ARKANSAS DEPARTMENT OF HUMAN SERVICES

**Division of Medical Services**
**Pharmacy Program**

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**MEMORANDUM**

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: **January 8, 2016**

SUBJ: **AR Medicaid DUR Board edits approved at the October 21, 2015 meeting:**

**Changes To Existing Prior Authorization (PA) Criteria Or Edits**: Benzodiazepines Solid Oral Dosage Forms and ODT Forms, Topical Pediculicide head lice treatments; Antipsychotic agents written for children; Aromatase Inhibitors: Arimidex® (anastrozole) and Femara® (letrozole) tablets;

**Point-of-Sale (POS) Clinical Edits with or without Claim Edits:** Intron® A (interferon alfa-2B) injection; Early Refill Edits Added To Non-Controlled Drugs, and Refill Too Soon logic added to all drugs;

**Clinical edits through the Manual Review PA Process:** Buprenorphine-containing agents for Office-Based Opioid Dependency Treatment Programs; HCV treatments Daklinza™ (daclatasvir) and Technivie™ (ombitasvir, paritaprevir and ritonavir); Entresto™ (sacubitri and valsartan); PCSK9 Inhibitors Repatha™ (evolocumab) injection and Praluent™ (alirocumab); Daraprim® (pyrimethamine) tablet; Orkambi™ ((lumacaftor/ivacaftor); Mupirocin 2% cream, Mupirocin 2% nasal ointment; Keveyis™ (dichlorphenamide) tablet;

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

**(Reimbursement rates stated in this memo are informational only and current as of the writing of this memo; the rates are approximate as they have been rounded to 2 decimals)**

***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. Pharmacies may be subject to audit and penalties for prescriptions that have not been credited to Medicaid in a timely manner. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.*

**REMINDER REGARDING 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, are incarcerated in a correctional or holding facility for individuals who are prisoners, including juvenile correctional facilities***, 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.*** Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

**REMINDER ABOUT DISPENSING USING EMERGENCY OVERRIDE:** In an emergency, for those drugs for which a five-day supply can be dispensed, an enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires a prior authorization, e.g., a drug that requires a clinical PA or a PA for a non-preferred drug. This provision applies only in an *emergency* situation when the MMA Prescription Drug Help Desk is unavailable, EBRx Call Center is unavailable, the state Medicaid Pharmacy Program office is closed, and the pharmacist is not able to contact the prescribing physician to change the prescription.

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. Frequency of the emergency override is limited to *once per year per class of drugs* for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. 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.

**1. CHANGES TO EXISTING POINT OF SALE PRIOR AUTHORIZATION (PA) CRITERIA OR EDITS:**

## The following changes for the BENZODIAZEPINE agents will be effective MARCH 8, 2016.

**A. CHANGES TO BENZODIAZEPINES, SOLID ORAL DOSAGE FORMS AND ODT FORMS:** The manufacturers' package inserts state that effectiveness of anxiolytic benzodiazepines (alprazolam, lorazepam, chlordiazepoxide, clonazepam, diazepam, clorazepate, oxazepam) for the treatment of anxiety, panic disorder, or generalized anxiety disorder in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. Because of the ability for benzodiazepines to produce physical dependency, benzodiazepines are not considered first-line treatment for long-term management of anxiety, panic disorder, or generalized anxiety disorder.

**The existing quantity edits and edits to prevent therapeutic duplication of benzodiazepines have been revised for all beneficiaries, including long-term care.** The changes are listed below.

- Unless otherwise stated, no therapeutic duplication is allowed between two benzodiazepines with > 10% of the days' supply remaining on the last fill;
- The maximum daily quantity edits for capsules and tablets, including ODT forms, have been decreased to the following:
  - The accumulation quantity edit that allowed up to 124 units of one or more solid oral dosage forms of benzodiazepines per 31 calendar days is removed;
  - Unless otherwise stated, the quantity edit of the single highest strength of a benzodiazepine tablet or capsule has been reduced to a maximum daily quantity of 2 units per day or a cumulative quantity of 62 units for a 31-day supply;
  - Unless otherwise stated, all other strengths of tablet or capsule forms of benzodiazepines have been reduced to a maximum daily quantity edit of 3 units per day or a cumulative quantity of 93 units for a 31-day supply;
  - Benzodiazepine long-acting (ER or XR) formulation quantity edits will remain at 1 unit per day, and 31 per 31 days' supply;
  - Unless otherwise stated, the Early Refill allowance for benzodiazepines, including benzodiazepine XR or ER formulations, have changed and will be set for after 90% of the days' supply has expended. For example, a refill or a change in therapy to a different benzodiazepine agent will be allowed an day 28 of a 30-day supply and on day 29 of a 31-day supply; i.e., if a claim filled on 12/1/2015 for a 31-day supply the beneficiary can refill or change therapy on day 29, or on 12/30/15; if a claim filled on 12/1/2015 for a 30-day supply, the beneficiary can refill or change therapy on day 28, or on 12/29/15.
  - Sedative hypnotic benzodiazepines quantity edits will remain at 1 unit per day; the early refill allowance has not changed for benzodiazepine sedative hypnotic agents, which does not allow any overlap with a refill or a switch to another benzodiazepine sedative-hypnotic;
  - All strengths of clobazam (Onfi®) tablet quantity edits will remain at 2 per day; the early refill allowance for clobazam has not changed and will remain at after 75% of the days' supply has expended;

*See chart below for summary of maximum daily quantity edits of solid oral dosage forms of benzodiazepines:*

| Generic Name (Brand name reference only) | Strength | Maximum Daily Quantity Edit (& Maximum Cumulative Quantity edit per 31-days' supply) |
|---|---|---|
| Alprazolam (Xanax) tablet & ODT | 0.25 mg, 0.5 mg, 1 mg | 3 units per day, (93) |
| Alprazolam (Xanax) tablet & ODT | 2 mg | 2 units per day, (62) |
| Chlordiazepoxide (Librium) Capsule | 5 mg, 10 mg, | 3 units per day, (93) |
| Chlordiazepoxide (Librium) Capsule | 25 mg | 2 units per day, (62) |
| Clonazepam (Klonopin) Tablet | 0.125 mg, 0.25 mg, 0.5 mg, 1 mg | 3 units per day, (93) |
| Clonazepam (Klonopin) Tablet | 2 mg | 2 units per day, (62) |
| Clorazepate (Tranxene) Tablet | 3.75 mg, 7.5 mg, | 3 units per day, (93) |
| Clorazepate (Tranxene) Tablet | 15 mg | 2 units per day, (62) |
| Diazepam (Valium) Tablet | 2 mg, 5 mg | 3 units per day, (93) |
| Diazepam (Valium) Tablet | 10 mg | 2 units per day, (62) |
| Lorazepam (Ativan) Tablet | 0.5 mg, 1 mg | 3 units per day, (93) |

| Generic Name (Brand name reference only) | Strength | Maximum Daily Quantity Edit (& Maximum Cumulative Quantity edit per 31-days' supply) |
|---|---|---|
| Lorazepam (Ativan) Tablet | 2 mg | 2 units per day, (62) |
| Oxazepam (Serax) Capsule | 10 mg, 15 mg | 3 units per day, (93) |
| Oxazepam (Serax) Capsule | 30 mg | 2 units per day, (62) |
| Clobazam (Onfi) Tablet | 10 mg, 20 mg | 2 units per day, (62) |
| Alprazolam (Xanax) ER and XR Tablet | 0.5 mg, 1 mg, 2 mg, 3 mg | 1 unit per day, (31) |
| Flurazepam (Dalmane) Capsule | 15 mg, 30 mg | 1 unit per day (31) |
| Temazepam (Restoril) Capsule | 7.5 mg, 15 mg 30 mg 22.5 mg | 1 unit per day (31) |
| Triazolam (Halcion) Tablet | 0.125 mg, 0.25 mg | 1 unit per day (31) |
| Estazolam (Prosom) Tablet | 1 mg, 2 mg | 1 unit per day (31) |

Prior to the implementation date of **MARCH 8, 2016,** if a patient has a condition or diagnosis, such as epilepsy or malignant cancer, and has a *medical necessity* requiring more than one benzodiazepine as concurrent therapy, the prescribing provider may fax a letter of medical necessity, along with all chart notes and documentation to substantiate the medical necessity, to Magellan-Arkansas Medicaid Pharmacy Unit at 1-800-424-7976 for a prior authorization review.

Abundant evidence documents the significant co-use of benzodiazepines (BZD) and opioids and the combination is among the most frequently abused of the psychoactive drug classes in the world. Preclinical evidence that BZDs increase the rewarding and reinforcing effects of opioids may give researchers the best indication of why these drugs are used concomitantly. Specifically, individuals may be co-using opioids and BZDs in order to amplify the μ agonist effects of opioids (e.g. opioid intoxication). Clinical studies have suggested that the concomitant use of BZDs and opioids is associated with the occurrence of fatal and non-fatal opioid overdoses. When BZDs and opioid drugs are used together to treat individuals, the treatment is complicated by the possibility of dual physical dependence of opioids and BZDs. When used together, the combination of opioid and BZD drugs has serious detrimental effects upon physical health, mental health, and sobriety, and increases the risk of opioid overdose[1].

Prescribing providers are encouraged to review patient profiles or the Prescription Drug Monitoring Program (PDMP) for therapeutic duplication of benzodiazepines, quantity, dose and strengths, and frequency of filled benzodiazepine prescriptions. Options to avoid rejected claims include titrating doses downward, optimizing the dose by adjusting strengths and quantities, and reducing the number of benzodiazepine agents prescribed to one agent. If a Medicaid beneficiary is receiving more than one benzodiazepine prescription as a Medicaid paid claim from the same or different prescribers, rejections will occur at the retail pharmacy. General benzodiazepine addiction information and examples of benzodiazepine scheduled tapers are offered below[2]:

- Benzodiazepine (BZD) addiction is an issue with many consequences, one of them being addiction withdrawal symptoms experienced when the BZD are discontinued.
- The type of BZD used plays an important part in determining the length and severity of drug withdrawal. Another factor to be aware of during BZD withdrawal is drug craving. Short-acting rather than intermediate- or long-acting benzodiazepines, are more likely to cause rebound symptoms because the longer the half-life the longer the therapeutic effects occur after discontinuation.
- Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol have occurred following abrupt discontinuance of BZD. The more severe withdrawal symptoms have usually been limited to those patients who received excessive doses over an extended period of time.
- Tapering benzodiazepine dosage is recommended with long-term use, i.e., greater than 4 to 6 weeks of oral drug and 7 days with intravenous midazolam for sedation of the critically ill patient. For elderly patients receiving benzodiazepines for insomnia over at least 3 months, an 8 to 10 week taper may be warranted, whereas, patients with generalized anxiety may tolerate a taper of 4 to 8 weeks.
- Several standard inpatient benzodiazepine withdrawal schedules exist. The following are examples of such tapers:
  A 50% dose reduction every 5 days,
  A 25% dose reduction weekly,
  A 25% dose reduction weekly until 50% of the dose remains followed by one-eighth dose reduction every 4 to 7 days.

[1]Jones, J., et.al. (2013) Polydrug abuse: A review of opioid and benzodiazepine combination use. **Retrieved December 3, 2015** **http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/**

[2] A. Olyaei PharmD, 2005, http://www.ohsu.edu/academic/medicine/residency//handouts/pharmpearls/Psychiatry%20CNS%20Neuro/BenzodiazepineDrugWithdrawalTaper.pdf ; retrieved August 10, 2010

- Generally speaking, the dose of BZD should be reduced every 2 weeks from 100% to 50% to 25% to 12.5%. In most patients, eight weeks after starting the dose reduction, patients should be withdrawn completely. Successful outcome was defined as being hypnotic-free at 3 to 6 months after discontinuing of BZD.

| Drug | Common Brand Names | Elimination Half Life in hours[a b] | Approximate Equivalent Oral Dosages[c] |
|---|---|---|---|
| Alprazolam | Xanax, Xanax XR | 9 - 20 | 0.5 mg |
| Chlordiazepoxide | Librium | 24 - 100 | 25 mg |
| Clonazepam | Klonopin | 19 - 60 | 0.5 mg |
| Clorazepate | Tranxene | 1.3 - 120 | 15 mg |
| Diazepam | Valium | 30 - 200 | 10 mg |
| Estazolam | ProSom | 8 - 24 | 1-2 mg |
| Flurazepam | Dalmane | 40 - 250 | 15-30 mg |
| Lorazepam | Ativan | 8 - 24 | 1 mg |
| Oxazepam | Serax | 3 - 25 | 20 mg |
| Quazepam | Doral | 39 - 120 | 20 mg |
| Temazepam | Restoril | 3 - 25 | 20 mg |
| Triazolam | Halcion | 1.5 - 5 | 0.25 mg |

[a]Half Life in hours from: Clinical Handbook of Psychotropic Drugs, 4th revised edition, Bezchlibnyk-Butler et al. editors (Clarke Institute of Psychiatry, Toronto), Hogrefe & Huber.

[b]The duration of apparent action is usually considerably less than the half-life. With most benzodiazepines, noticeable effects usually wear off within a few hours. Nevertheless, as long as the drug is present it will exert subtle effects within the body. These effects may become apparent during continued use or may appear as withdrawal symptoms when dosage is reduced or the drug is stopped. Notation on duration of action from http://en.wikipedia.org/wiki/List_of_benzodiazepines

[c]Estimated Equivalent Dose chart from C.H. Ashton, http://www.benzo.org.uk/manual/bzcha01.htm#24, retrieved Aug 11, 2010. "These equivalents do not agree with those used by some authors. They are firmly based on clinical experience during switch-over to diazepam at start of withdrawal programs but may vary between individuals.", from the Ashton Manual.

## The following edits will be effective FEBRUARY 16, 2016 unless otherwise stated.

**B. TOPICAL PEDICULICIDE HEAD LICE TREATMENTS**: Based on the Medicaid claims data and the timespan between fills for the permethrin agents, the utilization data does not reflect resistance to permethrin products in Arkansas. The Medicaid drug utilization data for the permethrin products show appropriate retreatment at approximately 10-13 days after the initial claim as is recommended in the package inserts and the American Academy of Pediatrics (AAP), as well as additional claims filled at much later dates that indicate either a self-reinfestation or an infestation from another source.

The successful treatment for head lice for all pediculicide agents is basically the same: removal of all nits (eggs) using a special fine-toothed comb to scrape all lice and nits off the hairs; using the highest heat settings possible, machine wash and dry clothing, bed linens, stuffed toys, blankets, and any other washable items, or dry clean the items, and vacuum furniture, car, carpet, etc.

The point-of-sale (POS) prior approval (PA) criteria for the pediculicide agents have been revised to the following:

- PERMETHRIN 1% and PIPERONYL BUTOXIDE/PYRETHRINS (OTC) NDCs that are currently covered remain available without PA for rebate-able NDCs; existing quantity limits remain;
- PERMETHRIN 5% (Rx) remain available without PA; existing quantity limits remain;
- OVIDE® lotion (malathion) 0.5% POS PA criteria revised to the following:
  - History of at least 2 claims from 7 days to 21 days back of the following:
    - Two permethrin1% claims OR,
    - Two permethrin 5% claims, OR
    - Two pyrethrin-piperonyl claims, OR,
    - One permethrin 1% and one permethrin 5%, OR
    - One permethrin 5% and one pyrethrin-piperonyl claim, OR
    - One permethrin 1% and one pyrethrin-piperonyl claim; AND
  - 2 pediculicide claims cannot have the same date of service (DOS); AND
  - No paid claim for Sklice (ivermectin) in previous 28 days, AND
  - No paid claim for Ovide (malathion) in previous 28 days, AND
  - Patient ≥ 6 years of age; AND
  - Quantity edit will remain as one container (59 ml) per claim
- SKLICE™ (ivermectin) 0.5% lotion: Changed to POS PA criteria listed below:

- History of at least 2 claims from 7 days to 21 days back of the following:
  - Two permethrin1% claims OR,
  - Two permethrin 5% claims, OR
  - Two pyrethrin-piperonyl claims, OR
  - One permethrin 1% and one permethrin 5%, OR
  - One permethrin 5% and one pyrethrin-piperonyl claim, OR
  - One permethrin 1% and one pyrethrin-piperonyl claim; AND
- 2 pediculicide claims cannot have the same DOS; AND
- No paid claim for Sklice (ivermectin) in previous 28 days, AND
- No paid claim for Ovide (malathion) in previous 28 days, AND
- Patient ≥ 6 months of age; AND
- Quantity edit will remain as one container (117 ml) per claim

- LINDANE SHAMPOO AND LINDANE LOTION: Remove from point-of-sale (POS) PA algorithm and change to manual review PA; quantity edits remain;

- EURAX® (crotamiton) cream & lotion, NATROBA™ (spinosad 0.9%) topical suspension, and ULESFIA® (benzyl alcohol) to remain as manual review PA; current quantity edits to remain.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**C. CHANGE IN LOWER AGE LIMIT FOR All ANTIPSYCHOTIC AGENTS WRITTEN FOR CHILDREN:** Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 6 years of age. This manual review is performed by the Medicaid Pharmacy Program child psychiatrist.

Medicaid has *increased the lower age limit that will require a manual review* PA to <**7** years of age for all new starts on an antipsychotic agent, including a change in the chemical entity. All documentation, chart notes, signed informed consent, and required lab work must be submitted and will be reviewed by the Medicaid Pharmacy Program child psychiatrist.

**Evidence-based Prescription Drug Program (EBRx) PA Call Center at (Toll Free) 1-866-250-2518 or Local 501-526-4200. The NEW EBRx FAX number is: 1- 800-424-5739.**

**D. AROMATASE INHIBITORS, ARIMIDEX® (anastrozole) AND FEMARA® (letrozole) tablets:** The aromatase inhibitor drugs are indicated for adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer; first and second-line treatment of advanced breast cancer; treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Some prescribers were using these agents off-label for infertility treatments in the Medicaid population, which is a non-covered service in Medicaid.

Point of sale denial criteria were added for the diagnoses codes of infertility in Medicaid history.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**2. NEW CLAIM EDITS, INCLUDING DOSE-OPTIMIZATION, QUANTITY EDITS, OR ACCUMULATION EDITS:**

**A. INTRON® A (INTERFERON ALFA-2B) POWDER FOR INJECTION AND SOLUTION FOR INJECTION:** INTRON® A is indicated for Intron® A is indicated for Hairy Cell Leukemia, Malignant Melanoma, Follicular Lymphoma, Condylomata Acuminata, AIDS-Related Kaposi's Sarcoma, Chronic Hepatitis C, and Chronic Hepatitis B.

A point-of-sale denial criterion for the diagnosis of hepatitis C in Medicaid history has been added to INTRON® A. All medications for treating hepatitis C require a manual review PA.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**B. EARLY REFILL EDITS ADDED TO NON-CONTROLLED DRUGS AND REFILL TOO SOON (RTS) LOGIC ADDED TO ALL DRUGS:**

The U.S. Government Accountability Office (GAO) issued a report to the Congressional Requestors in Aug. 2015 regarding "indicators of potential prescription-medication fraud and abuse among thousands of Medicaid beneficiaries and hundreds of prescribers during fiscal year 2011". As required by federal law, the Medicaid Drug Utilization Review program is a two-phase review process state Medicaid agencies use to promote safety while also monitoring prescription-drug activity for fraud. Federal law requires each state to report on the operation of its review program, a key monitoring tool that the Centers for Medicare & Medicaid Services (CMS) uses to oversee the review process in states, but GAO identified additional actions that could improve oversight. In the first phase, states use tools and eligibility screening to promote patient safety and avoid abuse before the drugs are dispensed. The second phase involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care, and implement corrective action when needed.

**Early Refill Hard Edit Added To Non-Controlled Drugs:**

Currently the Medicaid Pharmacy Program system has a hard edit on controlled drugs that prevents a refill of the medication sooner than 75% of the days' supply expended, or approximately 7 days early on a 30 or 31-day supply. The manual review PA to allow an early refill checks for a dose increase that will cause the beneficiary to run out of the medication before the drug claim will fill without a PA.

In keeping with the GAO recommendations to prevent fraud, abuse, gross overuse, or medically unnecessary care, the AR Medicaid Pharmacy Program will implement a hard edit on early refills for all non-controlled drugs to prevent refills sooner than 75% of the days' supply expended. The pharmacy or the prescriber can fax a copy of the new prescription to the Magellan fax number below to request a PA for an early refill. The manual review PA to allow an early refill will check for a dose increase that would cause the beneficiary to run out of the medication before the drug claim can be filled without a PA.

**Refill Too Soon (RTS) Logic Added:**

In addition to adding the hard edit to prevent non-controlled drugs from being filled earlier than 75% of the days' supply expended, the Medicaid system will implement refill-too-soon (RTS) logic for all drugs in the system.

The Refill Too Soon logic is an *Early Refill Accumulation Limit* that will allow a beneficiary, who fills prescriptions early, a maximum accumulation of *15-days' supply filled early during a 180-day look-back period of time.* The Refill Too Soon logic will apply to both controlled drugs and non-controlled drugs. *The RTS logic is not based on the prescription number*; the RTS logic will identify the same drug/same strength/same dosage form and add up the days' supply for each time the drug is filled early during the look-back period. The RTS logic will start with the date of service on the incoming claim and look back 180 days for the number of days filled early during that time period. Once the beneficiary has reached an accumulation of 15 days' supply filled early for same drug/same strength/same dosage form in the previous 180 days, the drug cannot be filled early again until the oldest "early" fill is outside of the date range.

Below is an example of the RTF logic with example refill dates showing how the logic adds up all "early" days' supply during the 180-day look-back period. Medicaid will continue to monitor the early fills to determine if additional changes to the RTS logic are needed for any of the drug classes.

| FOR EXAMPLE, 12/9/15 IS THE ORIGINAL CLAIM DATE | | | | NOTE THE DOSE HAS NOT CHANGED | | |
|---|---|---|---|---|---|---|
| SAMPLE FILL DATES | # DAYS SINCE FILL | DRUG/STRENGTH/DOSAGE FORM | PHARMACY Rx # | QTY / DAYS' SUPPLY | # DAYS EARLY | NOTES |
| 1/1/2016 | 23 | METHYLPHENIDATE 20 MG TAB. | N1358 | 90/30 | 7 | **The Beneficiary accumulated an additional 15 days' supply from "early" fills, which is 45 tablets "extra"** |
| 1/24/2016 | 23 | METHYLPHENIDATE 20 MG TAB. | N1921 | 90/30 | 7 | |
| 2/22/2016 | 29 | METHYLPHENIDATE 20 MG TAB. | N2057 | 90/30 | 1 | |
| 3/23/2016 | 30 | METHYLPHENIDATE 20 MG TAB. | N3159 | 90/30 | 0 | Cannot fill early |
| 4/22/2016 | 30 | METHYLPHENIDATE 20 MG TAB. | N4290 | 90/30 | 0 | Cannot fill early |
| 5/22/2016 | 30 | METHYLPHENIDATE 20 MG TAB. | N5922 | 90/30 | 0 | Cannot fill early |
| 6/21/2016 | 30 | METHYLPHENIDATE 20 MG TAB. | N8259 | 90/30 | 0 | Cannot fill early |
| In this example, an incoming claim must be dated 6/30/16 or later before the oldest "early" filled claim will be outside of the 180-day range. Note that in this scenario none of the refill dates were "late". The Beneficiary still has an accumulation of an "extra" 45 tablets. | | | | | | |

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**3. NEW AND REVISED CLINICAL EDITS THROUGH MANUAL REVIEW PRIOR APPROVAL (PA) PROCESS:**

***THE FOLLOWING CHANGES TO BUPRENORPHINE/NALOXONE AGENTS FOR USE IN OPIOID DEPENDENCY TREATMENT WILL BE EFFECTIVE FEBRUARY 8, 2016***

**A. BUPRENORPHINE-CONTAINING AGENTS AND COUNSELING CRITERIA IN OFFICE-BASED OPIOID DEPENDENCY TREATMENT PROGRAMS:** At this time, Medicaid has selected Suboxone® FILM as the buprenorphine/naloxone agent based on it being the most economical choice for the state. Other agents being requested will require documentation for medical necessity over the Suboxone® FILM and will be reviewed on a case-by-case basis.

Under federal law, Medication-Assisted Treatment (MAT) patients being treated for substance use disorders must receive counseling, which could include different forms of behavioral therapy. The AR Medicaid Pharmacy Program has required counselling as part of the PA criteria since 2010. The counseling requirements for PA approval for the buprenorphine and buprenorphine/naloxone have changed.

The revised counselling requirements are outlined below and are listed on the revised buprenorphine Statement of Medical Necessity PA request form that is posted on the Medicaid website. In addition, all PA requests for buprenorphine or buprenorphine/naloxone agents must be received from a physician prescriber who meets all credentialing requirements by SAMHSA and the DEA for prescribing a buprenorphine-containing agent for the purpose of treating a patient with an opioid use disorder.

Please review the revised buprenorphine/naloxone PA form for complete PA requirements and counseling criteria located at this link:
https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Buprenorphine_Naloxone_Buprenorphine.pdf.

*Submitting documentation for the required counseling or the urine drug screen results does not constitute Medicaid payment approval for counseling or urine drug screens.*

As a condition of coverage or payment for buprenorphine or buprenorphine/naloxone drug claim, ***counseling is required by a licensed clinician experienced in addiction counseling***.

- Beneficiaries may select counseling with a licensed clinician through the Division of Behavioral Health Services using a Funded Substance Abuse Treatment Facility***.*** There are 8 funded substance abuse treatment facilities in Arkansas that provide substance abuse counseling services to adults and may offer the services at a reduced cost or no cost, depending on income level of the Medicaid beneficiary. A list of these facilities is included on the website with the buprenorphine PA form.
- Beneficiaries may select counseling with a licensed clinician through an office-based treatment program and receive counseling from a LMSW, LCSW, LPC, LPE, LAC LADAC, a psychiatrist who has experience in addiction treatment, or an ABAM board certified physician.
- ALL individual and group counseling from the above services must be documented and include the name of counselor (physician, counselor, therapist, etc.), job title, time spent with the patient during the counseling session, and signature of the counselor. **Thirty (30) minutes is the *minimum time*** to qualify as an individual counseling session for the purposes of this PA request form from any of the above clinicians.
- For those beneficiaries who do not select the above counseling options or who do not have access to the above listed licensed clinicians due to location or cost, the beneficiary *must attend either Narcotics Anonymous or Alcoholics Anonymous* and obtain a sponsor in the 12-Step Program. The beneficiary must provide written documentation for each attendance, with date, time, and location.
- The required number of counseling visits or attendance to a 12-step program for each PA request is outlined below and on page 2 of the revised PA form.
- *If the prescriber doesn't require counseling as part of the opioid treatment program, Arkansas Medicaid Pharmacy Program will not approve a buprenorphine-containing agent for treatment.*
- Lack of documentation for individual or group counseling sessions or lack of attendance to 12-step sessions will result in delayed or denied Prior Authorizations.
- Results of current (within 30-days) urine drug screen are required to be submitted with each PA request. Positive drug screens after month-3 of treatment will result in delayed or denied Prior Authorization.

**Required number of counseling visits or 12-Step Program visits for PA approval:**

- For the first or initial approved PA, documentation of the beneficiary's first individual counseling or the treatment plan showing the counseling schedule is required. The initial approved PA will not exceed a 1-month timeframe.
- Continuation PAs for Month -2 and Month-3: The approved PA for month -2 and month-3 will not exceed a 1-month timeframe per request.
    - **To receive a PA beginning Month-2 of treatment:** provide documentation of a *minimum of two individual AND two group counseling sessions per month* from the 1st month of treatment; OR provide written documentation of beneficiary attending a 12-Step Program a *minimum of 8 times during 1st month of treatment;*
    - **To receive a PA beginning Month-3 of treatment:** provide documentation of a *minimum of two individual and two group counseling sessions per month* from the 2nd month of treatment; OR provide written documentation of beneficiary attending a 12-Step Program a *minimum of 8 times during 2nd month of treatment;*

- Continuation PAs for Month-4 and thereafter: Written documentation of counseling required for continuation PA requests. The 4th & subsequent PAs will not exceed a 3-month timeframe for each PA:2/2/
    - **To receive a PA beginning Month-4 of treatment*** provide documentation of a *minimum of one individual and one group counseling session* from 3rd month of treatment; OR provide written documentation of beneficiary attending a 12-Step Program *a minimum of 8 times during 3nd month of treatment;*
    - **To receive a PA beginning Month-7 of treatment* and thereafter:** provide documentation of a *minimum of one individual and one group counseling session per month* from previous 3 months of treatment; OR provide written documentation of beneficiary attending a 12-Step Program *a minimum of 5 times per month during previous 3 months.*

    **As noted above, drug screen results and counseling / 12-step documentation may alter length of approved PA, or may result in delayed approval, or denied approval.*

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

## The following edits will be effective IMMEDIATELY:

**B. CHANGES TO HCV DRUG THERAPY: DAKLINZA™ (GT-3) and TECHNIVIE™ (GT-4) AND ADDITIONAL REVISIONS:**

TN= treatment naïve; TE= treatment experienced; GT= Genotype

**NOTE**: ***Recent changes in the FDA approved package inserts for TECHNIVIE™ and VIEKIRA PAK™ state these agents are contraindicated for patients with Child-Pugh B or Child-Pugh C scores. Child-Pugh scores are now required for all GT-1 AND GT-4 HCV PA requests. Submitting these required test results does not constitute Medicaid payment approval for these tests*)**

**(1) DAKLINZA™ (daclatasvir) 60 mg TABLET:** DAKLINZA™ is indicated for use with sofosbuvir for the treatment of patients with chronic hepatitis C virus (HCV) GT-3 infection. The sustained virologic response (SVR) rates are reduced in patients with cirrhosis. The recommended dosage of DAKLINZA is 60 mg, taken orally, once daily in combination with sofosbuvir for 12 weeks.

EAC: SOVALDI® + RBV x 24 weeks = $174,870
EAC: DAKLINZA™ + SOVALDI® x 12 weeks therapy = $151,704

Approval criteria for GT-3 are the following:

- GT-3 F3 TN, or GT-3 F3 TE, or GT-3 F4 TE: approve DAKLINZA™ + SOVALDI® x 12 WEEKS;
- GT-3 F4 TN: treatment approval will remain as SOVALDI® + RBV x 24 weeks based on the very low SVR in the DAKLINZA™ package insert for the F4 TN population.

**(2) TECHNIVIE™ (ombitasvir, paritaprevir and ritonavir) TABLET:** TECHNIVIE™ indicated in combination with ribavirin for the treatment of patients with GT-4 chronic hepatitis C virus (HCV)

infection without cirrhosis. The RBV is weight based dose. Recommended dosage: Two tablets taken orally once daily (in the morning) Duration of therapy is 12 weeks.

EAC: SOVALDI® + PR x 12 weeks= $97,509;
EAC: TECHNIVIE™ + RBV X 12 WEEKS = $80,600.14

Approval criteria for GT-4 are the following:

- GT-4 F3 TN OR TE: approve TECHNIVIE™ + RBV x 12 weeks;
- GT-4 F4 TN: approval will remain as SOVALDI® + PR x 12 weeks; TECHNIVIE™ is not indicated for GT-4 F4;
- GT-4 F4 TE: there is no FDA approved drug for this population; each request will be reviewed on a case-by-case basis.

The revised HCV PA form can be found at this link:
https://arkansas.magellanrx.com/provider/docs/rxinfo/HepCTreatmntForm.pdf.

**SUMMARY OF THE HCV APPROVAL CRITERIA**

| **NOTE-- For purposes of this PA request: Advanced fibrosis = Metavir F3; Compensated cirrhosis = Metavir F4** | **DRUGS FOR PA APPROVAL** |
|---|---|
| GT-1 TN w/o cirrhosis (Metavir F3) *who have pre-treatment HCV RNA less than 6 million IU/ml:* | HARVONI® X **8** WEEKS |
| GT-1a TN or TE w/o cirrhosis (Metavir F3) | VIEKIRA PAK™ + RBV X 12 WEEKS |
| GT-1a TN with cirrhosis (Metavir F4) | VIEKIRA PAK™ + RBV X 12** WEEKS |
| GT-1a TE with cirrhosis (Metavir F4) | VIEKIRA PAK™ + RBV X 24 WEEKS |
| GT-1b TN or TE w/o cirrhosis (Metavir F3) | VIEKIRA PAK™ X 12 WEEKS |
| GT-1b TN or TE with cirrhosis (Metavir F4) | VIEKIRA PAK™ + RBV X 12 WEEKS |
| GT-2 TN or TE with cirrhosis (Metavir F4) or w/o cirrhosis (Metavir F3) | SOVALDI®+ RBV x 12 WEEKS |
| GT-3 TN or TE w/o cirrhosis (Metavir F3), GT-3 TE with cirrhosis (Metavir F4) | DAKLINZA™ + SOVALDI X 12 WEEKS |
| **NOTE-- For purposes of this PA request: Advanced fibrosis = Metavir F3; Compensated cirrhosis = Metavir F4** | **DRUGS FOR PA APPROVAL** |
| GT-3 TN with cirrhosis (Metavir F4) | SOVALDI® + RBV X 24 WEEKS |
| GT-4 TN or TE w/o cirrhosis (Metavir F3) | TECHNIVIE™ + RBV x 12 WEEKS |
| GT-4 TN with cirrhosis (Metavir F4) | SOVALDI + PR X 12 WEEKS |
| GT-4 TE with cirrhosis (Metavir F4) | *There is no FDA approved drug for this population. All requests will be reviewed on a case-by-case basis.* |
| GT=GENOTYPE; TN=TREATMENT NAÏVE; TE=TREATMENT EXPERIENCED; RBV=RIBAVIRIN; PR=PEGALATED INTERFERON+RIBAVIRIN | |
| ** "VIEKIRA PAK™ administered with ribavirin for **12** weeks may be considered for some patients based on prior treatment history". In *GT-1a TN infected subjects with cirrhosis*, there was not a significant clinical difference in the SVR12 rates between 24 and 12 weeks of treatment with VIEKIRA PAK™ plus RBV. | |

**Fax the HCV Statement of Medical Necessity Form, chart notes, and required labs to the AR Medicaid Pharmacy Program at 1-800-424-5851.**

C. **ENTRESTO™ (sacubitril and valsartan) tablet 24/25 mg, 49/51 mg, 97/103 mg** is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. ENTRESTO™ is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB.

The recommended starting dose of ENTRESTO is 49/51 mg twice-daily.

EAC: $6.45 each tablet; per day = $12.90; per 30 days = $387

Entresto™ will require a manual review PA on a case-by-case basis based on data in the package insert for indications, dose, and criteria used in the clinical trials, such as patients had to have been on an ACE inhibitor or ARB for at least four weeks and on maximally tolerated doses of beta-blockers. The Medicaid pharmacy profile will be reviewed for compliance. Left ventricular ejection fraction ≤ 35% will also be required. In addition, denial criteria will include patients with a systolic blood pressure of < 100 mmHg. Chart notes are required for the manual review as well as reviewing the Medicaid pharmacy profile.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

D. **PCSK9 AGENTS: REPATHA™ (evolocumab) 140 mg/ml SQ INJECTION AND PRALUENT™ (alirocumab) 75 mg/ml, 150 mg/ml SQ INJECTION:** REPATHA™ and PRALUENT™, have been approved

by the FDA, as an adjunct to diet and maximally tolerated statin therapy, to treat heterozygous familial hypercholesterolemia (HeFH) and clinical atherosclerotic cardiovascular disease. In addition, Repatha is also indicated as an adjunct to diet and other LDL-lowering therapies to treat HoFH.
The recommended subcutaneous dosage of REPATHA™ in patients with HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD is either 140 mg every 2 weeks OR 420 mg once monthly. The recommended subcutaneous dosage of REPATHA™ in patients with HoFH is 420 mg once monthly. In patients with HoFH, measure LDL-C levels 4 to 8 weeks after starting REPATHA, since response to therapy will depend on the degree of LDL-receptor function.

The recommended starting dose of PRALUENT™ is 75 mg administered subcutaneously once every 2 weeks, since the majority of patients achieve sufficient LDL-C reduction with this dosage. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks.

EAC: REPATHA™: $559.66 each syringe; 420 mg per month = $1,678.98; per 12 months = $20,147.76
EAC: PRALUENT™: $577.92 each syringe 75 mg or 150 mg; 1 syringe every 2 weeks x 1 year = $15,025.92

REPATHA™ and PRALUENT™ will require manual review PA on a case-by-case basis based on data in the package insert for FDA approved indications, dose, and criteria used in the clinical trials. Chart notes are required for the manual review as well as reviewing the Medicaid pharmacy drug profile.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**E. DARAPRIM® (pyrimethamine) 25 mg TABLET: Treatment of toxoplasmosis:** DARAPRIM® is indicated for the treatment of toxoplasmosis when used conjointly with a Sulfonamide, since synergism exists with this combination. DARAPRIM® is also indicated for the treatment of acute malaria, however, resistance to pyrimethamine is prevalent worldwide.

The dosage of DARAPRIM® for the treatment of toxoplasmosis must be carefully adjusted so as to provide maximum therapeutic effect and a minimum of side effects. The adult starting dose is 50 to 75 mg of the drug daily, together with 1 to 4 g daily of a sulfonamide of the sulfapyrimidine type, e.g. sulfadoxine. This dosage is ordinarily continued for 1 to 3 weeks, depending on the response of the patient and tolerance to therapy. The dosage may then be reduced to about one half that previously given for each drug and continued for an additional 4 to 5 weeks.
**EAC: $774 PER TABLET; 50 mg daily dose = $46,440 for 30-day supply; 75 mg daily dose = $69,660 for 30-day supply.**

DARAPRIM® will require a manual review PA on a case-by-case basis based on data in the package insert for indications and dose.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**F. ORKAMBI™:** ORKAMBI™ (lumacaftor/ivacaftor) is indicated for the treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene. Limitations of Use: The efficacy and safety of ORKAMBI™ have not been established in patients with CF other than those homozygous for the F508del mutation.

The dose for adults and pediatric patients age 12 years and older is two tablets orally every 12 hours with fat-containing food. Patients with a moderate hepatic impairment (Child-Pugh class B) dose are not to exceed 3 tablets per day; patients with severe hepatic impairment (Child-Pugh Class C) dose are not to exceed 2 tablets per day.

Serious adverse reactions related to elevated transaminases have been reported in patients with CF receiving ORKAMBI. In some instances, these elevations have been associated with concomitant elevations in total serum bilirubin.

It is recommended that ALT, AST, and bilirubin be assessed prior to initiating ORKAMBI, every 3 months during the first year of treatment, and annually thereafter. For patients with a history of ALT, AST, or bilirubin

elevations, more frequent monitoring should be considered. Patients who develop increased ALT, AST, or bilirubin should be closely monitored until the abnormalities resolve.

Dosing should be interrupted in patients with ALT or AST greater than 5 × upper limit of normal (ULN) when not associated with elevated bilirubin. Dosing should also be interrupted in patients with ALT or AST elevations greater than 3 × ULN when associated with bilirubin elevations greater than 2 × ULN. Following resolution of transaminase elevations, consider the benefits and risks of resuming dosing

EAC: $183.58 per tablet; a dose of 4 tablets per day = $734.32 per day; packaged as 112–count tablet box containing a 4-week supply (4 weekly cartons of 7 daily blister strips with 4 tablets per strip) = $20,560.96 per container (28 day supply); $267,292.48 per year.
Orkambi will require a manual review PA.

*Approval criteria will require, at a minimum, the following*:

- Must be ≥Age 12 years; *AND*
- Must have CF with homozygous for the F508del mutation in the CFTR gene; AND
- Provide the calculated Child-Pugh score *AND* the labs (INR, Bilirubin, Albumin) and chart notes (for encephalopathy and ascites) required to calculate the score; *AND*
- Liver function lab results must be submitted with every PA request.
    - For the initial PA approval, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) and bilirubin elevations must be less than 2 times the ULN;
    - For continuation PA approvals, the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal;,
    - Lab results must be measured and submitted every 3 months during the 1st year, then annually; *AND*
- Approved PA will not exceed 3 months during the first year of treatment; approved PA after the first year will not exceed 6 months;
- Patient must be tobacco free;

*Denial criteria:*

- Patients with a history of 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;
- Tobacco use;

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976. AR Medicaid Pharmacy Program fax 1-800-424-5851.**

**G. MUPIROCIN CREAM 2%, MUPIROCIN 2% NASAL OINTMENT:** MUPIROCIN CREAM and MUPIROCIN NASAL OINTMENT have been changed to manual review PA. The mupirocin ointment 22 gm tube is still available without a PA, however, the quantity limit of 1 tube per claim remains in effect.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

**H. KEVEYIS™ (dichlorphenamide) TABLET 50 mg:** KEVEYIS™ is an oral carbonic anhydrase inhibitor indicated for the treatment of primary hyperkalemic periodic paralysis (HYPP, HyperKPP), primary hypokalemic periodic paralysis (HOKPP), and related variants. Initial dosing of dichlorphenamide is 50 mg twice daily. The maximum recommended total daily dose is 200 mg. Hyperkalemic periodic paralyses (HYPP) attacks are usually mild and rarely require treatment. Glucose or other carbohydrates given during hyperkalemic periodic paralyses attacks may reduce the severity of the symptoms. For treatment of HYPP, thiazide diuretics have few short-term side effects; they are tried as first-line treatment. Thiazide diuretics and carbonic anhydrase inhibitors, e.g. acetazolamide, are used as prophylaxis treatment in HYPP. For HOKPP, moderate attacks may be self-treated in a non-medical setting by ingestion of oral potassium salts. The goal of preventive treatment in HOKPP is to reduce the frequency and intensity of paralytic attacks. This may be achieved by avoidance of triggering factors; adherence to a diet low in sodium and carbohydrate and rich in potassium and oral potassium supplementation. Factors that trigger paralytic attacks (e.g., unusually strenuous effort, carbohydrate-rich meals, sweets, alcohol, prolonged immobility, oral or intravenous corticosteroids, glucose infusions) should be avoided when possible. If dietary

intervention and oral potassium supplementation are not effective in preventing attacks, acetazolamide treatment may be necessary.

EAC: Keveyis™ = $140.87 per tablet; #62 tablets = $8,733.94 for 31 day supply;
EAC: Acetazolamide 250 mg tablet = $2.63 each;
MAC: Acetazolamide ER capsule 500 mg = $3.04 each

KEVEYIS™ will require manual review PA on a case-by-case basis. The PA review will require, at a minimum, a review of the patient's chart notes, other prescription and non-prescription therapy used for treatment, and guidelines for treating Hyperkalemic periodic paralyses and Hypokalemic Periodic Paralysis.

**Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.**

## FRIENDLY REMINDERS:

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. Pharmacies may be subject to audit and penalties for prescriptions that have not been credited to Medicaid in a timely manner. See the Provider Manual Update Transmittal or the Pharmacy Provider Manual Section 213.200.

2. **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, are incarcerated in a correctional or holding facility for individuals who are prisoners, including juvenile correctional facilities, are detained pending disposition of charges, or are held under court order as material witnesses. If medications are requested for incarcerated Medicaid beneficiaries, the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment. Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

3. **ANTIPSYCHOTIC AGENTS CRITERIA FOR CHILDREN < 18 YOA have an ongoing requirement for labs** for metabolic monitoring. When any provider sends a patient who is less than 18 years of age for the metabolic labs that are required 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.

4. **INFORMED CONSENT FORM FOR ANTIPSYCHOTIC AGENT PA FOR CHILDREN < 18 YOA:**
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.

5. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS**: 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 Evidence-based Prescription Drug Program (EBRx) PA Call Center at (Toll Free) 1-866-250-2518 or Local 501-526-4200. **The NEW EBRx FAX number is: (800) 424-5739**. If faxing the request, please include any supporting documentation for the request with the fax, and include beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.

6. **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.

7. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES 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. 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.

**8.** **DISPENSING USING EMERGENCY OVERRIDE:** In an emergency, for those drugs for which a five-day supply can be dispensed, an enrolled pharmacy provider may dispense up to a five-day supply of a drug that requires a prior authorization, e.g., clinical PA criteria or drug is non-preferred. This provision applies only in an emergency situation when the MMA Prescription Drug Help Desk is unavailable, the EBRx Call Center is unavailable, the state Medicaid Pharmacy Program office is closed, and the pharmacist is not able to contact the prescribing physician to change the prescription.

To file a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. Frequency of the emergency override is limited to *once per year per class* of drugs for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. 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.

9. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE,** and are in no way a contractual obligation by Arkansas Medicaid. 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. EAC is Estimated Acquisition Cost and, in the absence of a federal or state GUL or MAC, this reimbursement methodology is calculated using AWP-14% for brand agents and AWP-20% for generic agents.

10. **MANUAL REVIEW PA REQUESTS AND EXCEPTIONS TO ESTABLISHED CRITERIA ARE REVIEWED ON A CASE-BY-CASE BASIS.** Prescribers must provide a letter explaining the medical necessity of the request drug along with written documentation, e.g., chart notes, to substantiate the medical necessity of the request. The request may be faxed to **Magellan Medicaid Administration (MMA) 1-800-424-7976.**

11. **THE ANTENATAL & NEONATAL GUIDELINES, EDUCATION AND LEARNING SYSTEM (ANGELS) PROGRAM HAS DEVELOPED A PEDIATRIC GUIDELINE FOR STRONG-WILLED PRESCHOOLERS (YOUNG CHILDREN'S STRONG-WILLED /NONCOMPLIANT/ DISRUPTIVE BEHAVIOR) THAT HAS BEEN PEER REVIEWED AND FINALIZED.** The guideline covers the problems, etiology, and prevalence of children who have disruptive behavior problems or Oppositional Defiant Disorder (ODD). The guideline indicates that early intervention is important to effectively address disruptive behavior problems and prevent escalation of the problem into the school-aged years. The guideline points out that no medications are indicated for the treatment of disruptive behavior disorders. The most thoroughly researched and validated type of interventions to treat young children's disruptive behavior are often collectively referred to as Parent Management Training (PMT), Behavioral Parent Training (BPT), or sometimes just as Parent Training (PT). PMT approaches typically involve working with both the parent and child, teaching parents specific parenting skills to improve the parent-child relationship, improve compliance, and decrease disruptive behavior. The complete guideline is available at this link: http://www.uams.edu/cdh1/peds_guidelines.aspx? Providers are asked to create a user name and password to log in to view any of the available pediatric guidelines on the website.

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.

## ***ONGOING REMINDER ABOUT ANTIPSYCHOTIC AGENTS FOR CHILDREN FROM PREVIOUS COMMUNICATIONS:***

## Prescribers are required to monitor children < 18 years of age for metabolic changes every 6 months on an outpatient basis when the child is receiving any antipsychotic agent.

Acceptable *CPT codes* for the metabolic monitoring criteria are listed below [reminder, criteria requires CPT codes monitoring for both glucose (group-1) and lipids (group-2)]:

**Group-1 (glucose codes):** Criteria require one of the following CPT codes that contain glucose monitoring in the previous 9 months from claim date of in-process claim:

- 83036 (HbA1c), OR
- 80050 (General Health Panel), OR
- 80069 (Renal Function Panel), OR
- 80047 (Basic Metabolic Panel), OR
- 80048 (Basic Metabolic Panel), OR
- 80053 (Comprehensive metabolic panel ), OR
- 82962 (Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use) OR
- 82948 (Glucose; blood, reagent strip ) OR
- 82947 (Glucose; quantitative, blood),

***AND***, criteria require one of the following lipid panel tests or all of the individual lipid test monitoring codes in previous 9 months from claim date of the in-process claim:

**Group-2 (lipid codes)**

- 80061 (Lipid panel ), OR
- 83701 (High resolution fractionation and quantitation of lipoproteins panel), OR
- 82465 (Cholesterol, serum or whole blood, total ), AND 83718 (HDL cholesterol ), AND 84478 (Triglycerides ), AND 83721 (LDL Cholesterol)

**Please Note:** When any provider sends a patient who is less than 18 years of age for the metabolic labs required for the antipsychotic agents*, the provider must include* the PCP's name and Medicaid ID number *in 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 detailed information, pasted below:

**B. The referring physician's individual provider identification number must also accompany the order.**

1. If the client's PCP referred the client to the physician ordering the tests, the ordering physician must include with the order the PCP's individual provider identification number, in addition to his or her own individual provider identification number.
2. The reference facility retains the ordering physician's provider information with the client's medical record for the medical necessity audit trail.
3. The reference facility enters the PCP's provider identification number on its claim(s) to certify PCP referral.
4. If the Medicaid client is exempt from PCP Program requirements, the reference facility submits the individual provider identification number of the ordering physician on its Medicaid claim.