



Division of Medical Services
Pharmacy Program



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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: August 26, 2020

SUBJ: AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board July 15, 2020 meeting for the following: Manual review criteria for: Repatha®, Praluent®, Acthar® gel (repository corticotropin), Isturisa® (osilodrostat), Koselugo™ (selumetinib), Tukysa™ (tucatinib), Pemazyre™ (pemigatinib), Palforzia™ (peanut allergy powder), Tavegyl™ (levamisole), Retevmo™ (selpercatinib), Sunosi™ (solriamfetol), Wakix® (pitolisant) and Xyrem® (sodium oxybate).

Preferred Drug List (PDL) therapeutic classes from the August 12, 2020 Drug Review Committee Meeting for the following: Antidiabetic agents (oral, inhaled, injection and insulin), Antipsychotic long-acting injections, and PCSK9 inhibitors.

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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. OUTSIDE CONTACT WITH BOARD/COMMITTEE MEMBERS

Per the bylaws for the Drug Utilization Review board and Drug Review Committee, members of the board/committee should not be contacted by a member of the pharmaceutical industry or their representative on any agenda topic. Representatives would include lobbyists, patients or healthcare professionals.

Copied from the DUR board bylaws:

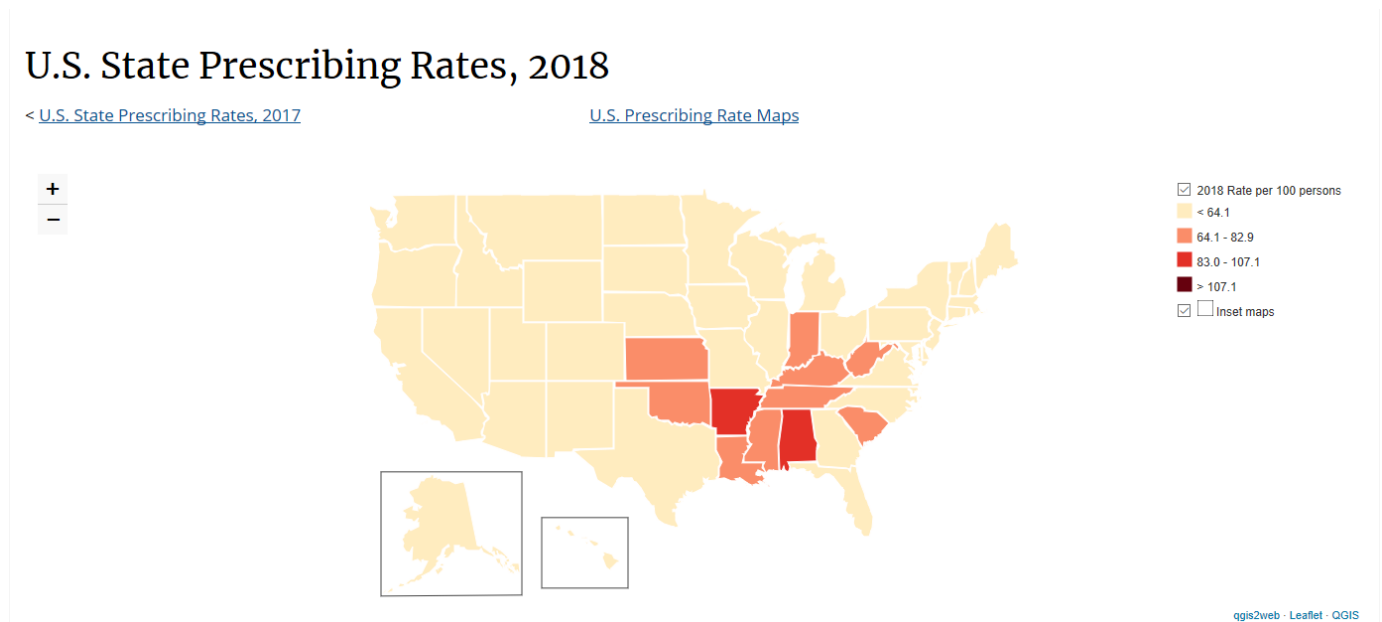
[To avoid the appearance of, or actual, conflicts of interest, DUR Board members shall not meet with pharmaceutical manufacturers, distributors or retailers or their representative with respect to any matters which are known to be under review by the DUR Board.](#)

Any correspondence should be made through the DUR/DRC chair, pharmacy program administrator or PDL clinical pharmacist. Any provided information will be forwarded to the board/committee members.

C. GUIDELINES FOR PRESCRIBING OPIOIDS

In the CDC drug surveillance report from 2017, Arkansas had the second highest rate of opioid prescriptions dispensed in the nation. The Arkansas rate was 105.4 opioid prescriptions per 100 people while the national average was only 58.5 prescriptions per 100 people. In Arkansas, our rate implies that enough opioid prescriptions were filled to allow every Arkansan to have received one.

<https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf>



Per the CDC recommendations for prescribing opioids for chronic pain:

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≈ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≈ 90 MME/day or carefully justify a decision to titrate dosage to ≈ 90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

For your convenience, below are links to the CDC website for opioid prescribing guidelines, national overdose data, instruction on calculating total MME/day and Arkansas take back website with additional useful information.

- 1) <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>
- 2) <https://www.cdc.gov/drugoverdose/index.html>
- 3) https://3ofxrg2wimd82awhm52p69u3-wpengine.netdna-ssl.com/wp-content/uploads/2020/03/calculating_total_daily_dose-a.pdf
- 4) <https://www.artakeback.org/media-center/resources/>

D. 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/>

EFFECTIVE OCTOBER 1, 2020:

II. PREFERRED DRUG LIST (PDL):

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

A. ANTIDIABETIC AGENTS

ALPHA-GLUCOSIDASE INHIBITORS

Preferred Agents

- Acarbose (generic for Precose®)

Non-preferred Agents

- Glyset® (miglitol)
- Miglitol (generic for Glyset®)
- Precose® (acarbose)

AMYLIN ANALOGUES

Non-preferred (manual review)

- Symlin® (pramlintide)

DPP4 INHIBITORS (manual review)

Preferred Agents

- Janumet® (sitagliptin/metformin)
- **Januvia® (sitagliptin)**
- **Tradjenta® (linagliptin)**
- **Onglyza® (saxagliptin)**

Non-preferred Agents

- **Alogliptin (generic for Nesina®)**
- **Alogliptin/metformin (generic for Kazano®)**
- **Alogliptin/pioglitazone (generic for Oseni®)**
- Glyxambi® (linagliptin/empagliflozin)
- Janumet® XR (sitagliptin/metformin extended release)
- Jentadueto® (linagliptin/metformin)
- Jentadueto® XR (linagliptin/metformin)
- Kazano® (alogliptin/metformin)
- Kombiglyze® XR (saxagliptin/metformin ER)
- Nesina® (alogliptin)
- Oseni® (alogliptin/pioglitazone)
- **Qtern® (saxagliptin/dapagliflozin)**
- **Steglujan® (sitagliptin/ertugliflozin)**
- **Trijardy® XR (linagliptin/empagliflozin/metformin ER)**

GLP-1 AGONISTS (manual review)

Preferred Agents

- Bydureon® pen/vial (exenatide ER)
- Byetta® pen (exenatide)

- Victoza® pen (liraglutide)

Non-preferred Agents

- Adlyxin™ injection (lixisenatide)
- Bydureon® BCise (exenatide ER)
- **Ozempic® injection (semaglutide)**
- **Rybelsus® tablet (semaglutide)**
- Soliqua® injection (lixisenatide/insulin glargine)
- Trulicity® pen (dulaglutide)
- Xultophy® injection (liraglutide/insulin degludec)

INSULINS

Rapid Acting Preferred

- Apidra SoloStar pen/vial (insulin glulisine)
- **Humalog U-100 cartridge (insulin lispro)**
- **Humalog U-100 Jr. KwikPen (insulin lispro)**
- Humalog U-100 vial (BRAND Only)/ KwikPen (BRAND Only) (insulin lispro)
- Novolog U-100 cartridge/FlexPen/vial (insulin aspart)

Rapid Acting Non-preferred

- Admelog SoloStar pen/vial (insulin lispro)
- Afrezza inhalation powder (insulin human)
- Fiasp vial/FlexTouch Pen/Penfill (insulin aspart)
- Humalog U-200 KwikPen (insulin lispro)
- **Insulin aspart cartridge/vial/FlexPen (generic for Novolog)**
- **Insulin lispro Jr. KwikPen (generic for Humalog)**
- Insulin lispro KwikPen/vial (generic for Humalog)
- Lyumjev pen/vial (insulin lispro-aabc)

Regular AND Intermediate Preferred

- **Humulin N U-100 vial OTC**
- Humulin R U-100 vial OTC
- **Humulin R U-500 KwikPen**
- Humulin R U-500 vial
- Novolin N U-100 vial
- **Novolin R U-100 vial OTC**

Regular AND Intermediate Non-preferred

- Humulin N KwikPen OTC
- **Novolin N U-100 FlexPen OTC**
- **Novolin R U-100 FlexPen OTC**

Long Acting Preferred

- Lantus SoloStar pen (insulin glargine)
- Lantus vial (insulin glargine)

- Levemir FlexTouch (insulin detemir)
- Levemir vial (insulin detemir)

Long Acting Non-preferred

- Basaglar KwikPen (insulin glargine)
- Soliqua® injection (insulin glargine/lixisenatide)
- Toujeo SoloStar pen (insulin glargine)
- Toujeo Max SoloStar pen (insulin glargine)
- Tresiba U-100 and U-200 FlexTouch (insulin degludec)
- Tresiba vial (insulin degludec)
- Xultophy® injection (insulin degludec/liraglutide)

Rapid/Intermediate Acting Combinations Preferred

- Humalog Mix KwikPen (insulin lispro/lispro protamine)
- Humalog Mix vial (insulin lispro/lispro protamine)
- Novolog Mix FlexPen (insulin aspart/aspart protamine)
- Novolog Mix vial (insulin aspart/aspart protamine)

Rapid/Intermediate Acting Combinations Non-preferred

- Insulin lispro Mix pen (generic for Humalog Mix)
- **Insulin aspart mix pen/vial (generic for Novolog Mix)**

Regular/Intermediate Acting Combinations Preferred

- Humulin 70/30 vial OTC
- **Humulin 70/30 KwikPen OTC**

Regular/Intermediate Acting Combinations Non-preferred

- **Novolin 70/30 vial OTC**
- **Novolin 70/30 FlexPen OTC**

MEGLITINIDES

Preferred Agents

- Nateglinide (generic for Starlix®)
- Repaglinide (generic for Prandin®)

Non-preferred Agents

- Repaglinide/metformin (generic for Prandimet®)
- Prandin® (repaglinide)
- Starlix® (nateglinide)

METFORMIN

Preferred Agents

- Metformin 500mg (generic for Glucophage®)
- Metformin 850mg (generic for Glucophage®)
- Metformin 1000mg (generic for Glucophage®)
- Metformin ER 500mg (generic for Glucophage® XR)
- Metformin ER 750mg (generic for Glucophage® XR)

Non-preferred Agents

- Fortamet® (metformin ER)
- Glucophage XR® (metformin ER)
- Glucophage® (metformin)
- Glumetza® (metformin ER)
- Metformin ER Gastric 500mg and 1000mg (generic for Glumetza®)
- Metformin ER Osmotic 500mg and 1000mg (generic for Fortamet®)
- Metformin solution (generic for Riomet®)
- Riomet® ER suspension (metformin ER)
- Riomet® solution (metformin)

SGLT2 INHIBITORS (manual review)

Preferred Agents

- Farxiga® (dapagliflozin)
- Jardiance® (empagliflozin)
- Synjardy® (empagliflozin/metformin)
- Xigduo® ER (dapagliflozin/metformin ER)

Non-preferred Agents

- Invokamet® (canagliflozin/metformin)
- Invokamet® XR (canagliflozin/metformin ER)
- Invokana® (canagliflozin)
- Segluromet™ (ertugliflozin/metformin)
- Steglatro™ (ertugliflozin)
- Synjardy® XR (empagliflozin/metformin ER)

SULFONYLUREAS

Preferred Agents

- Glimepiride (generic for Amaryl®)
- Glipizide (generic for Glucotrol®)
- Glipizide ER (generic for Glucotrol XL®)
- Glipizide/Metformin (generic for Metaglip®)
- Glyburide (generic for Diabeta®)
- Glyburide micronized (generic for Micronase®, Glynase®)
- Glyburide/Metformin (generic for Glucovance®)

Non-preferred Agents

- Amaryl® (glimepiride)
- Duetact® (glimepiride/ pioglitazone)
- Glucotrol®/Glucotrol XL® (glipizide)
- Glynase® (glyburide micronized)

THIAZOLIDINEDIONES (manual review)

Preferred Agents

- Pioglitazone (generic for Actos®)

Non-preferred Agents

- Actoplus Met® (pioglitazone/metformin)
- Actos® (pioglitazone)
- Avandia® (rosiglitazone)
- Duetact® (pioglitazone/glimepiride)
- Pioglitazone/glimepiride (generic for Duetact®)
- Pioglitazone/metformin (generic for Actoplus Met®)

B. ANTIPSYCHOTIC LONG-ACTING INJECTION

(ALL REQUIRE MANUAL REVIEW)

Preferred Agents with criteria

- 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 Sustenna® (paliperidone palmitate)**
- **Invega Trinza® (paliperidone palmitate)**
- Risperdal Consta® (risperidone microspheres)

Non-preferred Agents

- Perseris ER® (risperidone syringe kit)
- **Zyprexa Relprevv™ (olanzapine)**

Approval criteria:

- Absence of denial criteria
- All requests for recipients <18 years of age require manual review
- Manual review is required for all new therapy, and recipients >18 years of age must meet continuation criteria. If continuation criteria is not met at point-of-sale, a new prior authorization request is required.

Abilify Maintena®

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability
- Initiation of treatment after tolerability has been established requires 14 consecutive days of oral aripiprazole or another antipsychotic
- Continuation criteria: One paid claim for Abilify Maintena® in the past 45 days

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

- Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability
- 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
 - Administer 21 consecutive days of oral aripiprazole in conjunction with first Aristada® injection
- Continuation criteria:
 - One paid claim for Aristada® 441mg or 662mg in the past 45 days
 - One paid claim for Aristada® 882mg in the past 60 days

- One paid claim for Aristada® 1064mg in the past 75 days

Fluphenazine decanoate

- Requires previous history of a short-acting form of fluphenazine to assess tolerability
- Continuation criteria: One paid claim for fluphenazine decanoate in the past 45 days

Haloperidol decanoate

- Requires previous history of a short-acting form of haloperidol to assess tolerability
- Continuation criteria: One paid claim for haloperidol decanoate in the past 45 days

Invega Sustenna®

- Prior to approval must have taken oral paliperidone or oral or injectable risperidone to assess tolerability
- Continuation criteria: One paid claim for Invega Sustenna® in the past 45 days

Invega Trinza®

- Request requires adequate treatment of Invega Sustenna® for at least 4 months
- Requires completion of the Invega Trinza® form with each injection

Risperdal Consta®

- Prior to approval must have taken oral risperidone to assess tolerability
- Treatment requires concomitant oral risperidone or other antipsychotic medication for 3 weeks
- Continuation criteria: One paid claim for Risperdal Consta® in the past 45 days

Perseris®

- Prior to approval must have taken oral risperidone to assess tolerability
- Medical necessity over preferred long-acting injections must be established
- Continuation criteria: One paid claim for Perseris® in the past 45 days

Zyprexa Relprevv®

- Prior to approval must have taken oral olanzapine to assess tolerability
- Medical necessity over preferred long-acting injections must be established
- Continuation criteria: One paid claim for Zyprexa Relprevv® in the past 45 days

Denial criteria:

Therapeutic duplication with another long-acting antipsychotic in the past 23 days

C. PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 INHIBITORS

(ALL REQUIRE MANUAL REVIEW)

****See PA criteria below for both agents****

Non-preferred Agents

- Praluent® (alirocumab)
- Repatha® (evolocumab)

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

EFFECTIVE IMMEDIATELY:

1. Repatha® injection and Praluent® injection

REPATHA INDICATION:

1.1 Prevention of Cardiovascular Events

In adults with established cardiovascular disease, Repatha is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

1.2 Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia [HeFH])

Repatha is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

1.3 Homozygous Familial Hypercholesterolemia (HoFH)

Repatha is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with HoFH who require additional lowering of LDL-C.

PRALUENT INDICATION:

1.1 Prevention of Cardiovascular Events

Praluent is indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

1.2 Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia)

Praluent is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis consistent with FDA approved indications; **AND**
- Provider must submit current chart notes; **AND**
- Provider must submit chart notes during trials of statins **AND** ezetimibe; **AND**
- Compliance on previous lipid therapy is required unless contraindicated. Recipient's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance; **AND**
- Provider should submit current labs including lipids as well as labs corresponding with previous trials of statins **AND** ezetimibe taken concomitantly; **AND**
- Recipient should have an LDL-C ≥ 70 mg/dL and/or non-HDL-C ≥ 100 mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the recipient has a contraindication; **AND**
- Provider must submit diet plan for lowering cholesterol; **AND**
- If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; **AND**
- Initial approval for 2 months

DENIAL CRITERIA:

- Recipient does not have a diagnosis consistent with FDA approved indications; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**

- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe.

CONTINUATION CRITERIA:

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

QUANTITY EDITS:

- Repatha 140mg syringe/autoinjector—2 injections per month
- Repatha 420mg injection—1 injection per month
- Praluent 75mg syringe/pen—2 injections per month
- Praluent 150mg syringe/pen—2 injections per month

CRITERIA EFFECTIVE IMMEDIATELY; FORM EFFECTIVE AUGUST 26, 2020:

2. Acthar® gel

INDICATION:

Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. All other indications will be reviewed on a case-by-case basis.

APPROVAL CRITERIA:

- Recipient must be ≤ 2 years of age; **AND**
- Recipient must have a diagnosis for infantile spasms (West Syndrome) as indicated by:
 - Epileptic spasms; **AND**
 - Developmental problems; **AND**
 - Hypsarrhythmia on electroencephalography (EEG)
- Prior authorization request should be submitted prior to beginning Acthar if being hospitalized and sent again upon discharge; **AND**
- Provider must submit admission clinical notes with initial prior authorization request and discharge summary notes prior to discharge; **AND**
- Provider must submit current body surface area (BSA); **AND**
- Recipient has a history of previous vigabatrin (Sabril®) and corticosteroid usage with failure; **AND**
- Provider must complete the Acthar form with initial request and resubmit the form at time of discharge with specific taper directions; **AND**



Acthar PA form
071520 final.pdf

- PA will be approved at the time of discharge for the amount needed for completion of the taper. Recipients cannot fill Acthar as a pharmacy benefit and use during hospitalization.

DENIAL CRITERIA:

- Recipient has not trialed vigabatrin (Sabril®) and corticosteroids; **OR**
- Provider has not submitted all of the required information as outlined on the Acthar form; **OR**
- Provider intends to use Acthar purchased as a pharmacy benefit during an inpatient stay

AR MEDICAID DUR BOARD MEETING JULY 15, 2020

Arkansas Medicaid Prior Authorization Request Form
 H.P. Acthar® gel (corticotropin injection)
 Infantile Spasm

After completion of this form, please fax to the Arkansas Medicaid Pharmacy Unit. Fax: 1-800-424-5851
 For questions call: 1-501-683-4120.

AR MEDICAID ENROLLED PRESCRIBER ID NUMBER:	AR MEDICAID BENEFICIARY ID NUMBER:
Prescriber Name:	Beneficiary Name:
Address:	Address:
City: State: Zip:	City: State: Zip:
Phone: () Fax: ()	Patient's Date of Birth: / /
Pharmacy name:	If recipient is hospitalized, approved prior authorizations will be entered at the time of discharge for the quantity needed to complete the taper.
Phone: ()	

Is recipient ≤ 2 years of age? YES NO

Is this medication being prescribed by a neurologist? YES NO

Does the recipient have the diagnosis of Infantile Spasms? YES NO

Initial request for Infantile Spasms

- Should be made upon admission to the hospital to allow time for thorough review.
- Hospital use does not necessitate Medicaid approval of the PA request.
- Provider should submit the following for review:
 - Admission clinical notes
 - Documentation of previous therapies _____
 - Current BSA (m²) OR current height (cm) AND weight (kg) to allow for calculation of BSA _____
 - Expected taper plan with doses _____

Discharge request for Infantile Spasms

- Discharge clinical notes with documentation of number of doses received.
- Complete the following:

Initial Dose Schedule (Doses remaining after hospitalization)	Approval at Outpatient pharmacy will be based on volume needed at discharge from hospital	
75 U/m ² BID x _____ days	TOTAL _____ mL x _____ # days (Total to complete initial dosing)	
Dose Taper Schedule	Body Surface Area (BSA)	
30 U/m ² QD x _____ days	_____ mL x _____ days	Weight: _____ kg
15 U/m ² QD x _____ days	_____ mL x _____ days	Height/Length: _____ cm
10 U/m ² QD x _____ days	_____ mL x _____ days	Calculated BSA: _____ m ²
10 U/m ² QOD x _____ days	_____ mL x _____ days	Total number vials needed _____

Prescriber Signature: _____ Date: _____

Prescriber's original signature required; copied, stamped, or e-signature are not allowed. By signature the prescriber confirms the criteria information above is accurate and verifiable in recipient records.

****Please note that all information attested to herein is subject to Medicaid review and audit.*****

V071520

EFFECTIVE IMMEDIATELY:

3. Isturisa® (osilodrostat) 1 mg, 5 mg, and 10 mg tablets

INDICATION:

Cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

APPROVAL CRITERIA:

- Recipient \geq 18 years of age; **AND**
- Diagnosis of Cushing's disease and pituitary surgery AND/OR pituitary radiation are not options or have not been curative **OR** diagnosis consistent with FDA indication; **AND**
- Prescriber must be an endocrinologist; **AND**
- Prescriber must provide the following:
 - Current chart notes with documentation of surgery status; **AND**
 - Current labs including:
 - Urine free cortisol levels (normal is <150 nmol/24 hours OR 3.5-45mcg/24 hours); **AND**
 - Liver function tests; **AND**
 - Comprehensive metabolic panel; **AND**
 - Baseline electrocardiogram; **AND**
 - Assessment for Adrenalectomy
- Recipient should have a trial and failure of ketoconazole and mitotane unless contraindicated or recipient cannot tolerate both medications; **AND**
- Current labs should indicate the recipient does not have hypokalemia or hypomagnesemia; **AND**
- Recipients with risk factors for QT prolongation should have more frequent ECG monitoring.

DENIAL CRITERIA:

- Recipient does not meet the approval criteria; **OR**
- Dose requested is > 30 mg twice daily; **OR**
- Recipient has not trialed ketoconazole and mitotane OR had a contraindication or intolerance to both medications; **OR**
- Recipient is showing symptoms of adrenal insufficiency

CONTINUATION CRITERIA:

- Prescriber should submit current chart notes; **AND**
- Previously requested labs; **AND**
- ECG results of any recent tests; **AND**
- Recipient should indicate a positive response with a decrease in urine free cortisol levels and decrease in symptoms

QUANTITY EDITS:

- Due to titration and variety of doses, do not recommend quantity edits on 1 mg and 5 mg
- 10 mg tablets — #180/30 days

EFFECTIVE IMMEDIATELY:

4. Koselugo™ (selumetinib) 10 mg and 25 mg capsules

INDICATION:

Koselugo is a kinase inhibitor indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

APPROVAL CRITERIA:

- Recipient must be ≥ 2 years of age; **AND**
- Recipient must have a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **OR** diagnosis consistent with FDA indications; **AND**
- Recipient must have at least one measurable PN measuring at least 3 cm **AND** either a positive genetic test for NF1 **OR** have at least one other diagnostic criterion listed below:
 - 6 or more café-au-lait macules; **OR**
 - Freckling in axilla or groin; **OR**
 - Optic glioma; **OR**
 - 2 or more Lisch nodules; **OR**
 - Distinctive bony lesion; **OR**
 - First-degree relative with NF1
- Provider should submit the following:
 - Current chart notes with status of plexiform neurofibromas; **AND**
 - Current baseline left ventricular ejection fraction (LVEF); **AND**
 - Documentation of comprehensive ophthalmic assessment; **AND**
 - Current labs including serum CPK, baseline INR, CBC, and LFTs; **AND**
 - ANC $\geq 1500/\mu\text{L}$
 - Hemoglobin $\geq 9\text{g/dl}$
 - Platelets $\geq 100,000/\mu\text{L}$
 - Current body surface area (BSA)—no recommended dosage for recipients with BSA $< 0.55\text{m}^2$.
- Prescriber should provide plan for monitoring patients that require coadministration with vitamin-K antagonists or platelet antagonists; **AND**
- Initial PA for 3 months.

DENIAL CRITERIA:

- Recipient does not meet age requirement; **OR**
- Recipient does not have a diagnosis consistent with FDA approved indications; **OR**
- Recipient has disease progression or unacceptable toxicity and is unable to tolerate after 2 dose reductions; **OR**
- Recipient is unable to swallow a whole capsule; **OR**
- Recipient's BSA is $< 0.55\text{m}^2$; **OR**
- Recipient has retinal vein occlusion; **OR**
- Recipient has symptomatic or Grade 3 or 4 decreased LVEF; **OR**
- Recipient has Grade 4 diarrhea or Grade 3 or 4 colitis; **OR**
- Recipient has rhabdomyolysis; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is pregnant; **OR**
- Recipient is not using birth control when has reproductive potential; **OR**

- If recipient requires strong or moderate CYP3A4 inducers, Koselugo should be avoided; strong or moderate CYP3A4 inhibitors require dose decrease for Koselugo.

CONTINUATION CRITERIA:

- Provider should submit the following:
 - Documentation of ejection fraction assessed every 3 months for the first year; **AND**
 - Documentation of current labs including serum CPK, INR, CBC and LFTs; **AND**
 - Current chart notes with documentation of response to therapy; **AND**
 - Documentation of current BSA; **AND**
 - Current required dosage
- Recipient should continue contraception unless has no reproductive potential; **AND**
- Recipient should show improvement with the plexiform neurofibromas.

QUANTITY EDITS:

- 10 mg capsule — #270/30 days
- 25 mg capsule — #120/30 days

EFFECTIVE IMMEDIATELY:

5. Tukysa™ (tucatinib) 50 mg and 150 mg tablets

INDICATION:

Tukysa is a kinase inhibitor indicated in combination with trastuzumab (Herceptin®) and capecitabine (Xeloda®) for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have the diagnosis of advanced unresectable or metastatic HER2-positive breast cancer with at least one treatment in history and taking trastuzumab with capecitabine **OR** diagnosis consistent with FDA indications; **AND**
- Recipient must have previously received trastuzumab (Herceptin), pertuzumab (Perjeta®) and ado-trastuzumab emtansine (T-DM1) (Kadcyla®) separately or in combination; **AND**
- Recipient should have no history of failure with other TKIs specific for HER2-positive breast cancer (i.e. neratinib and lapatinib); **AND**
- Prescriber should submit the following:
 - Current chart notes with documentation of previous therapies; **AND**
 - Documentation that the recipient is taking trastuzumab (Herceptin) and capecitabine (Xeloda); **AND**
 - Current labs including CBC, renal function, and LFTs; **AND**
 - Pregnancy test results for recipient with child-bearing potential;
- Prescriber should add anti-diarrheal medication to recipient medication list for use as needed (81% of patients develop some grade of diarrhea); **AND**
- Prescriber should advise females of reproductive potential to use effective contraception as well as female partners of male patients.
- Initial PA for 1 month.

DENIAL CRITERIA:

- Recipient does not meet the above approval requirements; **OR**
- Recipient cannot tolerate the minimum dose of 150 mg twice daily; **OR**
- Recipient has history of failure with other TKIs specific for HER2-positive breast cancer (i.e. neratinib and lapatinib);
- Recipient is pregnant or breastfeeding; **OR**
- Recipient must be able to swallow pills; **OR**
- Recipient has Grade 4 diarrhea; **OR**
- Recipient has either one of the following:
 - Grade 4 ALT or AST (>20X ULN) OR Grade 4 Bilirubin (>10X ULN); **OR**
 - ALT or AST >3X ULN AND Bilirubin >2X ULN
- Recipient requires a strong CYP3A inducer (e.g. rifampin or phenytoin), moderate CYP2C8 inducer (e.g. rifampin) or a strong CYP2C8 inhibitor (e.g. gemfibrozil)—if unavoidable, dose may need to be adjusted; **OR**
- Recipients with severe renal impairment (CrCl < 30mL/min) because these patients should not take capecitabine.

CONTINUATION CRITERIA:

- Recipient has no evidence of disease progression or unacceptable toxicity; **AND**
- Provider should submit the following:
 - Current chart notes with documentation of response to therapy; **AND**
 - Documentation that recipient continues taking trastuzumab and capecitabine; **AND**
 - Current labs including CBC, renal function, and LFTs; **AND**
- Recipient is not pregnant or breastfeeding.

QUANTITY EDITS:

- 50 mg tablets — #120/30 days
- 150 mg tablets — #120/30 days

EFFECTIVE IMMEDIATELY:

6. Pemazyre™ (pemigatinib) 4.5 mg, 9 mg, and 13.5 mg tablets

INDICATION:

Pemazyre is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test OR diagnosis consistent with FDA indications; **AND**
- Recipient has progressed after at least 1 failed prior systemic therapy. Provide the medical necessity of pemigatinib over FOLFOX. (NCCN guidelines currently recommend FOLFOX as preferred therapy after progression with gemcitabine/cisplatin. But FOLFOX does not have current

data about the specific FGFR2 fusion mutation.) Provide documentation of that therapy including any radiation with response; **AND**

- Prescriber should submit the following:
 - Current chart notes with previous therapies tried; **AND**
 - Documentation of FGFR2 fusion or other rearrangement; **AND**
 - Current labs including serum phosphate (initiate phosphate lowering therapy if >7mg/dL with reduction in dose), CBC, LFTs; **AND**
 - Documentation of comprehensive ophthalmological exam; **AND**
 - Pregnancy test results for recipient with child-bearing potential.
- Initial PA for 2 months.

DENIAL CRITERIA:

- Recipient does not meet the above approval requirements; **OR**
- Recipient is unable to tolerate 4.5 mg once daily; **OR**
- Recipient has persistent symptoms for Retinal Pigment Epithelial Detachment (RPED); **OR**
- Recipient has continued serum phosphate >10mg/dL despite 2 dose reductions; **OR**
- Recipient requires concomitant strong or moderate CYP3A inhibitors (e.g. itraconazole, erythromycin, verapamil); if cannot be avoided, reduce Pemazyre dose; **OR**
- Recipient has not failed previous systemic therapy, and the medical necessity over FOLFOX was not provided; **OR**
- Recipient is pregnant.

CONTINUATION CRITERIA:

- Recipient must lack disease progression or unacceptable toxicity; **AND**
- Prescriber should submit the following:
 - Follow-up ophthalmological exam every 2 months for first 6 months and every 3 months thereafter; **AND**
 - Current chart notes with response to therapy; **AND**
 - Current labs including serum phosphate; **AND**
- Recipient is not pregnant or breastfeeding.

QUANTITY EDITS:

- 4.5 mg tablets — #14/21 days
- 9 mg tablets — #14/21 days
- 13.5 mg tablets — #14/21 days

7. Palforzia™

- Discussion was tabled to allow time for gathering additional information.

EFFECTIVE IMMEDIATELY:

8. Tabrecta™ (capmatinib) 150 mg and 200 mg tablets

INDICATION:

Tabrecta is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

APPROVAL CRITERIA:

- Recipient must be \geq 18 years of age; **AND**
- Recipient has been diagnosed with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber should submit the following:
 - Current chart notes with previous therapies tried; **AND**
 - Current labs including LFTs and CBCs; **AND**
 - Documentation of MET exon 14 skipping mutation; **AND**
- Recipient must have a negative status for epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; **AND**
- If Tabrecta™ must be co-administered with a P-gp substrate (e.g. digoxin) or BCRP substrate (e.g. rosuvastatin), prescriber should submit a plan for dosage decreases of the substrates; **AND**
- Initial PA may be approved for 3 months.

DENIAL CRITERIA:

- Recipient is unable to tolerate the minimum dose of 200 mg twice daily; **OR**
- Recipient has EGFR mutations or ALK-positive rearrangement; **OR**
- Recipient has Interstitial Lung Disease/Pneumonitis; **OR**
- Recipient has Grade 4 increase in AST and/or ALT without elevated bilirubin **OR** ALT and/or AST $>3X$ ULN with bilirubin $>2X$ ULN **OR** Grade 4 increase in bilirubin without elevated AST and/or ALT; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires coadministration with a moderate or strong CYP3A inducer (e.g. bosentan, rifampin or phenytoin); **OR**
- Recipient has disease progression on this medication

CONTINUATION CRITERIA:

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

QUANTITY EDITS:

- 150 mg tablet — #120/30 days
- 200 mg tablet — #120/30 days

EFFECTIVE IMMEDIATELY:

9. Retevmo™ (selpercatinib) 40 mg and 80 mg capsules

INDICATION:

Retevmo is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic REarranged during Transfection (RET) fusion-positive non-small cell lung cancer (NSCLC)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy

- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

APPROVAL CRITERIA:

- Recipient with diagnosis of NSCLC must be ≥ 18 years of age and with diagnosis of thyroid cancer must be ≥ 12 years of age; **AND**
- Recipient must have a diagnosis of either metastatic RET Fusion-positive NSCLC, advanced or metastatic RET-Mutant Medullary Thyroid Cancer requiring systemic therapy or advanced or metastatic RET Fusion-Positive Thyroid Cancer who are refractory to radioactive iodine (if radioactive iodine is appropriate) **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
 - Current labs including CBC, BMP, LFTs and TSH; **AND**
 - Current chart notes with documentation of diagnosis and previous therapies including radioactive iodine in RET Fusion-Positive Thyroid Cancer; **AND**
 - Documentation with the presence of a RET gene fusion or RET gene mutation; **AND**
 - Baseline ECG; **AND**
 - Current blood pressure; **AND**
- Recipient must be able to swallow pills; **AND**
- Hypokalemia, hypomagnesemia and hypocalcemia should be corrected prior to treatment and if developed during treatment; **AND**
- Initial PA would be approved for 1 month; once recipient demonstrates tolerability the PA can be approved for 3 months.

DENIAL CRITERIA:

- Recipient does not meet approval criteria; **OR**
- Recipient has been unable to tolerate Retevmo after 3 dose reductions (40 mg per day if <50 kg and 40 mg twice daily if >50 kg); **OR**
- Recipient has Grade 4 or uncontrolled hypertension; **OR**
- Recipient has Grade 4 QT Interval prolongation; **OR**
- Recipient has severe or life-threatening hemorrhagic events; **OR**
- Recipient should avoid strong and moderate CYP3A inhibitors (e.g. ketoconazole, clarithromycin or verapamil). Retevmo dose must be decreased if concomitant use is required; **OR**
- Recipient requires concomitant use of a proton pump inhibitor, histamine-2 receptor antagonist or locally acting antacid that cannot be taken at a separate time from Retevmo; **OR**
- Recipient with severe hepatic impairment requires dose decrease; **OR**
- Recipient is pregnant or breastfeeding.

CONTINUATION CRITERIA:

- Recipient does not demonstrate disease progression or unacceptable toxicity; **AND**
- Prescriber should submit the following:
 - Current chart notes with response to therapy; **AND**
 - Current labs including CBC, BMP and LFTs; **AND**
 - TSH levels and repeated ECG provided periodically; **AND**
 - Current blood pressure; **AND**
- Recipient is not pregnant or breastfeeding.

QUANTITY EDITS:

- 40 mg capsules — #180/30 days
- 80 mg capsules — #120/30 days

EFFECTIVE IMMEDIATELY:

10. Sunosi™ (solriamfetol) 75 mg and 150mg tablets

INDICATION:

- Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).
- Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA) **OR** diagnosis consistent with FDA indications. 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; **AND**
- Recipient must have a documented trial and failure of CII and CIII stimulants in the last year; **AND**
- Recipient profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy; **AND**
- Prescriber should submit the following for initial request for **narcolepsy**:
 - Most recent polysomnogram (PSG) results; **AND**
 - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
 - Mean sleep latency of less than 8 minutes per nap; **AND**
 - 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); **AND**
 - Current chart notes; **AND**
 - Baseline Epworth Sleepiness Scale (ESS); **AND**
- Prescriber should submit the following for initial request for **obstructive sleep apnea (OSA)**:
 - Most recent polysomnogram (PSG) results; **AND**
 - Current chart notes; **AND**
 - Documentation of plan for monitoring compliance of positive airway treatment; **AND**
 - CPAP or BiPAP usage report for documentation of compliance for at least 1 month.

DENIAL CRITERIA:

- Recipient does not have a confirmed diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea based on sleep study results; **OR**
- Recipient has not had a PSG for OSA diagnosis **OR** PSG and MSLT for narcolepsy diagnosis; **OR**
- Prescriber has not demonstrated the medical necessity over preferred CII or CIII stimulants; **OR**
- Recipient has not been compliant in using their CPAP or BiPAP before beginning therapy for excessive daytime sleepiness or after beginning therapy.

CONTINUATION CRITERIA:

- Prescriber should submit the following:
 - Current chart notes with documentation of response to therapy; **AND**
 - Current Epworth Sleepiness Scale (ESS); **AND**
 - Current CPAP or BiPAP usage report if has OSA diagnosis (recipient must remain compliant on positive airway pressure treatment); **AND**

- Recipient must demonstrate improvement in excessive daytime sleepiness and decreased ESS score.

QUANTITY EDITS:

- 75 mg tablet — #30/30 days
- 150 mg tablet — #30/30 days

EFFECTIVE IMMEDIATELY:

11. Wakix® (pitolisant) 4.45 mg and 17.8 mg tablet

INDICATION:

Wakix is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of excessive daytime sleepiness associated with narcolepsy **OR** diagnosis consistent with FDA indications. 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; **AND**
- Recipient profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy; **AND**
- If recipient is of child-bearing potential and on hormonal contraceptives, they should use alternative non-hormonal contraception; **AND**
- Recipient must have a documented trial and failure of CII and CIII stimulants in the last year; **AND**
- Recipient must have a documented trial of solriamfetol (Sunosi) in the last year; **AND**
- Prescriber should submit the following for initial request for narcolepsy:
 - Most recent polysomnogram (PSG) results; **AND**
 - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
 - Mean sleep latency of less than 8 minutes per nap; **AND**
 - 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); **AND**
 - Current chart notes; **AND**
 - Current labs including those for liver and renal function; **AND**
 - Baseline Epworth Sleepiness Scale; **AND**
 - Baseline ECG

DENIAL CRITERIA:

- Recipient does not have a confirmed diagnosis of excessive daytime sleepiness associated with narcolepsy; **OR**
- Recipient has not had a PSG and MSLT for narcolepsy diagnosis; **OR**
- Prescriber has not demonstrated the medical necessity over preferred CII or CIII stimulants; **OR**
- Recipient has billed pharmacy claims for benzodiazepines or opioids in the last 60 days; **OR**
- Recipient has severe hepatic impairment; **OR**
- Recipient has end stage renal disease; **OR**
- Recipient has known QT interval prolongation or requires other medications that prolong the QT interval.

CONTINUATION CRITERIA:

- Prescriber should submit the following:
 - Current chart notes with documentation of response to therapy; **AND**
 - Current Epworth Sleepiness Scale; **AND**
- Recipient must demonstrate improvement in excessive daytime sleepiness and decreased ESS score.

QUANTITY EDITS:

- 4.45 mg tablets— #60/30 days
- 17.8 mg tablets— #60/30 days

EFFECTIVE IMMEDIATELY:

12. Xyrem® (sodium oxybate)

INDICATION:

Xyrem is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

APPROVAL CRITERIA:

- Recipient must be ≥ 7 years of age; **AND**
- Recipient has a diagnosis of narcolepsy with cataplexy or narcolepsy with excessive daytime sleepiness (EDS). Requests for any other diagnosis will be reviewed on a case-by-case basis; **AND**
 - Recipient ages ≥ 7 years and < 18 years must have a trial of a CII stimulant in the last year
 - Recipient ≥ 18 years
 - Trial and failure of CII stimulant in the last year; **AND**
 - Trial and failure of CIII stimulant (modafinil or armodafinil) in the last year; **AND**
 - Trial and failure of solriamfetol (Sunosi) in the last year; **AND**
 - Trial and failure of pitolisant (Wakix) in the last year
- Prescriber, pharmacy and recipient must be enrolled in the Xyrem REMS program; **AND**
- Prescriber should submit the following for initial request:
 - Most recent polysomnogram (PSG) results; **AND**
 - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
 - Mean sleep latency of less than 8 minutes per nap; **AND**
 - 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) ; **AND**
 - Current labs including LFTs; **AND**
 - Current chart notes; **AND**
 - Baseline Epworth Sleepiness Scale (ESS) Score for recipients with excessive daytime sleepiness associated with narcolepsy; **AND**
 - Baseline description of cataplexy events for recipients with cataplexy diagnosis; **AND**
 - Letter explaining the medical necessity of receiving Xyrem.

DENIAL CRITERIA:

- Recipient does not meet the above approval criteria; **OR**
- Recipient has pharmacy claim(s) for sedative hypnotic agents in the last 30 days; **OR**
- Recipient has a documented diagnosis of drug or alcohol abuse in the last two (2) years; **OR**
- Recipient has a documented history of a suicide attempt in the last two (2) years; **OR**
- Recipient does not have a documented response to this medication.

CONTINUATION CRITERIA:

- Recipient must have a documented positive response
 - For narcolepsy with cataplexy—must demonstrate a decrease in cataplexy events.
 - For narcolepsy with excessive daytime sleepiness—must have an improvement in daily function and ESS.
- Prescriber must submit the following:
 - Current chart notes; **AND**
 - Current ESS for recipients with EDS; **AND**
 - Current description of cataplexy events (if applicable); **AND**
 - Current labs

QUANTITY EDITS:

- 540 ml (3 bottles) per 30 days

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/contact-us>

2. **MAT (Medication Assisted Treatment) with buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40: "Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care.* As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities. 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, in Part 5: Buprenorphine, Summary of Recommendations, # (5) "Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder."
<https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

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 FOR CONTROLLED AND 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.
9. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** Beginning February 16, 2016, 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. Once the beneficiary has accumulated an “extra” 15 days’ supply for that GSN, any incoming claim that is early will reject at point of sale. For example, if the prescription drug claim was for a 30-day supply and was filled 7 days early on February 16, 2016, and filled 7 days early again on March 10, 2016, the beneficiary can only refill the prescription 1 day early on the next refill date, which would be April 8, 2016 (1 day early). The accumulation edit is set so that the beneficiary cannot accumulate *more than an extra* 15 days’ supply early during a 180-day period. In this example, the drug claim cannot be filled early again until *after* August 14, 2016, which is 180 days from the February 16, 2016 date.

Effective August 8, 2018, the RTS logic with Early Refill Accumulation Limited edit was revised for the **non-controlled drugs** which now **allow an accumulation of 12 days’ supply during the previous 180-day period.**

Effective February 14, 2018, the RTS logic with Early Refill Accumulation Limit edit is **revised for the controlled drugs.** The revised edit for **controlled drugs** will only allow an extra 7-days’ supply accumulation through early fills in previous 180-day period rather than an accumulation of an extra 15-days’ supply. The RTS logic with Early Refill Accumulation Limit edit for non-controlled drugs will remain as is. Early refills for both controlled drugs and non-controlled drugs will continue to be monitored and may be adjusted in the future to reduce misuse.

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 has been updated (v072914) and is posted on the Medicaid website. As the form is updated and posted on the Medicaid website, providers are required to use the most current form. Effective, Dec. 10, 2013, the old versions will no longer be accepted.

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/> A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website: https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

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

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

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

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

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.

AR MEDICAID DUR BOARD MEETING JULY 15, 2020

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.