5)	) ADD/ADHD AGENTS	12
6)	) NARCOLEPSY AGENTS	14
7	) ATOPIC DERMATITIS (topical and biologics)	16
8)	) HUMAN IMMUNODEFICIENCY VIRUS (HIV)	18
III.	PRIOR AUTHORIZATION DRUG CRITERIA (NEW OR REVISED):	22
1)	) GENERAL MEDICATION COVERAGE POLICY	22

# AR MEDICAID DUR BOARD MEETING JULY 19, 2023

2)	DAYBUE™ (trofinetide) 200 mg/mL solution	24
3)	JOENJA® (leniolisib) 70 mg tablet	25
4)	VOWST™ (fecal microbiota spores, live-brpk) capsules	25
5)	VEOZAH™ (fezolinetant) 45 mg tablet	26
6)	FRIENDLY REMINDERS	27

#### I. ANNOUNCEMENTS

## 1) BENEFICIARY MEDICAID COVERAGE UPDATE

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

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

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

### 2) PRESCRIBER AND PHARMACY INFORMATION UPDATE

During the Public Health Emergency (PHE), Arkansas Medicaid was granted flexibility to allow providers to remain enrolled even when license or certification documentation on file expired. During the PHE, providers were notified about license and certification lapses, but their enrollment was not terminated. This was done to maintain the maximum number of providers accessible to beneficiaries during the PHE. The PHE ended effective May 11, 2023. Upon notification that the PHE would end, Arkansas Medicaid began working on a process to resume termination of providers with expired licenses or certifications. For those providers that did not respond and provide verification of their licensure or certification during the PHE, Arkansas Medicaid will be sending out 30-day notices by mail reminding providers to update their licensure and/or certification. Providers who have not submitted updated verifications after that 30 day notice will be terminated from Arkansas Medicaid. Bullet points:

- As a condition of enrollment, providers must provide verification of required licensure and/or certification. Beginning in May 2023, Arkansas Medicaid resumed normal rules for requiring submittal of required licenses and certification.
- During the PHE, initial notifications were sent to providers 30 days prior to their expiration date of their licenses and/or certification.
- Arkansas Medicaid recommends providers update licensure and certification information via the provider portal: <a href="https://humanservices.arkansas.gov/u/providerportal">https://humanservices.arkansas.gov/u/providerportal</a>
- For questions related to submitting updated verification of licensure and/or certification, please contact provider enrollment: Arkansas Division of Medical Services, Gainwell Technologies Enrollment Unit: Toll Free: (800) 457-4454 or Local (501) 376-2211.
- If providers are terminated for lapsed verification of licensure or certification, they may submit updated verification of licensure or certification to provider enrollment within 6 months of termination, and their enrollment may be reactivated.

## 3) ARKANSAS MEDICAID DUR/DRC BOARD OPEN POSITIONS

The Arkansas Medicaid Drug Utilization Review Board/Drug Review Committee (DUR Board) is established under the authority of 42 U.S.C. §1396r–8(g)(3) and 42 CFR § 456.716. The Board is responsible for establishing Prospective Drug Utilization Review (ProDUR) edits, Retrospective Drug Utilization Review (RDUR) criteria, and provider educational interventions. The Board is also responsible for making recommendations to the State concerning the preferred drug list (PDL).

#### AR MEDICAID DUR BOARD MEETING JULY 19, 2023

The Board's mission is to improve the quality of care of Arkansas Medicaid beneficiaries receiving prescription drug benefits and conserve program funds while ensuring therapeutically and medically appropriate pharmacy care.

The Board meets quarterly on the 3rd Wednesday of January, April, July, and October from 8:30am-12:30pm. The Board is composed of actively practicing physicians and pharmacists. Currently, the Board has 2 open pharmacist positions.

If you are interested in serving our Medicaid population, email a CV to Cindi Pearson, PharmD (DUR/DRC Coordinator) at cinnamon.pearson@dhs.arkansas.gov.

Updated bylaws dated October 2022 <a href="https://ar.magellanrx.com/documents/268611/269354/DUR-DRC+Bylaws+final+October+2022.pdf/42694488-b582-7a44-daa1-9271d1727cc7?t=1689686734484">https://ar.magellanrx.com/documents/268611/269354/DUR-DRC+Bylaws+final+October+2022.pdf/42694488-b582-7a44-daa1-9271d1727cc7?t=1689686734484</a>

## 4) RSV SEASON UPDATE

Until this year, the only RSV prophylaxis product has been SYNAGIS. In recent months, three new prophylaxis products have been FDA approved. AREXVY and ABRYSVO are considered vaccines, and BEYFORTUS is considered a monoclonal antibody like SYNAGIS. At the time of this memorandum, the maternal vaccine has not been FDA approved.

The Advisory Committee on Immunization Practices (ACIP) and CDC recommended both AREXVY and ABRYSVO for the treatment of adults aged 60 years of age and older, using shared clinical decision-making. Both of these products will be reimbursed like other adult vaccines and will not be available as a pharmacy NCPDP claim.

Concerning BEYFORTUS, ACIP and CDC recommended that all infants younger than 8 months who are born during or approaching their first RSV season receive one dose AND that children 8 to 19 months who are at increased risk of severe RSV and approaching their second RSV season receive one dose of the monoclonal antibody against RSV. They also recommended that this monoclonal antibody be covered by the Vaccines for Children (VFC) program.

Availability of BEYFORTUS for this upcoming RSV season (November-March) is questionable. Continue to monitor for communication from Arkansas Medicaid on coverage of the prophylaxis agents for children. Separate provider memorandums will be posted concerning RSV prophylaxis in the coming month(s).

## II. PREFERRED DRUG LIST

## PDL UPDATE EFFECTIVE OCTOBER 1, 2023

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

Non-preferred agents require a prior authorization submission. Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800- 424-7976. Any PA request for an off-label use will be reviewed on a case-by-case basis.

### 1) SHORT-ACTING BETA AGONISTS

Some of the brand preferred products are being removed from the market (i.e., ProAir HFA and Proventil HFA). As long as there is still product available, those products will remain preferred.

## Preferred Short Acting Beta Agonists agents

- Albuterol sulfate 0.63mg/3ml solution
- Albuterol sulfate 1.25mg/3ml solution
- Albuterol sulfate 2.5mg/0.5ml solution
- Albuterol sulfate 2.5mg/3ml solution
- Albuterol sulfate 5mg/ml solution

- ProAir HFA (albuterol)—BRAND ONLY
- ProAir RespiClick (albuterol sulfate inhalation powder)—BRAND ONLY
- Proventil HFA (albuterol)—BRAND ONLY
- Ventolin (albuterol) HFA—BRAND ONLY
- Xopenex HFA (levalbuterol)—BRAND ONLY

### Non-preferred Short Acting Beta Agonists agents

- Albuterol HFA (ALL generics)
- Levalbuterol HFA inhaler (generic for Xopenex HFA)
- ProAir Digihaler (albuterol sulfate inhalation powder)
- Xopenex (levalbuterol) inhalation solution

NOTE: Effective 10/1/2023, the generic albuterol HFA inhalers will be considered non-preferred again. Generic albuterol HFA inhalers were temporarily listed as preferred due to drug shortage on brand name products.

## 2) ANTIDEPRESSANTS (second generation)

#### **POS EDIT UPDATE EFFECTIVE DECEMBER 1, 2023**

## Preferred agents with criteria

- Bupropion HCI regular-release (generic for Wellbutrin)
- Bupropion HCl extended-release (generic for Wellbutrin XL)
- Bupropion HCl sustained-release (generic for Wellbutrin SR)
- Citalopram hydrobromide tablet (generic for Celexa)
- Desvenlafaxine succinate ER tablet (generic for Pristiq ER)
- Duloxetine (generic for Cymbalta)
- Escitalopram oxalate tablet and solution (generic for Lexapro)
- Fluoxetine HCl 10mg, 20mg, 40mg capsule, and 20mg/5ml solution (generic for Prozac)
- Fluoxetine HCL/Olanzapine (Symbyax)
- Fluvoxamine maleate tablet (generic for Luvox)
- Mirtazapine 7.5mg, 15mg, 30mg, 45mg tablet (generic for Remeron)
- Paroxetine HCl regular-release tablet (generic for Paxil)
- Sertraline HCl tablet and oral conc (generic for Zoloft)
- Trazodone tablet (generic for Desyrel)
- Venlafaxine HCl extended-release capsule (generic for Effexor ER)
- Venlafaxine HCl regular-release tablet (generic for Effexor)

## Non-preferred agents

- Aplenzin (bupropion hydrobromide extended-release tablet)
- Auvelity (dextromethorphan/bupropion) tablets
- Bupropion HCl extended-release tablet (generic for Forfivo XL)
- Celexa tablet (citalopram)
- Citalopram capsule (generic for Celexa)
- Citalopram solution (generic for Celexa)
- Desvenlafaxine extended-release tablet
- Duloxetine HCl 40 mg DR capsule (generic for Irenka DR)
- Effexor XR capsule (venlafaxine)
- Emsam patch (selegiline)
- Fetzima (levomilnacipran) capsules
- Fluoxetine HCl 10mg, 15mg, 20mg, and 60mg tablet (generic for Prozac)
- Fluoxetine HCl 90mg weekly capsule (generic for Prozac)
- Fluvoxamine maleate extended-release (generic for Luvox CR)
- Forfivo XL tablet (bupropion)
- Lexapro tablet (escitalopram)

- Marplan tablet (isocarboxazid)
- Mirtazapine orally disintegrating tablet (generic for Remeron SolTab)
- Nardil tablet (phenelzine)
- Nefazodone HCI (generic for Serzone)
- Paroxetine HCl controlled-release tablet, and 10mg/5ml suspension(generic for Paxil)
- Paroxetine mesylate capsules (generic for Brisdelle)
- Paxil IR tablet, CR tablet and suspension
- Pexeva tablet (paroxetine mesylate)
- Phenelzine tablet (generic for Nardil)
- Pristiq ER tablet (desvenlafaxine)
- Prozac capsule (fluoxetine)
- Remeron SolTab and tablet (mirtazapine)
- Savella tablets (milnacipran HCl)
- Sertraline capsule (generic for Zoloft)
- Spravato nasal spray (esketamine) (manual review criteria)
- Tranylcypromine tablet (generic for Parnate)
- Trintellix tablet (vortioxetine HBr)
- Venlafaxine ER tablet (generic for Effexor)
- Viibryd tablet (vilazodone)
- Vilazodone HCl tablet (generic for Viibryd)
- Wellbutrin SR tablet and XL tablet (bupropion)
- Zoloft tablet and oral conc (sertraline)

### Approval criteria for preferred agents

• Drug daily dose ≤ maximum daily dose (Table 1)

## Approval criteria for preferred agents resulting from a therapeutic duplication

- If applicable for a change in therapy or concomitant therapy of two agents and only one or neither are SSRIs and/or SSNRIs (including combinations) (Table 1.2):
  - o Drug in history reflects a minimal therapeutic dose (Table 1) for at least four weeks

#### OR

- If applicable for a change in therapy for two SSRIs and/or SSNRIs (including combinations) (Table 1.2)
  - Drug in history reflects a minimal therapeutic dose (Table 1) for at least four weeks, AND
  - No prior therapeutic duplication for two different SSRIs and/or SSNRIs (including combinations) (Table 1.2) within the past 365 days.

## Approval criteria for all non-preferred agents except milnacipran (continuation criteria)

 Continuation criteria is defined as at least 90 days' supply in the previous 186 days for the same drug, strength, and daily dose with the denial exception of a therapeutic duplication between an SSRI and/or SNRI between incoming claim and history

### Denial criteria for all agents

- Preferred agents
  - Therapeutic duplication of three agents
  - Therapeutic duplication of two SSRIs and/or SSNRIs (including combinations) (Table 1.2) more than once per 365 days
- Non-preferred drugs for patients who do not meet continuation criteria of >90 days' supply in the previous 186 days for the same drug, strength, and daily dose

#### Table 1

#### Minimum and maximum dose for second-generation antidepressants

Drug	Minimal daily therapeutic dose	Maximum daily dose
Bupropion (Wellbutrin®, Forfivo®)	150mg	450mg
Citalopram (Celexa®)	20mg	40mg
Desvenlafaxine (Pristiq ER®)	50mg	400mg
Duloxetine (Cymbalta®)	40mg	120mg
Escitalopram (Lexapro®)	10mg	20mg
Fluoxetine (Prozac®)	20mg	60mg
Fluoxetine/olanzapine (Symbyax®)*	25mg	75mg
Fluvoxamine (Luvox CR®)	100mg	300mg
Levomilnacipran (Fetzima®)	40mg	120mg
Milnacipran (Savella®)	100mg	200mg
Mirtazapine (Remeron®)	15mg	45mg
Nefazodone (Serzone®)	200mg	600mg
Paroxetine (Paxil®, Pexeva®)	20mg	60mg (CR 62.5mg)
Sertraline (Zoloft®)	50mg	200mg
Venlafaxine (Effexor®)	75mg	375mg
Vilazodone (Viibryd®)	20mg	40mg
Vortioxetine (Trintellix®)	10mg	20mg

<sup>\*</sup>Minimum therapeutic dose and maximum dose based on SSRI component of the combination agent.

Table 1.2

## Selective Serotonin (norepinephrine) Reuptake Inhibitors

ocicotive ociotomii (norepinepinine) reapt				
SSRI, SSNRI, or SSRI combinations				
Citalopram				
Desvenlafaxine ER				
Duloxetine				
Escitalopram				
Fluoxetine				
Fluoxetine/olanzapine				
Fluvoxamine				
Paroxetine				
Sertraline				
Venlafaxine				

## 3) LONG-ACTING INJECTABLE ANTIPSYCHOTICS

## **POS EDIT UPDATE EFFECTIVE OCTOBER 1, 2023**

## **Preferred Agents with Criteria**

- Abilify Asimtufii® (aripiprazole ER)
- Abilify Maintena® (aripiprazole ER)
- Aristada® (aripiprazole lauroxil ER)
- Aristada® Initio (aripiprazole lauroxil ER)
- Fluphenazine decanoate (generic for Prolixin® decanoate)
- Haloperidol decanoate (generic for Haldol® decanoate)
- Invega Hafyera® (paliperidone palmitate)
- Invega Sustenna® (paliperidone palmitate)
- Invega Trinza® (paliperidone palmitate)
- Perseris ER® kit (risperidone)
- Risperdal Consta® (risperidone microspheres)

## **Non-preferred Agents**

- Uzedy ER® (risperidone)
- Zyprexa Relprevv™ (olanzapine)

#### **GENERAL APPROVAL CRITERIA:**

Long-Acting injectable antipsychotics will be available through POS edits for the preferred agents based on requirements in the package insert. Non-preferred agents follow the below criteria and require documentation of the medical necessity over preferred options.

- All requests for beneficiaries < 18 years of age will continue to require manual review.
- Each product will require a trial of oral tolerability
- No therapeutic duplication with another long-acting antipsychotic allowed in the past 23 days
- Allowed ≤ 1 oral antipsychotic used concomitantly
- If medication is changed between LAIs, the proper time between doses must have elapsed to prevent overlapping of doses.
- Beneficiary must either meet criterion 1 or criterion 2 for the claim to process without a PA.

## Abilify Asimtufii® 720 mg and 960 mg

Maximum of 1 injection every 2 months

#### Criterion 1

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability with a 2
  year look back in Medicaid pharmacy claim history
- After the first Abilify Asimtufii injection, administer oral aripiprazole for 14 consecutive days OR if already stable on another oral antipsychotic, continue treatment with that medication for 14 consecutive days
- If changing from Abilify Maintena® to Abilify Asimtufii®, no oral doses are required. Dose can be given at next scheduled Abilify Maintena® dosing interval.

#### Criterion 2

Abilify Asimtufii® claim in the last 90 days or Abilify Maintena® in the last 45 days

### Abilify Maintena® 300 mg and 400 mg

Monthly dosing for 300 mg and 400 mg

#### Criterion 1

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability with a 2
  year look back in Medicaid pharmacy claim history
- After the first Abilify Maintena® injection, administer oral aripiprazole for 14 consecutive days OR
  if already stable on another oral antipsychotic, continue treatment with that medication for 14
  consecutive days

### Criterion 2

Abilify Maintena® claim in history in last 45 days or Abilify Asimtufii® in the last 90 days

#### Aristada® 441mg, 662mg, 882mg and 1064mg

 Monthly dosing for 441 mg and 662 mg; maximum duration of 6 weeks for 882 mg; maximum of every 8 weeks for 1064 mg.

#### Criterion 1

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability with a 2
  year look back in Medicaid pharmacy claim history
- Initiation of treatment after tolerability has been established requires one of the following:
  - Administer Aristada Initio® 675mg injection and one dose of oral aripiprazole 30mg with first Aristada® injection OR
  - Administer 21 consecutive days of oral aripiprazole in conjunction with first Aristada® injection

#### Criterion 2

 Aristada® 441 mg and 662 mg claim in history in last 45 days; Aristada® 882 mg and 1064 mg claim in history in the last 90 days.

#### Aristada Initio® 675 mg

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability with a 2
  year look back in Medicaid pharmacy claim history
- Administer with one dose of oral aripiprazole 30 mg with first dose of Aristada® injection
- Limit 1 per year

## Fluphenazine decanoate 25 mg/mL

Dosing individualized but many dose every 3 weeks

#### Criterion 1

Requires previous history of a short-acting form of fluphenazine to assess tolerability with a 2
year look back in Medicaid pharmacy claim history

#### Criterion 2

Fluphenazine decanoate claim in the last 180 days (5 mL vials)

### Haloperidol decanoate 50 mg and 100 mg

Monthly dosing

#### Criterion 1

 Requires previous history of a short-acting form of haloperidol to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

#### Criterion 2

Haloperidol decanoate claim in the last 45 days

#### Invega Hafyera® 1092 mg and 1560 mg

Maximum dosing every 6 months

#### Criterion 1

 Request requires adequate treatment of Invega Sustenna® for at least 4 months OR Invega Trinza® for at least one 3-month course

#### Criterion 2

 Invega Hafyera® claim in the last 7 months, Invega Sustenna® in the last 45 days, or Invega Trinza® in the last 120 days

## Invega Sustenna® 39 mg, 78 mg, 117 mg, 156 mg and 234 mg

Monthly dosing

### Criterion 1

 Prior to approval must have taken oral paliperidone, oral risperidone, or injectable risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

## **Criterion 2**

 Invega Sustenna® claim in the last 45 days, Invega Hafyera® in the last 7 months, or Invega Trinza® in the last 120 days

### Invega Trinza® 273 mg, 410 mg, 546 mg, and 819 mg

Maximum dosing every 3 months

#### Criterion 1

Request requires adequate treatment of Invega Sustenna® for at least 4 months

#### Criterion 2

 Invega Trinza® claim in the last 120 days, Invega Hafyera® in the last 7 months, or Invega Sustenna® in the last 45 days

#### Perseris® 90 mg and 120 mg

Monthly dosing

#### Criterion 1

 Requires previous history of oral risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

#### Criterion 2

Perseris® claim in the last 45 days, or Risperdal Consta® in the last 45 days, or Uzedy<sup>™</sup> 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy<sup>™</sup> 100 mg, 150 mg, 200 mg and 250 mg claim in the last 90 days

#### Risperdal Consta® 12.5 mg, 25 mg, 37.5 mg, and 50 mg

Maximum of 2 doses per month

#### Criterion 1

- Requires previous history of oral risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
- Treatment requires concomitant oral risperidone or other antipsychotic medication for 3 weeks

#### Criterion 2

Risperdal Consta® claim in the last 45 days, or Perseris® in the last 45 days, or Uzedy<sup>™</sup> 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy<sup>™</sup> 100 mg, 150 mg, 200 mg and 250 mg claim in the last 90 days

### Uzedy™ ER 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 200 mg, and 250 mg

- 50 mg, 75 mg, 100 mg, and 125 mg may be filled monthly; 150 mg, 200 mg and 250 mg may be filled every 2 months
- Requires the medical necessity over preferred options

#### Criterion 1

 Requires previous history of oral risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

#### Criterion 2

 Uzedy<sup>™</sup> 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy<sup>™</sup> 100 mg, 150 mg, 200 mg and 250 mg claim in the last 90 days, or Perseris® in the last 45 days, or Risperdal Consta® in the last 45 days

#### Zyprexa Relprevv® 210 mg, 300 mg, and 405 mg

- 150 mg, 210 mg and 300 mg may have 2 doses per month; 405 mg requires once monthly dosing
- Requires the medical necessity over preferred options

#### Criterion 1

 Requires previous history of oral olanzapine to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

#### Criterion 2

Zyprexa Relprevv® claim in the last 45 days

## 4) IMMUNOMODULATORS, ASTHMA

#### **MANUAL REVIEW CRITERION EFFECTIVE JULY 19, 2023**

\*\*\*Criteria for other indications are available separately in the PA criteria document. <a href="https://ar.magellanrx.com/documents/268611/269354/Prior+Authorization+Criteria.pdf/41f12c65-15fb-7523-1221-3ec8df71ada0?t=1689114596967">https://ar.magellanrx.com/documents/268611/269354/Prior+Authorization+Criteria.pdf/41f12c65-15fb-7523-1221-3ec8df71ada0?t=1689114596967</a>

## Preferred Agents with Criteria

- Dupixent® pen and syringe (dupilumab)
- Fasenra® pen and syringe (benralizumab)
- Xolair® syringe (omalizumab)

## **Non-Preferred Agents**

- Nucala® auto-inject, syringe, and vial (mepolizumab)
- Tezspire® (tezepelumab-ekko)
- Xolair® vial (omalizumab)

## **Approval Criteria for Asthma Diagnosis:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy or immunology
- Beneficiary must have a diagnosis consistent with FDA indications (current asthma indications below); AND
  - NUCALA—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype
  - FASENRA—add-on maintenance treatment of patients with severe asthma aged 12 years and older and with an eosinophilic phenotype
  - DUPIXENT—add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
  - TEZSPIRE—add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma
  - XOLAIR—adults and pediatric patients 6 years of age and older with moderate to severe
    persistent asthma who have a positive skin test or in vitro reactivity to a perennial
    aeroallergen and whose symptoms are inadequately controlled with inhaled
    corticosteroids

- Beneficiary must have moderate to severe asthma as defined by at least TWO of the following:
  - 1 or more exacerbations defined as:
    - Requires treatments with systemic corticosteroids; OR
    - Requires medical treatment (e.g., emergency room visits or hospitalizations)
  - Beneficiary must be compliant on at least two asthma maintenance medications with one being an inhaled corticosteroid at a maximized dose (ICS/LABA combination products count as two medications). Compliance will be reviewed on a case-by-case basis
  - Beneficiary has oral corticosteroid dependent asthma
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried for asthma with response
  - o Baseline labs (must fall within the manufacturer's requirements in the package insert)
    - Baseline blood eosinophil count for FASENRA, NUCALA, and DUPIXENT (if eosinophilic type) with eosinophils ≥150
    - Baseline serum IgE levels, body weight, and completed form for XOLAIR
  - Baseline Asthma Control Questionnaire (ACQ-5) for all patients <u>OR</u> Asthma Quality of Life Questionnaire (AQLQ) scores for adults only
  - Current Pulmonary Function Test results
  - If the request is for a non-preferred product, provide a letter of medical necessity for requested product over the preferred monoclonal antibody and other therapies outlined in treatment guidelines

#### **QUANTITY EDITS:**

- FASENRA--#1 pen/vial per 8 weeks (will need quantity override for first 3 months)
- DUPIXENT--#5 syringes per 50 days
- NUCALA--#3 prefilled syringes/autoinjectors per 28 days (based on other indications)
- TEZSPIRE--#1 syringe/pen every 28 days
- XOLAIR--#8 150 mg prefilled syringe/vial per 28 days; #1 75 mg prefilled syringe per 28 days

## 5) ADD/ADHD AGENTS

## **POS EDIT UPDATE EFFECTIVE OCTOBER 17, 2023**

## Preferred Agents with Criteria

- Adderall XR capsule (amphetamine/dextroamphetamine)—BRAND ONLY
- Amphetamine/dextroamphetamine salts tablet (generic for Adderall IR)
- Atomoxetine capsule (generic for Strattera)
- Clonidine ER tablet (generic for Kapvay ER)
- Clonidine IR tablet (generic for Catapres)
- Concerta tablet (methylphenidate ER)—BRAND ONLY
- Daytrana patch (methylphenidate)—BRAND ONLY
- Dexmethylphenidate ER capsule—(generic for Focalin XR)
- Dexmethylphenidate IR tablet (generic for Focalin)
- Dextroamphetamine 5 mg and 10 mg tablet (generic for Zenzedi)
- Focalin tablet (dexmethylphenidate)
- Focalin XR capsule (dexmethylphenidate)
- Guanfacine ER tablet (generic for Intuniv ER)
- Guanfacine IR tablet (generic for Tenex)
- Methylphenidate tablet (generic for Methylin, Ritalin IR)
- Vyvanse capsule (lisdexamfetamine)
- Vyvanse chew tablet (lisdexamfetamine)

#### **Non-Preferred Agents**

- Adhansia XR capsule (methylphenidate)
- Adzenys XR-ODT (amphetamine)
- Amphetamine suspension (generic for Adzenys ER)
- Amphetamine/dextroamphetamine salts ER capsule (generic for Adderall XR)
- Aptensio XR capsule (methylphenidate)
- Azstarys capsule (serdexmethylphenidate/dexmethylphenidate)
- Clonidine ER tablet (generic for Nexiclon XR)
- Cotempla XR-ODT (methylphenidate)
- Desoxyn tablet (methamphetamine)
- Dexedrine spansule (dextroamphetamine)
- Dextroamphetamine capsule (generic for Dexedrine spansule)
- Dextroamphetamine solution (generic for Procentra)
- Dyanavel XR suspension (amphetamine)
- Dyanavel XR tablet (amphetamine)
- Evekeo ODT (amphetamine)
- Evekeo tablet (amphetamine)
- Intuniv ER tablet (guanfacine)
- Jornay PM capsule (methylphenidate)
- Methamphetamine tablet (generic for Desoxyn)
- Methylin solution (methylphenidate)
- Methylphenidate CD/ER/LA capsules (generic for Metadate CD, Ritalin LA, Aptensio XR)
- Methylphenidate chew tablet (generic for Methylin)
- Methylphenidate ER tablet (generic for Concerta)
- Methylphenidate ER tablet (generic for Metadate ER, Ritalin SR)
- Methylphenidate ER tablet (generic for Relexxii ER)
- Methylphenidate patch (generic for Daytrana)
- Methylphenidate solution (generic for Methylin)
- Mydayis ER capsule (amphetamine/dexamphetamine salts)
- Procentra solution (dextroamphetamine)
- Qelbree capsule (viloxazine)
- Quillichew ER chew tablet (methylphenidate)
- Quillivant XR suspension (methylphenidate)
- Ritalin IR tablet (methylphenidate)
- Ritalin LA capsule (methylphenidate)
- Strattera capsule (atomoxetine)
- Xelstrym patch (dextroamphetamine)
- Zenzedi tablet (dextroamphetamine)

#### Approval criteria for preferred agents with criteria for children: < 19 years

- Beneficiaries < 6 years of age require a prior authorization request for all CII stimulants and nonstimulant medications
- All preferred extended-release CII stimulants
  - ≤ 1 therapeutic duplication between long-acting CII stimulants with 75% of the last fill per
     93 days AND
  - o If an incoming long-acting CII stimulant claim overlaps with a short-acting CII stimulant that was filled at a dose of ≥ to 2 units per day, the long-acting product will require prior authorization
- All preferred immediate-release CII stimulants
  - ≤ 1 therapeutic duplication between short-acting CII stimulants with 75% of the last fill per
     93 days AND
  - If an incoming short-acting CII stimulant claim overlaps with a long-acting CII stimulant, the short-acting product will only be approved for a dose of one unit per day

#### Approval criteria for CII stimulants and non-stimulants for adults

- Completed CII stimulant form is required for beneficiaries ≥19 years of age <a href="https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-">https://ar.magellanrx.com/document%20of%20Medical%20Necessity/d9a327df-d05c-665e-b17b-593f58e8c95e</a>
  - Currently, atomoxetine does not require a prior authorization
  - Beneficiary with ADHD
    - Beneficiary must have signs/symptoms in 2 or more settings using a standardized rating scale with at least one of the following:
      - Currently attends school (high school, college, or vocational)
      - Currently employed
      - Currently searching for employment (approval for maximum of 3 months without documentation of employment)
    - Beneficiary must have multiple symptoms of inattention and/or hyperactivity/impulsivity from the DSM-5 documented on the form for initial approval
    - Beneficiary with co-morbid conditions of bipolar disorder or schizophrenia must be controlled and adherent with appropriate medication therapy, or prescriber must provide adequate documentation as to why the co-morbid condition is no longer being treated
    - Prescriber must submit the following:
      - Completed CII stimulant form
      - Current chart notes
      - Documentation needed to support the diagnosis of ADHD
  - Beneficiary without ADHD may be approved for one of the following: (each request is reviewed on a case-by-case basis for medical necessity)
    - Narcolepsy with sleep study results confirming diagnosis
    - Traumatic Brain Injury (TBI)
    - Fatigue due to underlying illness (i.e., cancer or multiple sclerosis)
    - o Binge Eating Disorder (BED)—Vyvanse only

## 6) NARCOLEPSY AGENTS

### **MANUAL REVIEW CRITERION EFFECTIVE JULY 19, 2023**

### Preferred agents that require manual review for prior authorization

- Nuvigil (armodafinil)—BRAND ONLY
- Xyrem solution (sodium oxybate)—BRAND ONLY

### Non-preferred agents

- Armodafinil tablet (generic for Nuvigil)
- Lumryz ER suspension (sodium oxybate)—when rebate eligible
- Modafinil tablet (generic for Provigil)
- Provigil tablet (modafinil)
- Sodium oxybate solution (generic for Xyrem)
- Sunosi tablet (solriamfetol)
- Wakix tablet (pitolisant)
- Xywav solution (calcium, magnesium, potassium, and sodium oxybates)

## **APPROVAL CRITERIA:**

All requests for non-FDA approved diagnoses or for new indications without developed criteria will be reviewed on a case-by-case basis.

#### NARCOLEPSY

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with narcolepsy. Diagnosis
  of narcolepsy is based on International Classification of Sleep Disorders (ICSD-3) or Diagnostic
  and Statistical Manual of Mental Disorders (DSM-5) criteria. Requests for any other diagnosis will
  be reviewed on a case-by-case basis.
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy
- Prescriber should submit the following for initial request for narcolepsy:
  - Most recent polysomnogram (PSG) results
  - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
    - Mean sleep latency of less than 8 minutes per nap
    - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)
  - Current chart notes
  - Baseline Epworth Sleepiness Scale (ESS)
- Requests for non-preferred medications require a documented trial and failure of CII and CIII stimulants in the last year with documentation of the medical necessity over the preferred medications.

### **OBSTRUCTIVE SLEEP APNEA (OSA)**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with obstructive sleep apnea (OSA)
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides OSA
- Prescriber should submit the following for initial request for obstructive sleep apnea (OSA):
  - Most recent polysomnogram (PSG) results
  - Current chart notes
  - Documentation of plan for monitoring compliance of positive airway treatment
  - CPAP or BiPAP usage report for documentation of compliance for at least 1 month
- Requests for non-preferred medications require a documented trial and failure of CII and CIII stimulants in the last year with documentation of the medical necessity over the preferred medications.
- PA renewal requires CPAP or BiPAP compliance

## SHIFT WORK DISORDER (SWD)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with shift work disorder (SWD)
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides SWD
- Prescriber must submit the following for initial request for shift work disorder (SWD):
  - Most recent polysomnogram (PSG) results with sleep study performed during patient's normal sleep time

- Most recent multiple sleep latency test (MSLT) performed during patient's normal work time
  - Mean sleep latency of less than 8 minutes per nap
  - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)
- Current chart notes
- o Baseline Epworth Sleepiness Scale (ESS)
- Current work schedule

#### NARCOLEPSY WITH CATAPLEXY

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with narcolepsy with cataplexy
- Beneficiary ages ≥ 7 years and < 19 years must have a trial of a CII stimulant in the last year</li>
- Beneficiary ≥ 19 years must have both of the following unless contraindicated:
  - o Trial and failure of CII stimulant in the last year
  - Trial and failure of a preferred CIII stimulant in the last year
- Prescriber should submit the following for initial request:
  - Most recent polysomnogram (PSG) results
  - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
    - Mean sleep latency of less than 8 minutes per nap
    - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)
  - Current labs including LFTs
  - o Current chart notes
  - Baseline Epworth Sleepiness Scale (ESS) Score for excessive daytime sleepiness associated with narcolepsy
  - Baseline description of cataplexy events for beneficiaries with cataplexy diagnosis;
- Requests for non-preferred medications for beneficiary ≥ 19 years require a documented trial and failure of CII and CIII stimulants in the last year with documentation of the medical necessity over the preferred medications.
- Requests for non-preferred medications for beneficiary ≥ 7 years and < 19 years require a
  documented trial and failure of CII in the last year with documentation of the medical necessity
  over the preferred medications.</li>

#### 7) ATOPIC DERMATITIS (topical and biologics)

POS EDIT UPDATE EFFECTIVE OCTOBER 1, 2023 (Eucrisa® and tacrolimus ointment)

## **MANUAL REVIEW CRITERION EFFECTIVE JULY 19, 2023**

\*\*\*Criteria for other indications are available separately in the PA criteria document. <a href="https://ar.magellanrx.com/documents/268611/269354/Prior+Authorization+Criteria.pdf/41f12c65-15fb-7523-1221-3ec8df71ada0?t=1689114596967">https://ar.magellanrx.com/documents/268611/269354/Prior+Authorization+Criteria.pdf/41f12c65-15fb-7523-1221-3ec8df71ada0?t=1689114596967</a>

#### PREFERRED AGENTS

Tacrolimus ointment (generic for Protopic®)

## PREFERRED AGENTS WITH CRITERIA (\*specific manual review criteria)

- Adbry®\* syringe (tralokinumab-ldrm)
- Dupixent®\* syringe and pen (dupilumab)

## NON-PREFERRED AGENTS WITH CRITERIA (\*specific manual review criteria)

Note: Non-preferred agents require documentation of medical necessity over preferred agents in addition to other stated criteria.

- Cibinqo®\* tablet (abrocitinib)
- Elidel® cream (pimecrolimus)
- Eucrisa® ointment (crisaborole)
- Opzelura®\* cream (ruxolitinib)
- Pimecrolimus cream (generic for Elidel®)
- Protopic® ointment (tacrolimus)
- Rinvog®\* tablet (upadacitinib)

#### APPROVAL CRITERIA FOR OPZELURA

- Beneficiary must be ≥12 years of age
- Beneficiary should have mild or moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2-3 out of a 0-4 scale <u>OR</u> a diagnosis consistent with FDA indications
- Beneficiary must have uncontrolled mild to moderate atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
  - Trials of at least two different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
  - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- · Prescriber must submit ALL of the following:
  - o Current chart notes
  - Documentation of previous therapies
  - o Current IGA score
  - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

## **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria <u>OR</u> have a diagnosis supported on the official Compendia
- · Beneficiary has a history of skin cancer
- Beneficiary has severe atopic dermatitis
- Beneficiary's atopic dermatitis affects greater than 20% of BSA
- Prescriber requests continuance beyond 8 weeks without improvement
- Beneficiary has been approved for biologics, JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine

#### **QUANTITY EDITS:**

2 tubes (120 gm)/ 30 days

## APPROVAL CRITERIA FOR ATOPIC DERMATITIS (Adbry®, Cibingo®, Dupixent®, and Rinvog®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Beneficiary has a documented diagnosis of moderate to severe atopic dermatitis with at least TWO of the following (baseline at time of biologic request):
  - Baseline impacted body surface area (BSA) ≥ 10%
  - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16

- Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
- Baseline Investigator's Global Assessment (IGA) score ≥ 3
- Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in the official Compendia
- Beneficiary has no therapeutic duplication with monoclonal antibodies or cytokine & CAM antagonists
- Beneficiary must have a trial and failure of topical therapy and at a minimum must include
  - At least ONE topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) or superpotent (Class-1) for adults <u>OR</u> medium potency for children (unless contraindicated); **AND**
  - At least ONE trial of a topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., pimecrolimus or tacrolimus)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies with trial length of each medication
  - BSA prior to topical/systemic therapies and current impacted BSA
  - Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - o Letter of medical necessity over other treatment options for atopic dermatitis

### 8) HUMAN IMMUNODEFICIENCY VIRUS (HIV)

## **MANUAL REVIEW CRITERION EFFECTIVE JULY 19, 2023**

#### PREFERRED HIV AGENTS

- Abacavir tablet and solution (generic for Ziagen)
- Abacavir/lamivudine tablet (generic for Epzicom)
- Atazanavir capsule (generic for Revataz)
- Biktarvy tablet (bictegravir/emtricitabine/tenofovir)
- Cimduo tablet (lamivudine/tenofovir)
- Complera tablet (emtricitabine/rilpivirine/tenofovir)
- Delstrigo tablet (doravirine/lamivudine/tenofovir)
- Descovy tablet (emtricitabine/tenofovir alafenam)
- Dovato tablet (dolutegravir/lamivudine)
- Edurant tablet (rilpivirine)
- Efavirenz tablet (generic for Sustiva)
- Efavirenz/emtricitabine/tenofovir disoproxil fumarate tablet (generic for Atripla)
- Emtricitabine/tenofovir disoproxil fumarate tablet (generic for Truvada)
- Emtriva solution (emtricitabine)
- Evotaz tablet (atazanavir/cobicistat)
- Fosamprenavir tablet (generic for Lexiva)
- Genvoya tablet (elvitegravir/cobicistat/emtricitabine/tenofovir)
- Isentress powder, chew, tablet, and HD tablet (raltegravir potassium)
- Juluca tablet (dolutegravir/rilpivirine)
- Lamivudine tablet and solution (generic for Epivir)
- Lamivudine/zidovudine tablet (generic for Combivir)
- Lexiva suspension (fosamprenavir)
- Lopinavir/ritonavir solution and tablet (generic for Kaletra)
- Nevirapine tablet, suspension, and ER tablet (generic for Viramune)
- Norvir powder (ritonavir)
- Odefsey tablet (emtricitabine/rilpivirine/tenofovir)

- Pifeltro tablet (doravirine)
- Prezcobix tablet (darunavir/cobicistat)
- Prezista suspension and tablet (darunavir ethanolate)—BRAND only
- Revataz powder (atazanavir)
- Ritonavir tablet (generic for Norvir)
- Stribild tablet (elvitegravir/cobicistat/emtricitabine/tenofovir)
- Symfi Lo tablet (efavirenz/lamivudine/tenofovir)—BRAND only
- Symfi tablet (efavirenz/lamivudine/tenofovir)—BRAND only
- Symtuza tablet (darunavir/cobicistat/emtricitabine/tenofovir)
- Tenofovir disoproxil fumarate tablet (generic for Viread)
- Tivicay PD tablet for suspension and Tivicay tablet (dolutegravir sodium)
- Triumeq PD tablet for suspension and Triumeq tablet (abacavir/dolutegravir/lamivudine)
- Tybost tablet (cobicistat)
- Zidovudine tablet and syrup (generic for Retrovir)

## **NON-PREFERRED HIV AGENTS**

- Aptivus capsule (tipranavir)
- Atripla tablet (efavirenz/emtricitabine/tenofovir)
- Combivir tablet (lamivudine/zidovudine)
- Darunavir ethanolate tablet (generic for Prezista)
- Didanosine capsule (generic for Videx EC)
- Efavirenz capsule (generic for Sustiva)
- Efavirenz/lamivudine/tenofovir disoproxil fumarate tablet (generic for Symfi and Symfi Lo)
- Emtricitabine capsule (generic for Emtriva)
- Emtriva capsule (emtricitabine)
- Epivir solution and tablet (lamivudine)
- Epzicom tablet (abacavir/lamivudine)
- Etravirine tablet (generic for Intelence)
- Fuzeon vial (enfuvirtide)
- Intelence tablet (etravirine)
- Kaletra solution and tablet (lopinavir/ritonavir)
- Lexiva tablet (fosamprenavir)
- Norvir tablet (ritonavir)
- Retrovir syrup (zidovudine)
- Reyataz capsule (atazanavir)
- Rukobia tablet (fostemsavir tromethamine)
- Stavudine capsule (generic for Zerit)
- Sustiva capsule (efavirenz)
- Temixys tablet (lamivudine/tenofovir)
- Trizivir tablet (abacavir/lamivudine/zidovudine)
- Truvada tablet (emtricitabine/tenofovir)
- Viracept tablet (nelfinavir)
- Viramune XR tablet (nevirapine)
- Viread tablet and powder (tenofovir)
- Ziagen solution and tablet (abacavir)
- Zidovudine capsule (generic for Retrovir)

## NON-PREFERRED HIV AGENTS WITH CRITERIA

- Apretude\* vial (cabotegravir)
- Cabenuva\* vial (cabotegravir and rilpivirine)
- Maraviroc\* tablet (generic for Selzentry)
- Selzentry\* solution and tablet (maraviroc)
- Sunlenca\* tablet and vial (lenacapavir sodium)

Note: Trogarzo is available as a medical claim only. Prior authorization criteria may apply.

#### APPROVAL CRITERIA FOR CABENUVA

- Beneficiary meets the minimum age and weight recommended in the manufacturer's package /insert for this FDA approved indication (As of 7/27/2023, minimum age is 12 years old and weight is 35 kg).
- Beneficiary has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and is virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure or suspected resistance to cabotegravir or rilpivirine <a href="Moreoverline"><u>OR</u></a> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary should not be approved or continue on this therapy if requires coadministration with any of the following:
  - Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
  - Antimycobacterials: Rifabutin, rifampin, rifapentine
  - o Glucocorticoid (systemic): Dexamethasone (more than a single-dose treatment)
  - Herbal product: St John's wort (Hypericum perforatum)
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Labs including current RNA documenting viral suppression
  - o Attestation that beneficiary has been counseled on the importance of compliance
  - Confirmation whether beneficiary will start with oral lead in doses or move directly to the injection
  - Medical necessity over current oral therapy
- Prior authorization will be approved for 12 months.

#### RENEWAL REQUIREMENTS:

- Beneficiary remains compliant on all antiretroviral medications
- Beneficiary has a demonstrated continued virological suppression
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current labs including viral load

#### **QUANTITY EDITS:**

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

#### APPROVAL CRITERIA FOR APRETUDE

- Beneficiary meets the minimum age and weight recommended in the manufacturer's package insert for this FDA approved indication (As of 7/27/2023, minimum age is 12 years old and weight is 35 kg).
- Beneficiary must be considered at-risk for sexually acquired HIV-1 infections requiring preexposure prophylaxis (PrEP)
- Beneficiary must have a current negative HIV-1 test
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Has a positive HIV-1 test either prior to initiating Apretude® or during treatment
  - Medical necessity over oral PrEP options was not provided
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current HIV test results
  - o Medical necessity over oral PrEP options (e.g., generic Truvada® or Descovy®)
  - Document if beneficiary will have the 28-day oral lead-in therapy or begin with Apretude®
  - Attestation that the prescriber has counseled the patient about the importance of compliance
- Prior authorization will be approved for 12 months.

#### **QUANTITY EDITS**

• 1 injection every 2 months (quantity override will be needed for first 2 months loading dose)

#### **APPROVAL CRITERIA FOR SELZENTRY**

https://ar.magellanrx.com/forms-documents

#### INFORMATION FROM THE SELZENTRY FORM

#### Part 1: Initial Approval Criteria

Use of maraviroc for treatment-experienced or treatment-naïve patient (Please check all that apply; all must be true for patient to be eligible):

- 1. Under the care of an experienced HIV practitioner
- 2. Evidence of virologic failure (documented by viral load > 1,000 copies/mL not related to non-adherence to prescribed ARV)
- 3. Unable to construct a multi-drug regimen from preferred°, alternative\*, or acceptable^ regimens as defined by the Department of Health and Human Services Guidelines for Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents that includes at least two additional active antiretroviral drug in addition to maraviroc.
  - °Preferred Regimens (Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use)
  - \*Alternative Regimens (Regimens that are effective and tolerable but have potential disadvantages compared with preferred regimens. An alternative regimen may be the preferred regimen for some patients.)
  - ^Acceptable Regimens (CI) (Regimens that may be selected for some patients but are less satisfactory than preferred or alternative regimens)

### Part 2: Medicaid Approval Requirements for Trofile® Assay Test:

This section to be completed by AR Medicaid only. Patient meets criteria stated in Part 1 above.

If patient meets Part 1 criteria, Medicaid Utilization Review will be notified that patient meets Medicaid criteria for proceeding with Trofile® Assay Test.

- A highly sensitive tropism assay at baseline is required prior to initiation of maraviroc; the results
  of the tropism assay may take approximately 3 weeks and a prescription for maraviroc should not
  be written until the results indicate only CCR5 tropism.
- Prior approval from Medicaid is required for a repeat tropism assay. A repeat tropism assay should only be performed if the provider is considering a change of treatment due to increasing VL and/or decreasing CD4 count. If CXCR4 or DM virus is detected during therapy, the PA for maraviroc will be discontinued. In failing patients who have CCR5 virus, a maraviroc resistance assay may also be necessary.

#### Part 3: Approval or Denial for Selzentry® (maraviroc):

- 1. Does patient have confirmed infection with only CCR5 tropic virus as determined by Trofile® Assay Test result screening prior to maraviroc initiation? (Copy of lab test results required as part of the manual review process)
- 2. The prior approval is NDC and dose specific. AR Medicaid will allow up to a maximum of 1200 mg/day in the following dosing regimens. Please indicate intended dose\*:
  - o 150 mg tablet, 1 tablet twice daily
  - o 300 mg tablet, 1 tablet twice daily
  - o 300 mg tablet, 2 tablets twice daily

<sup>\*</sup>Caution and/or dosing adjustments may be warranted in patients with renal or hepatic impairment.

Please refer to prescribing information in manufacturer's package insert for dosing and contraindications.

#### APPROVAL CRITERIA FOR SUNLENCA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with HIV-1 infection and heavily treatment-experienced with multidrug resistant disease failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations OR a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Multidrug resistance is defined as resistance to =2 agents from =3 of the 4 main classes of ARV
- ARV classes include nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI) and integrase strand transfer inhibitor (INSTI)
- Beneficiary should not be approved with any of the following:
  - Concomitant administration of strong CYP3A inducers is required
  - Baseline HIV-1 RNA levels < 400 copies/mL</li>
  - o Prior to starting SUNLENCA, there is no current antiretroviral therapy
  - Not prescribed a concomitant optimized background regimen
- Prescriber must submit ALL of the following:
  - Current chart notes
  - o Documentation of previous therapies tried
  - Current labs including viral load
  - Documentation of which regimen prescribed
  - o Documentation of concomitant antiretrovirals prescribed
- PA will be approved for 1 year

#### RENEWAL REQUIREMENTS:

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

### **QUANTITY EDITS:**

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

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

### **EFFECTIVE JULY 19, 2023**

1) GENERAL MEDICATION COVERAGE POLICY

GENERAL CRITERIA FOR NEW-TO-MARKET MEDICATIONS, PRODUCTS WITH LABEL EXPANSIONS, AND NON-PREFERRED MEDICATIONS ON THE PDL

MANUAL GUIDELINES: Pertains to new-to-market FDA approved medications available on the Medicaid drug file prior to being reviewed by the Arkansas Medicaid DUR Board, medications with a label expansion including new indication, dosage change, or age change, and non-preferred medications on the PDL.

#### APPROVAL CRITERIA:

- Medication must be an outpatient drug with a federal rebate agreement in place.
- Medication must be prescribed for an FDA-approved indication with age, dose, and frequency based on manufacturer's packet insert. If the beneficiary's age or dose/frequency requested is not FDA approved, the age or dose/frequency must have support in the official Compendia (MicroMedex®).

- If the FDA-approved indication(s) does not match the beneficiary's diagnosis, the medication must have support for the requested diagnosis either in treatment guidelines or the official Compendia (MicroMedex®).
- Renewals for drugs requiring a PA requires a positive response and must continue to meet approval criteria

## Label expansion

- Medications previously reviewed by the DUR Board with a new FDA approved label expansion will not require a new review by the DUR Board.
- Any prior authorization requests will be reviewed based on the updated package insert.

### New-to-market medication with class on PDL

- If the new-to-market medication is included in an existing class/category on the preferred drug list (PDL):
  - o The new-to-market medication will be added as a non-preferred option.
  - The new-to-market medication will require a prior authorization with documentation of the medical necessity over preferred options.
  - If the PDL class has multiple preferred options, the beneficiary must have documentation of trial and failure of at least 2 different chemical entities unless otherwise noted.
  - If the PDL class has multiple preferred options with multiple mechanisms of action (MOA), the beneficiary must have documentation of trial and failure from each MOA unless there is a contraindication or otherwise noted.

Example: Second generation antidepressants have multiple MOA as preferred options (i.e., SSRI, SNRI, and aminoketone).

#### New-to-market medication with class not on PDL

• If the new-to-market medication's class/category is not on the preferred drug list (PDL), the documentation of medical necessity over older products in the same class is required along with a trial of at least 2 older products unless otherwise noted.

#### New-to-market medication with new formulation

- If the new-to-market medication is the same chemical entity as another medication already on the market but in a different dosage form, the existing dosage form must be tried first. If the original medication was a solid oral dosage form, the following scenarios would require a prior authorization with documentation of the medical necessity for the new formulation.
  - New-to-market is an oral, non-solid dosage form (may be considered in beneficiaries <7
    years of age or beneficiaries identified as NPO).</li>
  - New-to-market is an extended-release formulation.
  - New-to-market is a sprinkle formulation.

## New-to-market medication requiring a PA

- If the new-to-market medication is a novel product and/or requires extensive monitoring, a prior authorization will be required. The prescriber should submit the following for review:
  - Current chart notes and/or discharge summary
  - Documentation of all previous therapies tried with treatment timeframe and responses
  - o Current labs if warranted (e.g., oncology and hemophilia)
  - Letter of Medical Necessity outlining the rationale for this medication over others currently on the market
- Certain new-to-market medications reviewed by the DUR Board will defer to the FDA approved package insert and treatment guidelines (e.g., oncology)
- Once the new-to-market medication has been reviewed by the DUR Board, required criteria for approval will be consistent with the DUR Board vote. All new and renewal prior authorization requests will refer to the DUR Board approved criteria.
- Prior authorization requests for new-to-market medications that have not been reviewed by the DUR Board will be reviewed on a case-by-case basis using the manufacturer's package insert and treatment guidelines.

#### **EFFECTIVE JULY 19, 2023**

## 2) DAYBUE™ (trofinetide) 200 mg/mL solution

#### **APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Rett syndrome <u>OR</u> a diagnosis consistent with any new FDAapproved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a specialist with experience in Rett Syndrome (e.g., neurologist, geneticist) or prescriber must be in consultation with a specialist
- Provider must submit a detailed baseline clinical presentation of Rett syndrome including, but not limited to the following:
  - o Abnormal muscle tone/dystonia
  - Abnormal respiration pattern
  - Feeding difficulties
  - o Intellectual disability (i.e., I.Q. score < 70)
  - Loss of mobility or gait abnormalities
  - o Partial or complete loss of acquired hand skills
  - o Partial or complete loss of speech
  - Seizures
  - Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - o Moderate to severe renal impairment
  - o Intolerable diarrhea
  - No improvement in clinical presentation compared to baseline
  - Dose requested is not consistent with weight based dose recommendation
- Prescriber must submit <u>ALL</u> of the following:
  - Current chart notes with description of specific symptoms present in this beneficiary
  - o Documentation of the MECP2 mutation (if available)
  - o Attestation of a clinical diagnosis of RTT in the absence of a MECP2 mutation
  - Current weight
  - Current dose requested
  - o Current labs to determine renal function
  - o Treatment plan for severe diarrhea and weight loss
  - Baseline Rett Syndrome Behavior Questionnaire (RSBQ) and the Clinical Global Impressionimprovement (CGI-I) score if available
- Initial PA for 3 months

#### **RENEWAL REQUIREMENTS:**

- Beneficiary remains compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Prescriber must submit the following:
  - o Current chart notes with documentation of current clinical presentation
  - Current RSBQ and/or CGI-I if available
- Beneficiary continues to lack intolerable side effects
- Beneficiary must demonstrate an improvement in clinical presentation compared to baseline

### **QUANTITY EDITS:**

3600 mL per 30 days

#### **EFFECTIVE JULY 19, 2023**

## 3) JOENJA® (leniolisib) 70 mg tablet

#### **APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome
  (APDS) with a documented variant in either PIK3CD or PIK3R1 <u>OR</u> a diagnosis consistent with any
  new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a specialist with experience in APDS such as immunology, hematology/oncology, or pulmonology
- In addition to the APDS diagnosis, the beneficiary must demonstrate symptoms consistent with the diagnosis (e.g., sino-pulmonary infection, lymphoproliferation, enteropathy, organ dysfunction, etc.)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Pregnant
  - Weighs less than 45 kg
  - o Requires concomitant strong CYP3A4 inhibitors (e.g., itraconazole)
  - Requires concomitant moderate or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin)
  - Moderate to severe hepatic impairment
- Prescriber must submit ALL of the following:
  - Current chart notes with documentation of specific symptoms for this beneficiary and documentation of variant
  - Previous therapies including surgery
  - o Current negative pregnancy test for females of reproductive potential
  - Current weight
  - o MRI or CT imaging results documenting lesions with descriptions
  - Current labs including LFTs
  - Medical necessity over IVIG and sirolimus
  - Baseline % naïve B cell
- Initial PA for 3 months

#### **RENEWAL REQUIREMENTS:**

- Prescriber must submit ALL of the following:
  - o Prescriber must submit current chart notes
  - Response to therapy
- Beneficiary has a positive response with symptoms with documented decrease in lymph node lesions and/or increase in % naïve B cells

### **QUANTITY EDITS:**

#62/31 days

## **EFFECTIVE JULY 19, 2023**

4) VOWST™ (fecal microbiota spores, live-brpk) capsules

#### **APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Clostridioides difficile infection (CDI) following antibacterial treatment for recurrent CDI (rCDI) <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Beneficiary must have at least 3 separate confirmed *C difficile* infections within 12 months (definition of recurrent CDI) and given prior therapy with vancomycin and/or fidaxomicin. *C difficile* should be diagnosed based on positive diagnostic laboratory assay and typical manifestations with ≥ 3 loose stools in 24 hours.
- Beneficiary must have completed antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with VOWST
- Beneficiary must be prescribed magnesium citrate to take the day prior to beginning VOWST
- Beneficiary should not be approved if any of the following:
  - Prescribed concomitant antibacterial therapy
  - Does not meet the requirements for recurrent CDI
  - o Has not been treated with either vancomycin or fidaxomicin
- Prescriber must submit <u>ALL</u> of the following:
  - Current chart notes
  - Documentation of treatment for previous CDI episodes
  - o Previous laboratory assay results noting C difficile
  - o Medical necessity over vancomycin and fidaxomicin if have not been tried and failed
- PA for 1 claim

#### **QUANTITY EDITS:**

#12 per claim

### **EFFECTIVE JULY 19, 2023**

5) VEOZAH™ (fezolinetant) 45 mg tablet

#### **APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with menopause and experiencing moderate to severe vasomotor symptoms <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Documentation that moderate to severe vasomotor symptoms have been disruptive to daily life must be provided (e.g., sleep disruption, night sweats, daytime hot flashes, palpitations)
- Beneficiary must be confirmed as menopausal with 1 of the following:
  - o Spontaneous amenorrhea for ≥ 12 consecutive months
  - Spontaneous amenorrhea for ≥ 6 months with biochemical criteria of menopause (folliclestimulating hormone [FSH] > 40 IU/L); or
  - Having had bilateral oophorectomy ≥ 6 weeks prior to the screening visit.
- Beneficiary must have tried and failed hormone replacement therapy or have a contraindication to hormone replacement therapy
- Beneficiary should not be approved if any of the following:
  - o Has cirrhosis
  - o Has severe renal impairment or end-stage renal disease (eGFR < 30 mL/min/1.73m²)
  - Requires concomitant use with CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine)
- Prescriber must submit ALL of the following:
  - o Current chart notes
  - o Current labs including FSH level, LFTs, and CMP
  - Duration of symptoms
  - Medical necessity over hormone replacement therapy and other options supported in literature (i.e., SSRIs, SNRIs, anti-epileptics, clonidine)
- Initial PA for 3 months

#### RENEWAL REQUIREMENTS:

- Beneficiary has a documented improvement in symptoms
- Beneficiary is compliant on the medication (defined as 75% utilization)

- Prescriber must submit current chart notes with documentation of response
- Renewal PAs can be approved for 6 months

## **QUANTITY EDITS:**

#31/31 days

### 6) FRIENDLY REMINDERS

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

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

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 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: <a href="https://humanservices.arkansas.gov/divisions-shared-services/medical-services/">https://humanservices.arkansas.gov/divisions-shared-services/medical-services/</a>

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: <a href="https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/">https://afmc.org/health-care-professionals/arkansas-medicaid-providers/mmis-outreach-specialists/</a>

#### 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 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.

- 5. REGARDING MANUAL REVIEW PA REQUESTS: Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an exception to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the PDL, are all reviewed on a case-by-case basis through a manual review process. All manual review requests for prior authorization require, at a minimum, the prescriber to provide a letter explaining the medical necessity for the requested drug along with all written documentation to substantiate the medical necessity, e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc. Please note that starting the requested drug, including long-acting injectable antipsychotic agents, through either inpatient use, the use of office "samples", or by any other means, prior to a prior authorization request being reviewed and approved by the Medicaid Pharmacy Program does not necessitate Medicaid Pharmacy Program approval of the requested drug.
- 6. REGARDING EMERGENCY OVERRIDE: In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires prior authorization (e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug). This provision applies only in an emergency when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, and the pharmacist is not able to contact the prescribing provider to change the prescription. The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC 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, <a href="https://ar.magellanrx.com/provider-documents">https://ar.magellanrx.com/provider-documents</a>

## 7. HARD EDIT ON EARLY REFILL:

## Non-controlled drugs:

The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA, and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits or an approved PA must be in the system for the 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 was implemented January 20, 2021. This change includes opioids, CII stimulants, benzodiazepines, sedative hypnotics, etc.

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

#### Non-controlled drugs:

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

### **Controlled drugs:**

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

9. 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.

## 10. ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN:

### < 18 YEARS OF AGE:

Each new start of any antipsychotic agent for children < 18 years of age require a completed/signed informed consent form, current metabolic labs, and documentation of medical necessity with chart notes. Beneficiaries 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://ar.magellanrx.com/forms-documents

## < 10 YEARS OF AGE:

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

- 11. THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS FOR COVERED OUTPATIENT DRUGS FOR MEDICAID 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.
- 12. ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS)

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

https://ar.magellanrx.com/forms-documents

13. <u>OPIOID INFORMATION ON THE MAGELLAN WEBSITE:</u> 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. <a href="https://ar.magellanrx.com/provider-documents">https://ar.magellanrx.com/provider-documents</a>

## 14. HEPATITIS C TREATMENT INFORMATION

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

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

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

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

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

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

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