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| dhs | Division of Medical ServicesPharmacy Program | Detailed color version of the Great Seal of the State of Arkansas. |
| P.O. Box 1437, Slot S415 · Little Rock, AR 72203-1437Phone: 501-683-4120 · Fax: 1-800-424-5851 |

**MEMORANDUM**

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Jason Derden, Pharm.D. Division of Medical Services Pharmacy Program 

DATE: **AUGUST 30, 2018**

SUBJ: **AR Medicaid** **Prior Authorization Edits Approved at the AR Medicaid DUR Board JULY 18, 2018 meeting for the following:** Criteria Changes For MAT Drugs, EMFLAZA™ (deflazacort), mycophenolate, Codeine C&C products, Opioid & Benzodiazepine Drug Criteria Regarding Non-Fatal Poisoning Diagnoses; New criteria for AIMOVIG™ (erenumab-aooe), JYNARQUE™ (tolvaptan), LUCEMYRA™ (lofexidine), PALNZIQ™ (pegvaliase-pqpz), SYMDEKO™ (tezacaftor and ivacaftor)

**New Preferred Drug List (PDL) Drugs Approved at the AUGUST 8, 2018 Drug Review Committee Meeting include the following:** Drugs for TreatingOpioid Use Disorder (OUD); cystine-depleting agents;

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All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at <https://arkansas.magellanrx.com/provider/documents>/ Select “Resources” tab at the top right, then select “Documents” from the drop-down box. All Provider Memos are under the “Pharmacy” tab at the top.

*Medicaid Pharmacy Program drug reimbursement rate methodology changed April 1, 2017; reimbursement rates stated in this memo are informational only and are only current as of the date the memo was drafted; the rates stated are approximate as they may have been rounded.*

## ANNOUNCEMENT: Humira® (adalimumab) point of sale (POS) criteria change delay for Adult Crohn’s Disease and Adult Ulcerative Colitis

Revised Humira® POS approval criteria have been delayed and will be effective November 1, 2018. Please see the Medicaid Provider Memo dated May 31, 2018 for complete details regarding the revised criteria. New Humira® NDCs are being incorporated into the revised POS approval criteria and are available through manual review prior authorization until the POS approval criteria has been completed.

## REMINDER: Morphine Milligram Equivalents (MME) Final Reduction November 14, 2018:

The final MME will be reduced to ≤90 MME/day on November 14, 2018. The beneficiaries with a cancer diagnosis in Medicaid medical diagnosis history are excluded from the MME edit.

## REMINDER: OPIOID-NAÏVE Medicaid Beneficiaries and How the Edits Work:

**Effective MARCH 14, 2018**, for all *non-cancer* Medicaid beneficiaries, the Medicaid system will search the Medicaid drug claims history to determine if the beneficiary filled an opioid medication in the previous 60 days. *If there is no opioid drug claim in previous 60 days* the system considers the beneficiary to be “opioid-naïve” and *all* of the following criteria apply:

* The daily MME cannot exceed 50 MME/day; AND
* The days’ supply cannot exceed a 7-day supply; AND
* The maximum quantity per day for *any* short-acting opioid medication prescription for any beneficiary cannot exceed 6 units per day, even for the lower MME/day drugs;

**Example 1)**. A prescription is presented for oxycodone 10 mg/acetaminophen 325 mg, for a quantity of 30 tablets for a Medicaid beneficiary who has never received an opioid prescription:

The Medicaid maximum allowed MME/day is 50 MME/day for an opioid-naïve beneficiary. For this prescription, the MME for one tablet is 15 MME; 50 MME divided by 15 MME per tablet = 3.33 tablets per day for 50 MME/day;

A 7-day supply is the Medicaid maximum days supply allowed for an opioid-naïve beneficiary. 3.33 tablets per day, multiplied by a 7 day supply = 23 tablets; A quantity of 23 tablets is the maximum quantity allowed for this example for this strength tablet; the quantity written for #30 EXCEEDS the maximum MME/day allowed for an opioid-naïve Medicaid beneficiary;

The maximum Medicaid quantity per day for any short-acting opioid medication at any time is 6 units per day; *however*, the high strength and therefore high MME/day for this medication will not allow 6 units per day without exceeding the MME limit for an opioid-naïve beneficiary. For this example, given the high MME per tablet, the maximum Medicaid quantity allowed for this prescription example is a quantity of 23 tablets for the 7-day supply.

**Example 2)**. A prescription is presented for hydrocodone 5 mg/acetaminophen 325 mg, for a quantity of 30 tablets for a Medicaid beneficiary who has never received an opioid prescription:

The Medicaid maximum allowed MME/day is 50 MME/day for an opioid-naïve beneficiary. For this prescription, the MME for one tablet is 5 MME; 50 MME divided by 5 MME per tablet = 10 tablets per day; however, 10 tablets per day EXCEED the allowed quantity per day for any short-acting opioid drugs for any prescription;

A 7-day supply is the maximum Medicaid days supply allowed for an opioid-naïve beneficiary. Medicaid will allow up to 6 units per day for any short-acting opioid drug claim, and this lower MME strength short-acting opioid would meet the 6 units per day quantity limit if the prescription were written for 42 tablets.

The maximum Medicaid quantity per day for any short-acting opioid medication is 6 units per day. Hydrocodone 5 mg/APAP 325 mg is 5 MME per tablet and 5 MME per tablet multiplied by 6 units per day would be 30 MME per day, which would be within the Medicaid allowed MME/day for an opioid-naïve beneficiary. The prescription is written for a quantity of 30 tablets and depending on the instructions written by the prescriber the prescription could be a 5 to 7 day supply (quantity of 30 tablets @ 6 units per day = 5 day supply). The drug claim for the 30 tablets will pass the Medicaid edits for a 5 day to 7 day supply for the opioid-naïve beneficiary.

**Example 3)**. A prescription is presented for hydrocodone 10 mg/APAP325 mg, for a quantity of 40 tablets for an opioid-naïve Medicaid beneficiary.

The Medicaid maximum allowed MME/day is 50 MME/day for an opioid-naïve beneficiary. For this prescription, the MME for one tablet is 10 MME; 50 MME divided by 10 MME per tablet = 5 tablets per day would be allowed for this high MME short-acting opioid tablet.

A 7-day supply is the maximum Medicaid days supply allowed for an opioid-naïve beneficiary. 5 tablets per day, multiplied by a 7 day supply = 35 tablets; 35 tablets is the maximum Medicaid quantity allowed for this high MME per tablet short-acting opioid drug for an opioid-naïve beneficiary. A quantity written for 40 tablets EXCEEDS the maximum MME/day allowed for an opioid-naïve Medicaid beneficiary.

The maximum Medicaid quantity per day for any short-acting opioid medication is 6 units per day. Hydrocodone 10mg/APAP 325 mg is 10 MME per tablet. Medicaid will allow up to 6 units per day for any short-acting opioid medication; however, because the MME/day cannot exceed 50 MME/day, only 5 units per day is the Medicaid limit, multiplied by a 7 day supply = 35 tablets is the maximum Medicaid quantity that can be dispensed for this short-acting opioid due to the high MME per tablet and the maximum of a 7-day supply for an opioid-naïve beneficiary. The prescription is written for #40 tablets; however, only 35 tablets will pass the Medicaid opioid-naive quantity and MME limits for the 7-day supply.

## ANNOUNCEMENT: Accessing AR Medicaid Pharmacy Program Provider Memos

*To reduce paper waste*, only the Table of Contents section of the October/November 2018 Medicaid Pharmacy Program Provider Memo will be mailed to enrolled prescribing providers and pharmacy providers with the full memo available on the Medicaid Pharmacy Program website. (See below) Beginning January 1, 2019, there will be no mailed Pharmacy Program Provider Memos and an electronic RA 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 AR Medicaid Pharmacy Program.

The AR Medicaid Pharmacy Program Provider Memos can be found at this link, <https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx>, then select **OTHER LINKS** **drop down box** at upper left, select **MAGELLAN MEDICAID ADMINISTRATION**, select the **Administrator box**, select **RESOURCES dropdown arrow** at upper right, Select **Documents**, Select **PHARMACY tab** in the top row of tabs, select **MEMORANDUMS**. The Memo can also be found at: <https://arkansas.magellanrx.com/provider/documents/>, select the **Pharmacy tab** and then select **Memorandums**.

The **Ctrl F** key will allow the user to search for a key word. Beginning with the January 2018 memo and forward, the online version for the Provider Memos contain active hyperlinks in the Table of Contents: open the Provider Memo and hover the mouse over the Table of Contents, press Ctrl on the computer keyboard until the mouse "hand" appears, then place the "hand" on the item desired and click the mouse. The hyperlink will move directly to that item.

## ANNOUNCEMENT: CHANGE TO STATE SUPPORTED BRAND LIST

**EFFECTIVE OCTOBER 1, 2018**, the brand name drug(s) listed below will be removed from the State Supported Brand Medication list and will begin reimbursing at the generic rate:

* ZETIA (ezetimibe) tablet

## ANNOUNCEMENT: Diphenoxylate Hydrochloride and Atropine Sulfate oral solution:

Diphenoxylate Hydrochloride and Atropine Sulfate TABLETS are not indicated for children age under 13 years of age. In children *under* 13 years of age, use the oral solution. A minimum age edit of 13 years was placed on the TABLETS with an effective date of July 10, 2018. Diphenoxylate hydrochloride and atropine sulfate ORAL SOLUTION is not recommended in children *under* 2 years of age because this age group may be predisposed to delayed diphenoxylate toxicity. In addition, because of the greater variability of response in children under 2 years of age, an over dosage may result in severe respiratory depression and coma, possibly leading to permanent brain damage or death.

**EFFECTIVE AUGUST 10, 2018**: A minimum age edit of 2 years was placed on the diphenoxylate hydrochloride and atropine ORAL SOLUTION.

**EFFECTIVE OCTOBER 1, 2018**

## PREFERRED DRUG LIST (PDL) ADDITIONS:

The Opioid Use Disorder treatment drugs were re-reviewed and the cystine-depleting agents were reviewed at the August 8, 2018 PDL meeting. The Preferred status and Non-preferred status drugs were selected based on a review of comparative effectiveness as well as cost-effectiveness for the state Medicaid program and are listed below. *Prior Authorization criteria* and quantity limits **will remain** in place for Preferred-status drugs as noted below.

**OPIOID USE DISORDER (OUD) TREATMENTS:**

**Medicaid Pharmacy Program billing:**

**Preferred agents with criteria**

* buprenorphine sublingual tablets
* Suboxone® Film (buprenorphine/naloxone sublingual film)

**Non-preferred agents**

* buprenorphine/naloxone buccal film (Bunavail®)
* buprenorphine/naloxone sublingual (SL) tablets (Zubsolv®)
* buprenorphine/naloxone SL tablets (generic)

**Medicaid Physician’s Program billing:**

* Vivitrol IM (naltrexone for extended-release injectable suspension)
* Sublocade SQ Injection (buprenorphine extended-release)
* Probuphine (buprenorphine implant for subdermal administration)

**CYSTINE-DEPLETING AGENTS:
Preferred**

* potassium citrate ER Tablet 5 mEq., 10 mEq., 15 mEq. (e.g., UROCIT-K)

**Preferred with Manual Review PA Criteria**

* Cuprimine (penicillamine) capsule
* Depen (penicillamine) tablet
* Thiola (tiopronin) tablet

**Non-preferred Agents**

None

## PRIOR AUTHORIZATION DRUG CRITERIA, NEW OR REVISED, FOR THE FOLLOWING DRUGS:

**EFFECTIVE IMMEDIATELY**

### AIMOVIG™ (erenumab-aooe) Subcutaneous (SQ) injection, 70 mg/mL:

Medicaid estimated reimbursement rate: NDC package of one syringe 70 mg/1 mL: $575 per mL; NDC package of 2-pack of 70 mg/1 mL: $575.50 for the 2-pack.

AIMOVIG will require manual review PA on a case-by-case basis using all of the following:

**APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary is an adult ≥18 years;
* Beneficiary is ≤50 years of age at migraine onset;
* Beneficiary has chronic migraine (≥15 days per month with migraine headache lasting 4 hours a day or longer) without aura and/or migraine with visual sensory, speech and/or language, retinal or brainstem aura, each lasting ≥ 4 hours OR if shorter, associated with use of a triptan or ergot-derivative on the same calendar day;
* Beneficiary has documented history of chronic migraines for ≥ 12 months and has monthly triptan claims;
* Beneficiary has documented history of chronic migraines and has monthly claims in Medicaid history of 1st line migraine prophylaxis agents in ≥ 2 different drug classes (1st line prophylaxis agents include propranolol, timolol, amitriptyline, divalproex, sodium valproate, and topiramate);

**CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:**

* Provider must submit chart notes since previous PA approval;
* Beneficiary is adherent to prescribed dose of AIMVOG™;
* Beneficiary has appropriate use of Triptan agent (i.e., no overuse, no early fills);
* Beneficiary must have at least a 50% reduction from baseline in monthly migraine days after 3rd month of AIMOVIG;

**DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:**

* Beneficiary does not have a 50% reduction from baseline in monthly migraine days after 3rd month of AIMOVIG;
* Beneficiary is not adherent to prescribed dose;
* Beneficiary is > 50 years of age at migraine onset;
* Beneficiary has history of cluster headache, cervical dystonia, chronic headache tension type, or hemiplegic migraine headache;
* Beneficiary has medication overuse headache caused by opiate overuse or other headache medication overuse;
* Beneficiary is unable to differentiate migraine from other headaches;
* Beneficiary has received Botox for migraine in the previous 3 months;
* Beneficiary has active chronic pain syndromes (such as fibromyalgia and chronic pelvic pain);
* Beneficiary is on chronic use of opioid drugs;
* Beneficiary has history of seizure disorder or other significant neurological conditions associated with headaches other than migraine;
* Beneficiary has severe renal impairment (eGFR < 30 mL/min/1.73m2);
* Beneficiary has had Myocardial infarction (MI), stroke, transient ischemic attack (TIA), unstable angina, or coronary artery bypass surgery or other revascularization procedure within 12 months prior to PA request;
* Beneficiary is < 18 years of age or > 65 years of age;

**QUANTITY EDIT:**

* The recommended dose is 1 injection monthly; the quantity limit is 1 injection per month; a quantity of 2 injections per month will require additional prior authorization;

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE OCTOBER 1, 2018**

### BUPRENORPHINE-CONTAINING AGENTS AND VIVITROL® IM:

Medication Assisted Treatment (MAT) Drugs for treating opioid use disorder (OUD) include the SL/buccal buprenorphine-containing agents, SUBLOCADE™ SQ Injection (buprenorphine extended-release) prefilled syringe, PROBUPHINE® (buprenorphine) Implant for treating OUD in an office-based setting, and VIVITROL® IM (naltrexone for extended-release injectable suspension) 380 mg Vial for treating OUD and alcohol dependence in an office-based setting.

SUBOXONE® Film 2 mg-0.5 mg film = $4.35 each film; 4 mg-1 mg film = 7.80 each film; 8 mg-2 mg = 7.83 each film; #30 = $234.90; #90 =$704.70; \*12 mg/3 mg = $15.72 each, #30 = $471.60 (\*12 mg/3 mg quantity limit of 1 film per day, #30 per 30-day supply). SUBOXONE® Film is the preferred agent on the PDL;

SUBLOCADE 100 mg/0.5 mL and 300 mg/1.5 mL= J-Code currently not available in the AR Medicaid Physician’s Program so pricing information is not available at the time this Provider Memo was written.

VIVITROL 380 mg IM inj. = J-Code: J-2315; Physician’s Program reimbursement listed as $3.92/mg, or $1,489.60 for one 380 mg vial;

PROBUPHINE® Implant = J-Code: J-0570; Physician’s Program reimbursement $1,410.75 each implant; package size of 4 implants to be inserted at one time = $5,643 (6 month implant);

The Medication Assisted Treatment (MAT) prior authorization (PA) approval criteria for buprenorphine-containing drugs have been revised, and the buprenorphine-containing PA form now includes SUBOXONE FILM, buprenorphine SL tablets, SUBLOCADE SQ, and PROBUPHINE Implant. In addition, a separate PA form is available for MAT with VIVITROL IM. VIVITROL IM does not require a waiver from Substance Abuse and Mental Health Services Administration (SAMHSA) and is not a controlled drug. **All Physician-Administered MAT Drugs (VIVITROL IM, PROBUPHINE IMPLANT, and SUBLOCADE SQ) are covered and billed through the Medicaid Physician’s Program.** All requests for Physician-Administered MAT drugs will be reviewed by the clinical reviewers in the Medicaid Pharmacy Program. The clinical reviewers in the Medicaid Pharmacy Program will notify the Medicaid Physician’s Program of all PA approvals for Physician-Administered-Drugs. ***MAT Prescribing Providers must obtain all required referrals from the beneficiary’s Primary Care Physician (PCP) for office visits to administer injectable physician-administered MAT drugs.*** Requests for Suboxone Film and buprenorphine SL tablets will continue to be reviewed by the PDL PA Call Center.

Please refer to the revised MAT PA forms (MAT PA Buprenorphine and MAT PA VIVITROL) posted on the AR Medicaid Pharmacy Program website for the specific approval criteria required for MAT drugs. A brief summary of the changes are noted below. <https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_VivitrolIM.pdf>

<https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Buprenorphine_Agents.pdf>

* Medicaid beneficiaries meeting the criteria of negative Urine Drug Screens (UDS) *and* attending the required number of BH counseling sessions each month will have the prior authorizations approved for longer periods of time.
* **Behavioral Health (BH) Substance Use Disorder (SUD) counseling is now a Medicaid covered benefit for Medicaid beneficiaries**. As a condition of coverage or payment for *any* Medication Assisted Treatment (MAT) DRUG, a *minimum of 1 (one) Behavioral Health (BH) counseling session each month is required*. The BH counseling must be performed by a licensed clinician experienced in addiction counseling and the BH Agency must be certified by Division of Aging, Adult and Behavioral Health Services (DAABHS). Twelve BH counseling sessions per state fiscal year (July-June) are available without an extension of benefits (EOB) and if medically necessary, an EOB may be requested by the BH Agency and additional counseling services may be provided. The first 3 BH counseling sessions can occur prior to a PCP referral. After the first 3 BH counseling sessions, the beneficiary’s PCP must approve a referral for the BH Agency for continued coverage as a Medicaid-covered service.
* ***The BH counseling requirement is not waived if the beneficiary fails to request his/her PCP to obtain a referral for BH counseling in order for the BH counseling to be a covered Medicaid benefit.***

The list of certified BH Agencies, provided by Division of Provider Services & Quality Assurance (DPSQA), is posted on the AR Medicaid Pharmacy Program website at this link <https://arkansas.magellanrx.com/provider/docs/other/ARDHS_DPSQA_Certified_Behavioral_Health_Agencies.pdf> for convenience so that the **MAT Prescribing Provider can assist his/her patient in selecting a BH Agency and assist in setting the first BH counseling appointment**. As of the date of this Provider Memo, **there are 295 certified BH Agency locations in the state available for BH counseling** and **all 75 counties are represented**. ***When reviewing the BH Agency list,*** ***please keep in mind that there may be multiple locations for the same BH Agency name within a city or county and they may not be sorted together.***

* As a condition of coverage or payment for *any* MAT DRUG, the **Medicaid beneficiary must agree to work with his/her PCP to obtain required referrals for MAT BH counseling** and other referrals necessary for the MAT prescribing provider. **Medicaid beneficiaries are required by Medicaid to choose a PCP for coordinating and approving care within the Medicaid system.** For the purposes of these prior approval criteria for payment for a MAT DRUG, if a PCP has not been assigned, the **beneficiary is responsible for contacting ConnectCare at 1-800-275-1131 and requesting assistance in choosing a PCP**. For more information regarding AR Medicaid Beneficiary PCP requirements, see the ARMedicaid website, Beneficiary Information Screen, at this link <https://medicaid.mmis.arkansas.gov/Beneficiary/PCP.aspx>.

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE OCTOBER 1, 2018:**

### CODEINE Cough and Cold (C&C) Products and FDA Labeling Changes for Children < 18 Years:

The Medicaid age criteria for C&C products containing codeine have been revised due to FDA safety warnings that the risks of these medications to children outweigh the benefits. The FDA conducted an extensive review and convened a panel of outside experts to review these medications. Both of these determined codeine and hydrocodone increased the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18 years. The revised Medicaid age edit for the C&C products containing codeine will require the beneficiary to be ≥18 years of age. Medicaid Pharmacy Program covers the C&C products for Medicaid beneficiaries < 21 years of age.

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE IMMEDIATELY:**

### EMFLAZA™ (deflazacort) Tablet (6 mg, 18 mg, 30 mg, 36 mg, Oral Suspension 22.75 mg/ mL 13 mL package size:

Medicaid pricing segments below rounded for approximate Medicaid reimbursement rate:

EMFLAZA™ 6 mg tablet = $47.67 each tablet; supplied in bottles of 100 tablets; #30 = $1,430

 18 mg tablet = $143.00 each tablet; supplied in bottle of 30 tablets; #30 = $4,290

 30 mg tablet = $238.35 each tablet; supplied in bottle of 30 tablets; #30 = $7,150

 36 mg tablet = $265.60 each tablet; supplied in bottle of 30 tablets; #30 = $7,968

 22.75 mg/mL oral suspension. = $241.55 per mL, billing unit is per mL,

One 13 ml package size (less than 1 tablespoonful) = $3,140

Example using EMFLAZA™ and standard weight based dose for Duchenne Muscular Dystrophy (DMD) of 0.9 mg/kg/day once daily:

Dosing example for 30 kg (66 lbs.) patient = 27 mg daily dose; If rounded up to 30 mg tablet daily, 30 mg daily = $7,150 for 30 day supply;

EMFLAZA™ dosing example for a 75 kg (165 lbs.) patient = 67.5 mg daily; if rounded down to 66 mg using 30 mg + 36 mg = 66 mg daily = $15,118.50 for 30-day supply, $181,422 for 12 months;

For 75 kg patient, if rounding *up* to nearest possible dose, 72 mg daily (2 tablets daily of 36 mg) = **$15,936 for 30-day supply**; **$191,232 for 12 months;**

COMPARISON TO PREDNISONE TABLET

Prednisone: 5 mg tablet = $0.09 each tablet; 10 mg tablet = $0.11 each tablet;

20 mg tablet = $0.13 each tablet; 50 mg tablet = $0.26 each tablet;

 1 mg/1mL oral solution = $0.60 per mL, billing unit is per mL;

120 ml package size = $71.92

Example using PREDNISONE and standard weight-based dose for DMD of 0.75 mg/kg daily;

Dosing example for 30 kg (66 lb.) patient = 22.5 mg daily; If rounded *up* to 25 mg/day; 20 mg x 30 = $3.90; 5 mg #30 = $2.70; **25 mg/day= $6.60 for a 30 day supply**

Dosing example for a 75 kg (165 lbs.) patient = 56 mg daily; if rounded *down* to 55 mg using 50 mg + 5 mg = $7.80 + $2.70 = **$10.50 for 30-day supply**; **$126 for 12 months;**

For 75 kg patient, if rounding *up* to nearest possible dose = 60 mg daily using 3 x 20 mg tablets daily = #90 tablets = **$11.70 for a 30-day supply; $144 for 12 months;**

EMFLAZA™ (deflazacort) will continue to require manual review PA on a case-by-case basis and will use all of the following:

**EMFLAZA™ APPROVAL CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary has confirmed genetic diagnosis of Duchenne muscular dystrophy (DMD);
* Beneficiary is ≥5 years of age;
* Prescriber must submit a letter explaining the medical necessity of receiving EMFLAZA™ over other glucocorticosteroids, such as prednisone or prednisolone;
* Prescriber must submit documentation to substantiate the medical necessity request of EMFLAZA™ over other glucocorticoid agents, including submitting chart notes, data on all previous glucocorticosteroids tried, and include explanation of failure or explanation of an adverse effect caused by prednisone or prednisolone that is not also caused by EMFLAZA™;
* Prescriber must submit patient specific measurable treatment goals for outcomes with EMFLAZA™ and include the treatment plan if the measurable treatment goals are not met and EMFLAZA™ is discontinued;
* The EMFLAZA™ dose prescribed is 0.9 mg/kg/day;
* Prescriber must submit beneficiary’s weight, dose, and previous dosing schedule for other glucocorticoid(s) tried, such as prednisone or prednisolone;
* EMFLAZA™ is prescribed by neuromuscular specialist
* Prescriber must provide the calculated Child-Pugh score AND the labs (INR, Bilirubin, Albumin) AND chart notes (e.g., for encephalopathy and ascites) required to calculate the Child-Pugh score;
* Beneficiary has not lost the ability to stand or ambulate and a wheelchair has not been issued to the beneficiary;

**CONTINUATION CRITERIA APPROVAL REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary is adherent to prescribed dose of EMFLAZA;
* Prescriber to submit documentation that beneficiary has not had loss of ambulation or loss of ability of stand;
* Beneficiary has not been issued a wheelchair;

**DENIAL CRITERIA REQUIRE ANY ONE OF THE FOLLOWING:**

* Beneficiary is < 5 years of age;
* Beneficiary has not received prednisone or prednisolone;
* Beneficiary did not receive the weight based dose on a daily schedule of prednisone or prednisolone (0.75 mg/kg/day);
* Beneficiary is classified as Child Pugh C;
* Beneficiary has loss of ambulation, or loss of ability of stand, or has been issued a wheelchair;

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE IMMEDIATELY**

### JYNARQUE™ (tolvaptan) Tablets, 45 mg-15mg; 60 mg-30 mg; 90 mg-30 mg;

Each is packaged as morning dose and an afternoon dose (8 hrs later), a 7-day blister card contains 14 tablets.

Medicaid estimated reimbursement rate, all strengths are the same rate: $232.88 each tablet;

**#14 tablets, 7 DAY card = $3,260; #56 tablets, 28 day supply = $13,040**

JYNARQUE™ will require manual review PA on a case-by-case basis using all of the following:

**JYNARQUE™APPROVAL CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary is an adult ≥18 years of age;
* Beneficiary has diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) and is at risk of rapidly progressing in the disease;
* Prescriber must submit chart notes indicating the beneficiary’s PKD stage;
* Beneficiary is not receiving kidney dialysis;
* Prescriber must submit initial liver test results for ALT, AST, and bilirubin for the 1st one month PA;
* Beneficiary has normal serum sodium concentrations prior to starting drug; Prescriber to submit initial blood sodium test results;
* The initial recommended dose is 60 mg/day (using the 45 mg-15 mg package). If dose is tolerated, the dose can be up-titrated at *weekly intervals.* The prescriber should work with the patient during up-titration using the tablet strengths in the package before requesting the PA for the next strength.
	+ 45 mg – 15 mg tablets;
	+ 60 mg – 30 mg tablets;
	+ 90 mg – 30 mg tablets;
* Reduced dose adjustment as stated in package insert is required for co-administration with moderate CYP 3A inhibitors;

**CONTINUATION CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary must be adherent to prescribed dose;
* Prescriber must submit chart notes;
* Prescriber must submit beneficiary’s current dose with each PA request; once beneficiary is on a stable dose, each strength is available as a 28-day carton containing a total of 56 tablets; each 28-day carton has its own NDC; PA entered will be for the specific NDC;
* Prescriber must perform the liver tests at the frequency required by the Risk Evaluation and Mitigation Strategy (REMS) and assess ALT, AST and bilirubin prior to initiation of JYNARQUE, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter and must submit all results obtained since previous PA approval date with each PA request;
* PA will be month to month until beneficiary is stable and tolerates the dose, then each PA approval may be approved for a 3-month period at a time;

**DENIAL CRITERIA REQUIRE ANY ONE OF THE FOLLOWING:**

* Beneficiary is already receiving kidney dialysis;
* Beneficiary is not adherent to prescribed dose;
* Beneficiary does not meet approval criteria;
* Beneficiary has history of signs or symptoms of significant liver impairment or injury, does not include uncomplicated polycystic liver disease;
* Beneficiary has concomitant use of strong CYP 3A inhibitors, which is contraindicated;
* Beneficiary has uncorrected abnormal blood sodium concentrations;
* Beneficiary is unable to sense or respond to thirst;
* Beneficiary has hypovolemia;
* Beneficiary has hypersensitivity to tolvaptan or any of its components;
* Beneficiary has uncorrected urinary outflow obstruction;
* Beneficiary has anuria;
* Beneficiary is breast feeding;

**QUANTITY EDIT: Each of the 3 NDC packages contain 56 tablets for a 28-day supply. The quantity limit for each NDC package size is limited to 2 tablets per day, 28 day supply.**

* *Note regarding up-titration: the PA for the NDC will be entered at the time of the PA request. Depending on the quantity dispensed, the prescriber should work with the patient* to finish the tablets in the package dispensed for up-titration before requesting a PA for the next strength.
	+ 45 mg – 15 mg;
	+ 60 mg – 30 mg;
	+ 90 mg – 30 mg;

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE IMMEDIATELY**

### LUCEMYRA™ (lofexidine) Tablet 0.18 mg:

Medicaid Estimated Reimbursement Rate is approximately $20.70 per tablet.

Packaged as a bottle of 36 tablets ($745) and a bottle of 96 tablets ($1,986);

LUCEMYRA™ will require manual review PA on a case-by-case basis using all of the following:

**LUCEMYRA™ APPROVAL CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary is an adult ≥ 18 years;
* Beneficiary is physically dependent on opioid drug(s) and currently has acute withdrawal symptoms due to abrupt opioid discontinuation;
* Beneficiary is not currently receiving any opioid medications;
* The prescribed dose will not exceed 16 tablets (2.88 mg) per day, or 4 tablets (0.72 mg) in a single dose, or 14 days of treatment with LUCEMYRA™;
* Beneficiary is not hospitalized during this treatment;
* Prescriber must submit chart notes and treatment plan;

**CONTINUATION CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* No continuation past 14 days of treatment;

**DENIAL CRITERIA REQUIRE ANY ONE OF THE FOLLOWING:**

* Beneficiary does not meet approval criteria;
* Beneficiary is hospitalized at time of request;
* Request is for greater than 96 tablets
* Request is for greater than 14 days of treatment in previous 365 days;

**QUANTITY LIMIT:**

* One 14-day treatment allowed once per 365 days;
* The quantity allowed for a one-time treatment will not exceed **96 tablets**;
* One claim allowed per 365 days,
* One claim will pay for one bottle of 96 tablets or one bottle of 36 tablets;

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE: OCTOBER 1, 2018**

### MYCOPHENOLATE 250 mg Capsule, 500 mg Tablet, and Oral Solution:

Medicaid reimbursement rate: 250 mg capsule = $0.19; 500 mg tablet = $0.26

The point of sale approval criteria will be revised and the requirement of diagnosis of organ transplant in Medicaid history in the previous 3 years will be removed from the tablet, capsule, and oral solution criteria.

The oral solution will retain the “swallow” criteria and will continue to look at the beneficiary’s age in the system and the oral solution will continue to approve for beneficiaries younger than 7 years of age, or approve for beneficiaries who are 7 years or older AND have an NPO diagnosis in Medicaid history in the previous 365 days that may indicate the beneficiary cannot swallow solid oral dosage forms.

**Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; fax letter of medical Necessity along with any documentation to substantiate the medical necessity of the request to**

**1-800-424-7976**

**EFFECTIVE NOVEMBER 14, 2018:**

### NON-FATAL POISONING DIAGNOSES CODES REVISED CRITERIA:

According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.

Currently the Medicaid Pharmacy Program has point of sale criteria that apply to all incoming opioid drug claims and all incoming benzodiazepine drug claims that look for non-fatal drug poisoning (overdose) diagnoses in a Medicaid beneficiary’s medical diagnosis history. If an ICD-10 poisoning diagnosis code is found in the medical history in the previous 90 days, the incoming opioid claim or the incoming benzodiazepine drug claim will deny at point of sale and the prescribing provider must contact the Medicaid Pharmacy Program. ***The look-back period is being extended to 365 days back from the date of the incoming opioid claim or the incoming benzodiazepine drug claim.*** This edit excludes terminal cancer patients who have a cancer diagnosis in the Medicaid medical history in the previous 365 days.

To recap the revised prior authorization criteria:

For beneficiaries who have a **non-fatal drug poisoning (“overdose”) diagnosis** in Medicaid medical history in the **previous 365 days**, the incoming opioid claim or the incoming benzodiazepine claim, or both, will deny at point of sale. The prescribing provider may request a prior authorization for the beneficiary to continue the opioid drug, the benzodiazepine drug, or both drugs. A summary of the criteria is noted below:

* Submit a letter to the Medicaid Pharmacy Program explaining the medical necessity of the beneficiary to continue receiving the opioid, the benzodiazepine, or both medications, despite the recent non-fatal poisoning (overdose) diagnosis in Medicaid history; AND
* Provide an opioid taper schedule to decrease the opioid(s) dose and reduce the beneficiary’s daily MME dose; AND
* The prescriber must agree to not provide prescriptions for cash for opioids or for benzodiazepines that avoid the Medicaid dose edits, quantity edits, or MME edits; AND
* If the poisoning diagnosis was due to an opioid, an unspecified narcotic, or unspecified drug or substance”, the prescriber must provide proof that the beneficiary filled a naloxone vial or naloxone pre-filled syringe (naloxone vials and naloxone pre-filled syringes do not require a Prior Authorization with Medicaid Pharmacy Program); AND
* If the poisoning was due to a benzodiazepine, or the beneficiary is receiving both a benzodiazepine and an opioid medication, provide a benzodiazepine taper schedule and information as to why the beneficiary cannot be switched to a different, non-benzodiazepine medication, for treatment of the anxiety disorders, panic disorder, agitation, insomnia, etc.; AND
* Any approved PAs will include the reduced dose of the drug(s) in question; AND
* Prior Authorizations will be on a month-to-month basis for an undetermined amount of time.

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**1-800-424-7976.**

**EFFECTIVE IMMEDIATELY**

### PALYNZIQ™ (pegvaliase-pqpz) SQ Injection:

Medicaid approximate reimbursement rate: billing unit is per 1 mL; the reimbursement rate amount was adjusted to reflect the 0.5 mL syringes and the 1 mL syringe below.

2.5 mg/0.5 mL is $488 for the 0.5 ml syringe; 1 syringe/carton;

10 mg/0.5 mL is $488 for the 0.5 ml syringe; 1 syringe/carton;

20 mg/1 mL is $488 for the 1 mL syringe; available as 10 syringes/carton but the billing is per mL (e.g., 10 mL would be 10 syringes);

**30 x 20 mg/1mL syringes for 30 days @ 20 mg/day = $14,640;**

**60 x 20 mg/1mL syringes for 30 days @ 40mg/day = $29,280**

PALYNZIQ™ will require manual review PA on a case-by-case basis using all of the following:

**PALYNZIQ™ APPROVAL CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary is an adult ≥18 years of age;
* Beneficiary has phenylketonuria and has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L while adherent to a strict Phenylalanie (Phe)-limited diet;
* Prescriber must submit beneficiary’s blood phenylalanine concentration with PA request;
* Beneficiary is adherent to a Phe-restricted diet that restricts phenylalanine protein;
* Prescriber must submit chart notes to substantiate that beneficiary was a non-responder to KUVAN while adherent to the Phe-restricted diet;
* If female beneficiary is child-bearing age, she must be willing to use 2 acceptable methods of contraception while receiving PALYNZIQ;
	+ Females who have been in menopause for at least 2 years, have had a tubal ligation at least 1 year prior to first dose of PALYNZIQ, or have had a total hysterectomy do not need to use any other forms of contraception while receiving PALYNZIQ.
	+ Males post vasectomy 2 years with no known pregnancies for at least 2 years do not need to use any other forms of birth control while receiving PALYNZIQ.
* Prescriber must administer the initial dose of PALYNZIQ and closely observe the beneficiary for at least 60 minutes following the injection;
* Prescriber must ensure beneficiary is capable of recognizing signs and symptoms of anaphylaxis and can administer the autoinjector of epinephrine;
* Prescriber must prescribe and ensure beneficiary filled the Medicaid preferred autoinjector of Epinephrine Authorized Generic of Epipen;
* If approved, due to the recommended dosing schedule, the initial PA will be approved for 5 weeks at 2.5 mg once weekly for 4 weeks, and 2.5 mg twice weekly for 1 week, for a total of six 2.5 mg syringes; quantity will be entered at the time of the PA approval;

**CONTINUATION CRITERIA REQUIRE ALL OF THE FOLLOWING**

* For 2nd PA, beneficiary must be adherent to prescribed dose, prescriber must submit dose being requested, must submit assessment on patient tolerability, submit blood phenylalanine concentrations, and submit dietary protein and phenylalanine intake;
* If dose is up-titration per package insert, 2nd approved PA will be for 4 weeks and include quantity limit of 14 of the 10 mg syringes;

|  |  |
| --- | --- |
| 10 mg once weekly  | 1 week  |
| 10 mg twice weekly  | 1 week  |
| 10 mg four times per week  | 1 week  |
| 10 mg once daily  | 1 week  |

* For the **3rd PA request** (Month-3), beneficiary must be adherent to prescribed dose; prescriber must submit dose being requested, must submit documentation of assessment on patient tolerability, blood phenylalanine concentrations, and submit dietary protein and phenylalanine intake;
* If the 3rd PA request is for up-titration to 20 mg/day, data submitted for this dose request must document beneficiary has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline, or beneficiary has not achieved a blood phenylalanine concentration less than or equal to 600 micromol/L); if approved, a QUANTITY LIMIT of 30 X 20 mg syringes (3 cartons of 10 syringes will be entered at the time of the PA approval;
* Continued PA approvals for 20 mg/day will be month-to-month PA reviews; at each monthly review, beneficiary must be adherent to prescribed dose; prescriber must submit dose being requested, submit documentation of assessment on patient tolerability, submit blood phenylalanine concentrations, and submit documentation that beneficiary is adherent to the strict Phe-restricted diet. Quantity limit will be entered with each PA request approval;
* After **24 weeks of 20 mg/day dose**, if prescriber is requesting **up-titration to 40 mg daily**, prescriber must submit blood phenylalanine concentration level; the beneficiary must be adherent to the strict Phe-restricted diet, must have been adherent to the prescribed 20 mg daily dose for 24 weeks, and beneficiary **has not achieved a 20% reduction in blood phenylalanine** concentration from pre-treatment baseline, or **beneficiary has not achieved a blood phenylalanine concentration less than or equal to 600 micromol/L)**. If approved, Quantity limit of 60 x 20 mg syringes will be entered at the time of the PA approval.
* To remain on 40 mg/day dose, at each subsequent PA request, beneficiary must be adherent to prescribed dose, beneficiary must be adherent to strict Phe-restricted diet; prescriber must submit assessment on patient tolerability, prescriber must submit blood phenylalanine concentration; If continuation dose is approved, approval will be month-to-month up to 16 weeks of treatment at 40 mg/day dose; Quantity limit of 60 x 20 mg syringes per month will be entered at the time each PA is approved;
* To **continue 40 mg/day beyond 16 weeks**, prescriber must submit current blood phenylalanine concentration level and beneficiary must show at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline *or* a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily; beneficiary must be adherent to prescribed dose; beneficiary must be adherent to strict Phe-restricted diet;

**DENIAL CRITERIA REQUIRE ANY ONE OF THE FOLLOWING:**

* HIV positive;
* Beneficiary is pregnant;
* Beneficiary is < 18 years of age;
* Beneficiary has a history of substance abuse in the past 12 months or current alcohol or drug abuse;
* Beneficiary was not adherent to a strict Phe-restricted diet;
* Beneficiary did not have adequate trial of Kuvan;
* Beneficiary was not adherent to prescribed dose of PALYNZIQ;
* Beneficiary did not show at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily;

**QUANTITY EDIT:**

* Quantity limit for the required strength to be entered at the time of each PA approval;

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**1-800-424-7976**

**EFFECTIVE IMMEDIATELY**

###  SYMDEKO™ (tezacaftor/ivacaftor fixed dose and co-packaged with ivacaftor):

**SYMDEKO**: SYMDEKO is co-packaged as a tezacaftor/ivacaftor fixed-dose combination tablet and an ivacaftor tablet. The tezacaftor/ivacaftor fixed dose combination tablets are tablets containing 100 mg of tezacaftor and 150 mg of ivacaftor. The ivacaftor tablets are tablets containing 150 mg of ivacaftor.

Medicaid estimated reimbursement rate for SYMDEKO:

Each tablet in the SYMDEKO package is approximately $400; packaged as 56 tablets = **$22,400 for a 28 day supply**;

Comparison of costs to the 2 other CF drugs:

**KALYDECO®**: Medicaid reimbursement rate, each tablet is approximately $427; packaged as 56 tablets (1 tablet twice daily); #56: **$23,912/28 day supply**;

**ORKAMBI®**: 100-125; 200-125; packaged as 112 tablets (2 tablets twice daily): Each tablet is approximately $186.78; #112: **$20,919/28 day supply**

SYMDEKO™ will require manual review PA on a case-by-case basis using all of the following:

**SYMDEKO™ APPROVAL CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary must have diagnosis of Cystic Fibrosis (CF) with the presence of mutations in both copies of the gene for the CFTR protein;
* Beneficiary is homozygous for the F508del mutation, or two copies of F508del mutation, to be indicated for tezacaftor/ivacaftor, or beneficiary has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in-vitro data and/or clinical evidence (list is per chart in SYMDEKO package insert); prescriber must provide the beneficiary’s CFTR mutation genotypes;
* Beneficiary is 12 years of age or older;
* Beneficiary is adherent to standard of care therapies for treating CF;
* If the beneficiary failed therapy with Kalydeco® or Orkambi® and is requesting a switch to SYMDEKO™ submit chart note documentation of failure;
* If beneficiary had an adverse effect from Kalydeco® or Orkambi® and is requesting a switch to SYMDEKO™ submit a completed FDA MedWatch form with the PA request for Symdeko documenting the adverse effect; the MedWatch form will be submitted to the FDA;
* Prescriber must provide the calculated Child-Pugh score AND the labs (INR, Bilirubin, Albumin) AND chart notes (for encephalopathy and ascites) required to calculate the Child-Pugh score;
* Prescriber must submit liver enzyme data (ALT, AST) prior to initiating therapy;
	+ - * For the initial PA approval and continuation reviews, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) with bilirubin elevations less than 2 times the ULN, OR the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal without bilirubin elevation;
* Prescriber must submit patient specific measurable treatment goals for outcomes with SYMDEKO™ and include the treatment plan if the measurable treatment goals are not met and SYMDEKO™ is discontinued;
* Beneficiary is a non-smoker;

**CONTINUATION CRITERIA REQUIRE ALL OF THE FOLLOWING:**

* Beneficiary must be adherent to daily prescribed therapy, and the Medicaid drug profile will be reviewed for compliance;
* Beneficiary is adherent to standard of care therapies for treating CF;
* Prescriber must submit liver enzyme data (ALT, AST) every 3 months during the 1st year of treatment and then annually; if beneficiary has history of ALT or AST elevations, test results must be submitted every 3 months;

o For continuation reviews, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) with bilirubin elevations less than 2 times the ULN, OR the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal without bilirubin elevation; Lab results must be measured and submitted every 3 months during the 1st year then annually; if had elevated labs, the lab tests continue every 6 months

* Prescriber must provide patient specific measurable goals for treatment outcomes with ivacaftor/ tezacaftor and include the treatment plan for possible ivacaftor/ tezacaftor discontinuation if the treatment goals are not met;
* Prescriber must submit documentation to substantiate the following:

o Stabilization or improvement in lung function (FEV1);

o Stabilization or improvement in weight gain;

o Reduction in exacerbations/hospitalizations.

* Beneficiary to remain non-smoker;
* After 12 months of SYMDEKO therapy, in addition to above criteria, prior approval continuation will be dependent upon the review of several key clinical areas in order to determine an overall positive treatment response to the drug.
	+ - * The current medical results and chart notes will be compared to the previous medical history for an overall picture of the patient’s progress, stabilization, or decline in health.
* The clinical review will continue to include reviewing ppFEV1, BMI or weight, pulmonary exacerbations and exacerbations requiring hospitalization, and patient overall Quality of Life (QoL) using one of the specific validated questionnaires (CFQ 14+ for teenagers and adults; CFQ-Child, ages 6 through 13; CFQ Child P, a parent-proxy evaluation for children aged 12–13, or CFQ-R (Cystic Fibrosis Questionnaire-Revised)). Beneficiary has improved the Quality of Life score from baseline by a minimum of 4 points.
	+ - * After the first year, each approved PA will not exceed 6 months.

**DENIAL CRITERIA REQUIRE ANY ONE OF THE FOLLOWING:**

* Beneficiary < 12 years of age;
* Beneficiary is pregnant or nursing;
* Beneficiary classified as Child-Pugh C;
* Beneficiary does not have diagnosis of Cystic Fibrosis (CF) with the presence of mutations in both copies of the gene for the CFTR protein;
* In the event of significant elevations of transaminases, e.g., patients with ALT or AST >5 × upper limit of normal (ULN), or ALT or AST >3 × ULN with bilirubin >2 × ULN, dosing should be interrupted and laboratory tests closely followed until the abnormalities resolve;
* Patients with an active colonization with organisms such as Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus; OR
* Patients who had 3 or more abnormal liver function tests (ALT, AST, AP, GGT ≥3 × the ULN or total bilirubin ≥2 × the ULN); OR
* Therapeutic duplication with Kalydeco or Orkambi;
* Tobacco use;

**QUANTITY EDIT:**

* 56 tablets for a 28 day supply;

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**1-800-424-7976**

## FRIENDLY REMINDERS:

1. **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>

1. **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.”

**Per ASAM National Practice Guidelines**, the bold and italics were added for emphasis, but the following statement is pulled from the “At Induction” section of “Part 5: Buprenorphine”, under Dosing, “Once it has been established that the initial dose is well tolerated, the buprenorphine dose can be increased fairly rapidly to **a dose *that provides stable effects for 24 hours*** **and is clinically effective**”. <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

1. **CIRCUMVENTING MEDICAID LIMITS FOR OPIOIDS AND BENZODIAZEPINES:**

Beneficiaries who pay *cash* for opioids to avoid Medicaid dose and quantity limits *or* pay cash *in addition to* the opioids paid for by Medicaid, result in a much higher daily MME than what is calculated in the Medicaid system edits, are above the CDC recommendations, and could *put the patient at risk for overdose*. **According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.**

1. **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on MAY 8, 2018 to ≤ 150 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that cause the total MME/day to exceed the existing limit of ≤ 150 MME/day will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).

***The last reduction is scheduled for NOVEMBER 14, 2018 with a reduction to ≤ 90 MME/day.***

1. **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.***
2. **Chronic Pain Patients Who Do *Not* Need Treatment for Addiction**: Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: “Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. *They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids in the course of their medical treatment*.” Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment. <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. **“CLAIM EDITS”** referred to in this memo include quantity edits, cumulative quantity edits, monthly quantity edits, age edits, gender edits, accumulation quantity edits, and daily dose edits.
4. **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 board certified child & adolescent psychiatrist.
5. **SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE*, EFFECTIVE MARCH 8, 2017*:** The current point of sale (POS) prior approval (PA) criteria for the second generation antidepressants, including Trazodone, were developed based on utilization for adults, and the minimum and maximum therapeutic doses were based on adult doses. ***Second Generation Antidepressants, Trazodone, or Tricyclic Antidepressants for Children ≤ 3 years of age will require manual review prior approval (PA) by the Medicaid Pharmacy Program child psychiatrist.*** The prescriber must submit the request in writing, explain the medical necessity for the child to receive the drug requested, and include chart notes and any other documentation that will substantiate the request and the dose. Each request will be reviewed on a case-by-case basis.
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 situation 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/>.

1. **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 a 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.

1. **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.
2. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-controlled drug or a controlled drug 1 day early to 7 days early without a PA or sooner with a PA), 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.

1. **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.

1. **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.
2. **INFORMED CONSENT FORM FOR ANTIPSYCHOTIC AGENT PA FOR CHILDREN < 18 YEARS OF AGE:**

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.

1. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS:** **Effective JULY 1, 2016**, Providers requesting a Prior Authorization (PA) for a drug on the PDL or calling to request a Prior Authorization (PA) for an antipsychotic medication should call the **PDL PA Call Center at 1-800-424-7895**. **The PDL FAX number is: 1-800- 424-5739**. Please fax a letter explaining the medical necessity and include any supporting documentation, the beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.
2. **FOR NON-PDL DRUGS AND FOR NON-ANTIPYSCHOTIC DRUG REQUESTS:** Providers requesting a Prior Authorization (PA) should call the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For Prior Authorization (PA) requests requiring manual review, you may fax your request to the MMA Help Desk Fax at 1-800-424-7976. Please include any supporting documentation for the request with the fax, and include beneficiary ID number, beneficiary name, and physician Medicaid provider ID with your request. An approval, denial, or request for additional information will be returned by the close of business the following business day.
3. **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.
4. **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>

1. **AR MEDICAID PHARMACY PROGRAM IS ON FACEBOOK:**  The Arkansas Medicaid Pharmacy Program is now on Facebook.  Please join our group page titled “AR Medicaid Pharmacy Provider Help Group”.  This is a closed group for providers of Arkansas Medicaid services or those who work for a provider of Arkansas Medicaid services and join requests will be verified.  The group is administered by a State of Arkansas employee and a Magellan Medicaid Administration employee on his/her own time.  The purpose of the group page is to help the provider community with any issues that involve billing or prescribing covered outpatient drugs through the Arkansas Medicaid Pharmacy Program.  We will not disclose any PHI and will delete any posts that contain PHI.  Want to know what criteria is needed for a drug?  Don’t know who to call to handle your issue?  Just post your questions and we will answer.

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.