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: **June 8, 2016**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board April 20, 2016 meeting:**

CHANGES TO EXISTING POINT OF SALE PRIOR AUTHORIZATION (PA) CRITERIA OR EDITS:
OPIOID CEILING DOSE OF MORPHINE MILLIGRAM EQUIVALENTS (MME) FOR OPIOID DRUGS; C-II STIMULANTS and C-III STIMULANTS (modafinil or armodafinil) for non-ADD/ADHD diagnoses; ANTIPSYCHOTIC AGENTS FOR CHILDREN < 18 years of age; GROWTH HORMONES (somatropin); ANADROL®-50 (oxymetholone);

NEW AND REVISED CLINICAL EDITS THROUGH THE MANUAL REVIEW PA PROCESS:
HCV Therapies: ZEPATIER™ (elbasvir and grazoprevir), HARVONI® (ledipasvir and sofosbuvir); VIEKIRA PAK™ (ombitasvir, paritaprevir, and ritonavir tablets and dasabuvir tablets), DAKLINZA™ (daclatasvir), SOVALDI® (sofosbuvir); TECHNIVIE™ (ombitasvir and paritaprevir and ritonavir); KALYDECO® (ivacaftor); ORKAMBI™ (lumacaftor/ivacaftor); NARCAN® (naloxone) NASAL Spray; VIBERZI™ (eluxadoline); LOTRONEX® (alosetron); ALECENSA® (alectinib); UPTRAVI® (selexipag); LANOXIN® (digoxin); STRENSIQ™ (asfotase alfa); CORLANOR® (ivabradine HCl); TRESIBA® (insulin degludec injection) LA INSULIN PEN; GLEEVEC® (imatinib) 400 mg;

CLAIM EDITS, INCLUDING DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS:
Select Cough and Cold Products containing Codeine;

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 are only current as of the writing of this memo; the rates stated are approximate as they have been rounded)

SUBMITTING A PA REQUEST:
All prior authorization (PA) requests submitted to AR Medicaid Pharmacy Program for 1) a medication that requires a Manual Review PA, or 2) a medication that requires a manual review as an exception to the established point-of-sale criteria, must be submitted to the Program directly from the prescribing provider. The Medicaid Pharmacy Program will not accept PA requests of this nature from pharmacists, community pharmacies, specialty pharmacies, third party agents, such as "covermymeds.com", or drug company advocacy groups. For these types of PA requests, the prescriber must submit a letter explaining the medical necessity of receiving the drug and chart notes to substantiate the request. Medicaid will notify the prescriber if additional information is required to complete the review.

FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS FOR CHILDREN: 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 for children < 18 years of age should call the **PDL PA Call Center at 1-800-424-7895**. **The PDL FAX number is: 1-800- 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.

REMINDER: *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.

REMINDER*: 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.

REMINDER: *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, the PDL PA Call Center is unavailable, the state Medicaid Pharmacy Program office is closed, and the pharmacist is not able to contact the prescribing provider 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 drug class or drug category*** 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, https://arkansas.magellanrx.com/provider/documents/.

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

1) OPIOID CEILING DOSE USING MORPHINE MILLIGRAM EQUIVALENTS (MME) PER DAY FOR ALL OPIOID CLAIMS (INCLUDES BOTH ORAL SHORT-ACTING AND ORAL LONG-ACTING OPIOIDS AGENTS):

In 2013, AR had 319 drug overdose deaths; in 2014, AR had 356 drug overdose deaths. Per the CDC statistics, *Arkansas showed a 11.6% increase in drug overdose death from 2013 to 2014.* Although AR did not rank high in the number of overdose deaths compared to other states, ***AR was included in the list of 13 states that have the highest number of opioid prescriptions per person*** when compared to the remaining other 37 states.

CMS (Centers for Medicare and Medicaid Services) sent a memo to Medicaid agencies sharing statistics regarding best practices in Medicaid states for addressing prescription opioid overdoses, misuse, and addiction in the Medicaid populations. Per this CMS document, "Research shows the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid beneficiaries are prescribed painkillers at twice the rate of non-Medicaid patients *and are at three-to-six times the risk of prescription painkillers overdose*." The CDC website states "**Higher dosages of opioids are associated with higher risk of overdose and death**—even relatively low dosages (20-50 morphine milligram equivalents (MME) per day) increase risk. Higher dosages haven't been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME)."

The AR Medicaid PDL notice regarding changes to the preferred drug list for long-acting opioids was mailed to providers May 9, 2016. The letter stated **METHADONE** 5 mg and 10 mg tablets and METHADONE oral solutions will **move to NON-PREFERRED status on the PDL, *effective August 8, 2016***. Prescribers are encouraged to *begin downward titration of the methadone dose* for chronic pain patients. There are several guidelines available for tapering methadone down, such as from the CDC and the VA (http://emergency.cdc.gov/coca/ppt/2012/08_01_12_methadone_fin.pdf, slide 50). *Methadone claims for treating chronic pain will reject at point of sale beginning on the above date.*

The Medicaid Retrospective Drug Utilization Review (RDUR) program and the Medicaid Pharmacy Program may be mailing educational letters to prescribing providers over the next few months regarding his/her patients receiving high doses of opioids, including methadone, for treating chronic pain. The letters will

provide additional information for converting the opioids to total morphine milligram equivalents (MME) per day as a reference point. **Prescribers are encouraged to begin downward titration of the high opioid doses now. *Retail Pharmacists must enter the correct days' supply on all opioid prescription claims submitted* to Medicaid to prevent the system miscalculating a higher MME dose that will reject at point-of-sale.**

EFFECTIVE OCTOBER 11, 2016, the Medicaid Pharmacy Program **will implement a maximum ceiling dose of 300 morphine milligram equivalents (MME) per day for chronic pain patients** receiving short-acting and or long-acting opioids given separately or together, whether from same prescriber or different prescribers. *Malignant or terminal cancer patients with an appropriate diagnosis in the Medicaid system will be exempt from these criteria*. The Medicaid pharmacy program system will convert the dose of all opioid drug claims to morphine milligram equivalents (MME) per day based on the quantity dispensed and the days' supply entered by the retail pharmacist on the drug claim. All opioid drug claims with overlapping days' supply will be added together and the total daily MME dose cannot exceed 300 MME per day. If a patient is receiving both a short-acting and a long-acting opioid for concurrent therapy, the MMEs will be added together and cannot exceed 300 MME. Opioid claims *will reject at point of sale* if the patient's total daily opioid dose is > 300 MME, or if the incoming claim with overlapping days' supply will cause the total daily dose to exceed 300 MME.

Examples of opioid IR drug claims expressed as morphine milligram equivalents (MME)/day are shown below:

- 30 mg/day hydrocodone/APAP (10 mg TID, quantity #90/30 days dispensed) = 30 MME/day
- 90 mg oxycodone IR/day (30 mg TID, quantity 90/30 days dispensed) = 135 MME/day

Methadone conversions to morphine milligram equivalents can vary widely due to methadone's *very long half-life* and *accumulation in the body* from chronic use of the drug.

Examples of estimated MMEs below are based on *chronic methadone* use calculations[1] and are shown only for *illustrative purposes* as examples of how the system could calculate the daily MME a beneficiary is receiving. The MMEs shown below are ***not*** to be used as a conversion dose to daily morphine.

- 40 mg methadone/ day (10 mg QID, #120 tablets/30 days) = *320 MME to 1,200 MME/day*
- 100 mg methadone/day (10 mg x10 tabs/day, #300 tablets/30 days) = *1,400 MME to 3,000 MME/day*
- 200 mg methadone/day (10 mg x 20 tabs/day, #600 tablets/30 days) = *4,800 MME to 6,000 MME/day*
- 250 mg methadone/day (10 mg x 25 tabs/day, #750 tablets/30 days) = *7,500 MME/day*

Examples of morphine milligram equivalents (MME) *dose for concurrent use of short-acting opioid plus long-acting opioid:*

Oxycodone-APAP 10-325 tablet, #90/30 days' supply	=	*45 MME*
Methadone[2] 10 mg # 240 for 30 days' supply	=	*960 MME[2]*
TOTAL DAILY MME	=	*1,005 MME DAILY*

Oxycodone IR 30 mg tablet, #90/30 days' supply	=	*135 MME*
Morphine ER 60 mg, #90/ 30 days' supply	=	*180 MME*
TOTAL DAILY MME	=	*315 MME DAILY*

Per the CDC, http://www.cdc.gov/drugoverdose/pdf/alternative_treatments-a.pdf **Opioids are not the first-line therapy for chronic pain** outside of active cancer treatment, palliative care, and end-of-life care. Evidence suggests that non-opioid treatments, including non-opioid medications and nonpharmacological therapies can provide relief to those suffering from chronic pain, and are safer.

***This long advance notice of implementation is given to encourage prescribers to begin opioid downward titrations now for chronic pain patients to less than a total of 300 morphine milligram equivalents (MME) per day* to avoid the opioid claims rejecting at point of sale on the implementation date.**

[1] Considerable variability exists for chronic use of high dose methadone. The CDC methadone conversion factors (http://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf) were extrapolated to calculate the high doses and GlobalRPh Calculator (http://www.globalrph.com/opioidconverter2.cgi) was used for 2nd estimation.

[2] Considerable variability exists for methadone conversions for available converting factors. Used the CDC conversion factor reference (http://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf) and the GlobalRPh Calculator (http://www.globalrph.com/opioidconverter2.cgi) for methadone 80 mg/day, which could range from 960 MME to 2,400 MME.

PDL PA Call Center at 1-800-424-7895; t**he PDL FAX number is: 1-800- 424-5739. Or call 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) **EFFECTIVE SEPTEMBER 13, 2016, C-II STIMULANTS AND C-III STIMULANTS (modafinil or armodafinil) used for non-ADD/ADHD diagnoses (narcolepsy, shift-work sleep disorder and Obstructive Sleep Apnea (OSA)/ or Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS)):**
The point-of-sale approval criteria will change to manual review PA for C-II stimulants and C-III stimulants (modafinil or armodafinil) for treating excessive daytime sleepiness due to one of the following diagnoses: narcolepsy, Obstructive Sleep Apnea (OSA)/ or Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS)), or shift-work sleep disorder. The prescriber will be required to send a letter explaining the medical necessity for the stimulant and provide the documentation required below.
In addition, over the next month, prescribers will receive a personal letter that will include his/her patient list that are receiving a C-II or a C-III stimulant medication and have one of these *non*-ADD/ADHD diagnoses in history. Prescribers are asked to fax the appropriate documentation, as noted below, from the patient's chart, for a PA review ***prior to*** the implementation date to avoid unnecessary rejected claims at point of sale.

   i) **The point-of-sale (POS) prior approval (PA) criteria for C-II and C-III stimulants that search the recipient's Medicaid diagnosis history for a diagnosis of narcolepsy, OSA/OSAHS, and shift-work sleep disorder will be removed from the POS PA system, and will require a manual review PA.**

   ii) The manual review PA request for a C-II or C-III stimulant for treating excessive daytime sleepiness due to narcolepsy, OAP/OSAHS, or shift-work sleep disorder will be reviewed on a case-by-case basis and require documentation as noted below.

      (1) For all narcolepsy requests for a PA for a C-II or a C-III stimulant, prescribers are required to fax in the most recent test results of the polysomnogram (PSG) and the multiple sleep latency test (MSLT) with the letter explaining the medical necessity for receiving the stimulant;

      (2) For all requests for a C-III stimulant for shift-work sleep disorder, the prescriber must include a copy of the beneficiary's work schedule with work times and days, name and contact information of business where the beneficiary works, any pertinent sleep exams (for example, daytime PSG and start of shift MSLT), and the letter explaining the medical necessity for the stimulant;

      (3) For all requests for a C-III stimulant for OSA or OSAHS: Per the OSA Guidelines, the primary treatment is nightly use of nasal Continuous Positive Airway Pressure (CPAP) or nasal or facial mask used with intermittent assist device with continuous positive airway pressure device (Bilevel Positive Airway Pressure (Bi-PAP)). CPAP has been shown to improve daytime sleepiness, mood, and cognitive function in people with both mild and moderate apnea. Achieving maximum improvement in neurocognitive symptoms may take as long as 2 months of CPAP nightly adherence. Nasal CPAP is the most effective treatment for OSA and is the standard of care for this condition. Patients with moderate-to-severe sleep disorder breathing should be treated with nasal CPAP because of the increased risk of cardiovascular morbidity. Per the OSA Guidelines, pharmacologic therapy is not part of primary treatment. Modafinil or armodafinil are recommended for treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective PAP treatment and who are lacking any other identifiable cause for his/her sleepiness. Before using a stimulant, other causes of residual sleepiness must be ruled out including: suboptimal objective adherence with PAP; ill-fitting PAP masks; insufficient sleep; poor sleep hygiene; other sleep disorders such as narcolepsy or restless legs syndrome/periodic limb movements of sleep; other medications that cause sleepiness (e.g., opioids, benzodiazepines, antidepressants, etc.) and depression.

         Prescribers requesting a C-III stimulant (modafinil or armodafinil) for excessive daytime sleepiness after successful treatment correcting OSA, upper airway resistance syndrome (UARS), and snoring, must include results of polysomnography (PSG), documentation of compliance of primary treatment (CPAP or BiPAP), chart notes, and the treatment plan for ongoing evaluation of compliance of CPAP or BiPAP in follow-up visits.

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) ***EFFECTIVE DECEMBER 1, 2016*, ANTIPSYCHOTIC USE IN CHILDREN-- CHANGE IN LOWER AGE LIMIT FOR MANUAL REVIEW:**
Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 7 years of age. This manual review is performed by the Medicaid Pharmacy Program board certified child & adolescent psychiatrist.

AR Medicaid Pharmacy Program has *increased the lower age limit that will require a manual review PA* to <10 years of age 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 will be reviewed by the Medicaid Pharmacy Program child & adolescent psychiatrist.

PDL PA Call Center at 1-800-424-7895. The PDL FAX number is: 1-800- 424-5739.

THE FOLLOWING EDITS WILL BE EFFECTIVE JULY 13, 2016, UNLESS OTHERWISE STATED

4) **GROWTH HORMONES (somatropin): GENOTROPIN®, HUMATROPE®, NORDITROPIN®, NUTROPIN AQ Pen®, NUTROPIN DEPOT®, OMNITROPE®, SAIZEN®, ZOMACTON™, ZORBTIVE®:**
Changes are as follows:
   i) **All existing point-of-sale (POS) prior approval (PA) criteria for somatropin growth hormone (GH) will be removed and the requests for GH will be changed to manual review PA on a case-by-case for the initial PA as follows:**
      (1) All requests for somatropin injection for growth hormone deficiency, such as Pituitary dwarfism, Panhypopituitarism, Iatrogenic pituitary disorder, unspecified disorder of the pituitary gland, Craniopharyngioma, or septo-optic dysplasia, or CKD in children or chronic renal insufficiency in children or a child with ESRD awaiting transplantation, < 18 years of age for Prader-Willi Syndrome (PWS), < 18 years of age for Turner Syndrome (TS), or short bowel syndrome in patients receiving specialized nutritional support will require a manual review PA on a case-by-case basis.

      (2) For the manual review PA, the prescriber will be required to submit chart notes and supporting documentation, such as age appropriate documentation of GH deficiency, for beneficiaries < 18 years of age tests confirmed by provocative GH Stimulation Testing, MRI or CT scan within the past two years, documented test for hypothyroidism (T3 or T4 level) within the past two years, and beneficiaries > 14 years of age X-ray of the femur or finger within 365 days. For those beneficiaries > 18 years of age, documentation of appropriate replacement therapies, such as thyroid hormones, hydrocortisone, estrogen, testosterone and/or documentation for GH stimulation testing or IGF-1.

   ii) The existing POS Continuation Criteria will remain as follows:
      (1) For beneficiaries < 13 years of age for females and < 14 years of age for males with a billed diagnosis of pituitary dwarfism within the previous 2 years AND a paid claim in Medicaid history for growth hormone in the previous 6 months.

      (2) For beneficiaries < 18 years of age with a billed diagnosis of panhypopituitarism, Turner's Syndrome, Prader-Willi Syndrome, or septo-optic dysplasia, within the previous 2 years AND a paid claim in Medicaid history for growth hormone within the previous 6 months.

   iii) The existing POS Denial Criteria will remain as follows:
      (1) History of any of the following:
         (a) Age > 65 years of age;
         (b) History of malignancy in the past 365 days;
         (c) History of renal transplant in the past 365 days;
         (d) Pregnancy;

      (2) Diagnosis of Prader-Willi Syndrome concurrently with any of the following
         (a) Severe obesity;
         (b) Sleep apnea;
         (c) History of severe respiratory impairment;

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.

5) ANADROL-50 (OXYMETHOLONE) TABLET:
Anadrol®-50 Tablets is indicated in the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond. The usual effective dose is 1-2 mg/kg/day.
EAC: $41.96 per tablet;

The portion of the existing POS PA criteria that is used to define hypoplastic anemias due to the administration of myelotoxic drugs will be removed. All PA requests for using oxymetholone for hypoplastic anemias due to the administration of myelotoxic drugs will be reviewed through the manual review PA process on a case-by-case basis. The prescriber must submit a letter explaining the medical necessity, chart notes, and other agents tried.

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 UNLESS STATED OTHERWISE

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

1) HCV THERAPIES: ZEPATIER™ (elbasvir and grazoprevir) , HARVONI® (ledipasvir and sofosbuvir); VIEKIRA PAK™ (ombitasvir, paritaprevir, and ritonavir tablets and dasabuvir tablets), DAKLINZA™ (daclatasvir), SOVALDI® (sofosbuvir); TECHNIVIE™ (ombitasvir and paritaprevir and ritonavir):
i) All GT-1a patients are required to have NS5A resistance-associated polymorphism testing. The lab test results must be included with the PA request.
ii) Child-Pugh Score (CPS) is required for GT-1, GT-2 and now also for GT-3. Supporting documentation for the CPS is required.
iii) The HCV therapy PA form has been revised and is available on the Medicaid Pharmacy Program website. See the summary list below for the changes.

HCV POPULATION	DRUG APPROVALS AND LENTH OF THERAPY	TREATMENT EAC FOR DAA ONLY
GT-1 < 6 MILLION IU/Ml, TN, F3, + RAV Resistance	HARVONI X 8 WEEKS	$65,016
GT-1 < 6 MILLION IU/Ml, TN, F3, - RAV Resistance	ZEPATIER X 12 WKS	$56,347
GT-1a, F3, CPS-A, TN or **TE-PR**, + RAV Resistance	ZEPATIER + RBV X 16 WKS	$75,130
GT-1a, F3, CPS-A, TN or TE-PR, - RAV Resistance	ZEPATIER X 12 WKS	$56,347
GT-1a, F3, CPS-A, **TE-PI**, + RAV Resistance	HARVONI X 12 WEEKS	$97,524
GT-1a, F3, CPS-A, TE-PI, - RAV Resistance	ZEPATIER + RBV 12 WKS	$56,347
GT-1a, F3, **CPS-C**, TN OR TE, +RAV, *OR* - RAV Resistance;	HARVONI + RBV X 12 WEEKS	$97,524
GT-1a, F3, **CPS-B** ONLY, TN OR TE, - RAV Resistance	DAKLINZA + SOVALDI + RBV X 12 WKS	$151,704
GT-1a, F4, CPS-A, TN, +RAV Resistance	ZEPATIER + RBV X 16 WKS	$75,130
GT-1a, F4, CPS-A, TN, - RAV Resistance	ZEPATIER X 12 WKS	$56,347
GT-1a, F4, CPS-A, **TE-PR**, +RAV Resistance	ZEPATIER + RBV X 16 WKS	$75,130
GT-1a, F4, CPS-A, TE-PR, - RAV Resistance	ZEPATIER X 12 WKS	$56,347
GT-1a, F4, CPS-A, **TE-PI, +RAV** Resistance	HARVONI + RBV X 12 WEEKS	$97,524
GT-1a, F4, CPS-A, TE-PI, - RAV Resistance	ZEPATIER + RBV X 12 WEEKS	$56,347
GT-1a, F4, **CPS-C**, TN OR TE, +RAV, *OR* - RAV Resistance	HARVONI + RBV X 12 WEEKS	$97,524
GT-1a, F4, **CPS-B ONLY**, TN OR TE-PR, - RAV Resistance	DAKLINZA + SOVALDI + RBV X 12 WKS;	$151,704
GT-1b, F3, CPS-A, TN or TE-PR	ZEPATIER X 12 WKS	$56,347
GT-1b, F3, CPS-A, TE-PI	ZEPATIER + RBV X 12 WKS	$56,347
GT-1b, F4, CPS-A, TN or TE-PR	ZEPATIER X 12 WKS;	$56,347
GT-1b, F4, CPS-A, TE-PI	ZEPATIER + RBV X 12 WKS;	$56,347
GT-1b, F3 or F4, **CPS-B** or **C**, TN or TE	HARVONI + RBV X 12 WKS	$97,524
GT-2, F4 OR F3, CPS-A, TN or TE	SOVALDI + RBV X 12 WEEKS	$86,688
GT-3, **F3,** TN or TE, CPS A	DAKLINZA™ + SOVALDI X 12 WKS	$151,704
GT-3, F4, **TN**, CPS-A ONLY	SOVALDI + RBV X 24 WKS	$173,376
GT-3, **F4**, **TN**, **CPS-B or C**	DAKLINZA™ + SOVALDI + RBV X 12 WKS	$151,704
GT-3, **F4**, TE-PR, **CPS A, B, or C**	DAKLINZA™ + SOVALDI + RBV X 12 WKS	$151,704
GT-4, F3, CPS-A, TN	ZEPATIER X 12 WKS	$56,347
GT-4, F3, CPS-A, TE-PR	ZEPATIER + RBV X 16 WKS	$75,130
GT-4, F4, CPS-A, TN	ZEPATIER X 12 WKS	$56,347

GT-4, F4, CPS-A, TE-PR	ZEPATIER + RBV X 16 WKS	$75,130
GT-**4**, F4, **CPS-B OR C**, TN OR TE	*DATA INSUFFICIENT FOR HARVONI DOSING RECOMMENDATIONS*	*N/A*
GT-5, F3 or F4, CPS-A, TN or TE,	HARVONI X 12 WKS	$97,524
GT-6, F3 or F4, CPS-A, TN or TE,	HARVONI X 12 WKS	$97,524
GT = GENOTYPE		
For purposes of this PA request: Advanced fibrosis = Metavir F3; Compensated cirrhosis = Metavir F4		
TN = TREATMENT NAÏVE		
TE = TREATMENT EXPERIENCED		
TE-PR = TREATMENT EXPERIENCED with PegINF/RBV (pegylated interferon and ribavirin)		
TE-PI = TREATMENT EXPERIENCED with PROTEAS INHIBITOR (boceprevir, simeprevir, or telaprevir)		
CPS = CHILD PUGH SCORE, CAN BE CPS-A, B OR C		
RAV = NS5A resistance-associated polymorphisms, either negative (-) results or positive (+) results for resistance variants.		

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

2) KALYDECO® (ivacaftor) TABLET:

Ivacaftor is indicated for the treatment of cystic fibrosis (CF) in patients 2 years and older who have one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R. In addition, KALYDECO® received FDA approval for patients age 2 years and older for the treatment of CF in patients who have an R117H mutation in the CFTR gene when combined with another CFTR CF-causing mutation.

R117H is a mutation that is known to be affected by intragenic modification. The *R117H does not act as a CF-causing mutation if it is not in combination with another CF-causing mutation.*

Whether or not R117H causes disease is based on another region of the CFTR gene called the poly-T tract. The poly-T tract is present in every copy of the CFTR gene and occurs in one of three forms: 5T, 7T, or 9T. *Depending on which poly-T form is present in the same copy of the CFTR gene with R117H*, differing outcomes may occur. These possible combinations and their outcomes are listed in the table below.

In order to correctly interpret the table, it is necessary to know the phase of the mutations. The phase refers to the specific combination of mutations that are present together in the same copy of the CFTR gene. For instance, a patient may have the following mutations: R117H/G551D and 5T/7T. Determining the phase means determining which poly-T variation (5T or 7T) is in the same copy of the CFTR gene as R117H and which is in the same copy as G551D.

One mutation:	Second mutation: R117H + ?	Predicted outcome:
CF-causing mutation, such as F508del	R117H and 5T	R117H **will likely** act as a disease-causing mutation. Most patients with this combination of mutations and the 5T form of the poly-T tract will have elevated sweat chloride and clinical symptoms of CF. Symptoms for these patients may be variable. There is an increased risk for male infertility.
CF-causing mutation, such as F508del	R117H and 7T	R117H is **unlikely** to act as a disease-causing mutation (particularly for females), but may result in male infertility. However, a person with this combination of mutations and this form of the poly-T tract may have borderline or elevated sweat chloride and mild clinical symptoms of CF.
CF-causing mutation, such as F508del	R117H and 9T	R117H is **highly unlikely** to act as a disease-causing mutation. The vast majority of individuals will not have CF. Male fertility is typically **not** affected by R117H and 9T.

EAC: KALYDECO® 150 mg tablet, 50 mg granule packet, or 75 mg granule packet is $440.37 per each. The granule packets contain 28-day supply = $24,660.72; the 56-count carton unit dose tablets= $24,660.72 for 28-day supply; the 60-count tablet bottle = $26,422.20 for 30-day supply;

Ivacaftor requires a manual review PA on a case-by-case basis for CF patients. The existing manual review PA criteria have not changed for KALYDECO® (ivacaftor) except that the age requirement has been lowered to the patient must be at least 2 years of age.

For PA requests regarding the R117H mutation, requests will be reviewed on a case-by-case basis. Prescriber must submit documentation of the R117H mutation and the phase of the mutations explained above, and the standard documentation for clinical symptoms of CF.

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) ORKAMBI™ (lumacaftor/ivacaftor) TABLET:

ORKAMBI™ 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. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Adults and pediatric patients age 12 years and older: two tablets (each containing lumacaftor 200 mg/ivacaftor 125 mg) taken orally every 12 hours with fat-containing food.

EAC: $183.58 per tablet; $734.32 per day; $20,560.96 per 28-day supply; packaged as 112-count tablet box.

Requests for ORKAMBI™ are evaluated on a case-by-case basis and the initial approval criteria have not changed. Continuation criteria are outlined below.

Continuation of the prior approval (PA) is based on documentation to substantiate the patient has achieved a clinically meaningful response to treatment while on Orkambi, based on at least one of the following:

- Improvement or stable FEV_1 by week 24 and thereafter; OR
- BMI or weight improvement or stable by week 24 and thereafter; OR
- Decreased number of pulmonary exacerbations; OR
- Submit documentation of improvement in Quality of Life (QoL) using one of the following validated questionnaires:
    - CFQ 14+ for teenagers and adults;
    - CFQ-Child, ages 6 through 13;
    - CFQ Child P, a parent-proxy evaluation for children aged 8–13
    - CFQ-R (Cystic Fibrosis Questionnaire-Revised)

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.

4) NARCAN® (naloxone) NASAL SPRAY:

NARCAN® Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

EAC: NARCAN Nasal Spray is $64.50 for each NARCAN® Nasal Spray, $129 for the carton of 2 individual spay containers.

NARCAN® Nasal Spray 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. In addition, NARCAN® NASAL Spray has a quantity edit of 2 individual NARCAN sprays, which is 1 carton (1 carton of 2 nasal sprays) per month.

The naloxone 0.4 mg/ml vial and prefilled syringe and the 1 mg/ml prefilled syringe are available without a 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.

5) IRRITABLE BOWEL SYNDROM WITH DIARRHEA:

i. VIBERZI™ (eluxadoline) 75 MG AND 100 MG TABLET

VIBERZI™ is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). The recommended dosage of VIBERZI is 100 mg taken orally twice daily with food.

VIBERZI™ is contraindicated in patients with:

- Known or suspected biliary duct obstruction; or sphincter of Oddi disease or dysfunction. These patients are at increased risk for sphincter of Oddi spasm;
- Alcoholism, alcohol abuse or alcohol addiction, or in patients who drink more than 3 alcoholic beverages per day. These patients are at increased risk for acute pancreatitis;

- A history of pancreatitis; or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction. These patients are at increased risk for acute pancreatitis;
- Severe hepatic impairment (Child-Pugh Class C). These patients are at risk for significantly increased plasma concentrations of eluxadoline;
- A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction. These patients may be at risk for severe complications of bowel obstruction

EAC: 75 mg and 100 mg tablets are $16.51 each tablet; 62 tablets = $1,023.62

VIBERZI™ 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 and all other therapies tried. In addition, VIBERZI™ has a maximum quantity limit of 2 tablets per day and 62 tablets for a 31 day supply.

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.

ii. LOTRONEX® (alosetron) TABLET:

LOTRONEX® is indicated only for women with severe diarrhea-predominant irritable bowel syndrome (IBS) who have:

- chronic IBS symptoms (generally lasting 6 months or longer),
- had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
- not responded adequately to conventional therapy.

Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following:

- frequent and severe abdominal pain/discomfort,
- frequent bowel urgency or fecal incontinence,
- disability or restriction of daily activities due to IBS.

To lower the risk of constipation, LOTRONEX® should be started at a dosage of 0.5 mg twice a day. Patients who become constipated at this dosage should stop taking LOTRONEX® until the constipation resolves. They may be restarted at 0.5 mg once a day. If constipation recurs at the lower dose, LOTRONEX should be discontinued immediately.

LOTRONEX® is contraindicated in patients with

- chronic or severe constipation or sequelae from constipation;
- intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions ;
- ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state;
- Crohn's disease or ulcerative colitis;
- Diverticulitis;
- severe hepatic impairment;
- concomitant use of Fluvoxamine;

EAC: 0.5 mg tablet = $30.24 each tablet; 62 tablets for 31-day supply = $1,874.88
1 mg tablet = $60.48 each tablet; 62 tablets for 31-day supply = $3,749.76

LOTRONEX® 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 and all other therapies tried. In addition, LOTRONEX has a maximum quantity limit of 2 tablets per day and 62 tablets for a 31 day supply

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.

6) ALECENSA® (alectinib) CAPSULE 150 mg:

ALECENSA® is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who has progressed on or are intolerant to crizotinib.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of

clinical benefit in a confirmatory trial. The recommended dose of ALECENSA is 600 mg orally twice daily with food. See package insert for full dosing instructions.

EAC: 150 mg capsule = $53.01 per capsule; 600 mg dose (4 x 150 mg) = $212.04 per day;
240 capsules for 30-day supply = $12,722.40

ALECENSA® 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. In addition, ALECENSA® has a maximum quantity limit of 8 capsules per day and 240 capsules for a 30 day supply.

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.

7) UPTRAVI® (selexipag) TABLET 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,400 mcg, 1,600 mcg:

UPTRAVI ® is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. The recommended starting dose of UPTRAVI is 200 micrograms (mcg) given twice daily. See package insert for full dosing instructions.

EAC: available in bottles of 60:

200 mcg	$160.65 each tablet	#60 for 30-day supply = $ 9,639.00
400 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
600 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
800 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
1,000 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
1,200 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
1,400 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40
1,600 mcg	$249.74 each tablet	#60 for 30-day supply = $14,984.40

EAC for the titration pack, includes #140 of 200 mcg & #60 800 mcg tablet; = $22,476

UPTRAVI ® will require manual review PA on a case-by-case basis based on data in the package insert for FDA approved indication of pulmonary arterial hypertension (PAH, WHO Group I) with WHO Functional Class II-III symptoms, FDA approved dose, and criteria used in the clinical trials. Chart notes are required for the manual review PA as well as reviewing the Medicaid pharmacy drug profile. Patient must be non-smoker. In addition, UPTRAVI ® has a maximum quantity limit of 2 tablets per day and 60 tablets for a 30 day supply; titration pack limited to 1 titration pack per 2 years.

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.

8) LANOXIN® (digoxin) TABLET 187.5 MCG and 62.5 mcg:

The LANOXIN® 187.5 mcg is a new strength to market. The 62.5 mcg strength came to market about July 2013.

MAC: 125 mcg tablet is $0.15870; 45 tablets = $7.14
EAC: 187.5 mcg tablet is $7.43 per tablet; 30 tablets = $222.90;
EAC: 62.5 mcg $6.91 per tablet; 30 tablets = 207.30

LANOXIN® 187.5 mcg tablet and LANOXIN 62.5 mcg tablet will require manual review PA on a case-by-case basis. Digoxin 125 mcg tablet available without a PA or quantity limits.

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.

9) STRENSIQ™ (asfotase alfa) INJECTION, for SUBCUTANEOUS USE 18 MG/0.45 ML VIAL, 28 MG/0.7 ML VIAL, 40 MG/ML VIAL, and 80 MG/0.8 ML VIAL:

STRENSIQ™ is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

The recommended dosage regimen of STRENSIQ™ for the treatment of perinatal/infantile-onset HPP and Juvenile-Onset HPP is 6 mg/kg per week administered subcutaneously as either:

- 2 mg/kg three times per week, or
- 1 mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

Please refer to the package insert for the specific weight-based dosing tables. STRINSIQ vials are single use only and any unused product must be discarded.

EAC: There are 4 different vial strengths and the billing unit is per ml; the calculation for the reimbursement for the vial is noted below:
18 mg/0.45 ml vial = $1,300.32 each vial
28 mg/0.7 ml vial = $2,022.72 each vial
40 mg/1 ml vial = $2,889.60 each vial
80 mg/0.8 ml vial = $5,779.20 each vial

EAC Examples: 20 kg patient @ 2 mg/kg three times per week = $34,680 per 4 weeks.
20 kg patient @ 3 mg/kg three times per week = $69,360 per 4 weeks

STRENSIQ™ will require manual review PA on a case-by-case basis. The provider is required to provide all of the following information:
Initial PA request:

1) Documentation of a diagnosis of perinatal/infantile- and juvenile-onset hypophosphatasia (HPP); AND
2) Clinical manifestations consistent with hypophosphatasia must be present; AND
3) Diagnosis must be confirmed with both biochemical and molecular genetic testing; AND
4) Baseline documentation:
   a) Height/weight; AND
   b) Respiratory status (PFTs, vent settings, x-rays, or other scans); AND
   c) Renal Ultrasound; AND
   d) Detailed Radiology report that is repeatable and will be used to determine efficacy; AND
   e) Ophthalmology exam;
   AND
5) Treatment plan:
   a) Treatment plan shall include how improvement or lack of improvement, of baseline parameters (specifically growth and radiographical findings) will be determined for continuation of drug or for requests of any dose adjustments.
   b) Treatment plan must include a timeline to reassess efficacy based on the baseline parameters.

Renewal of PA:

1) Prior authorizations will be approved on a month by month basis with assessment of parameters listed in approval criteria 4 (baseline documentation) preformed at a minimum of every 6 months or as agreed upon by the prescriber and Arkansas Medicaid Pharmacy Program;
2) Dose adjustments, based on lack of response to therapy related to items listed in criterion 4 (baseline documentation) above, will be communicated to Arkansas Medicaid for approval prior to any dose increase.
3) Documentation indicating a positive response in growth or radiographical findings is required to continue treatment past 12 months.

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.

10) CORLANOR® (ivabradine) tablet:

CORLANOR® is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

The recommended starting dose of Corlanor is 5 mg twice daily with meals. Assess patient after two weeks and adjust dose to achieve a resting heart rate between 50 and 60 beats per minute (bpm). Please refer to the package insert for dosing information.

Please refer to the package insert for more information on the contraindications: acute decompensated heart failure, blood pressure less than 90/50 mmHg, sick sinus syndrome, sinoatrial block, or 3 degree AV block, unless a functioning demand, pacemaker is present, resting heart rate less than 60 bpm prior to treatment severe hepatic impairment pacemaker dependence (heart rate maintained exclusively by the pacemaker), concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.

EAC: 5 mg and 7.5 mg tablet is $6.45 each; #62 = $399.90

CORLANOR® will require a manual review PA based on information in the FDA approved package insert for indications, contraindications, and dose. Chart notes are required for the review. In addition, a quantity edit of 2 tablets per day and a cumulative quantity 62 per 31 days has been added.

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.

11) TRESIBA® (insulin degludec injection) LONG-ACTING INSULIN PEN:

TRESIBA (insulin degludec injection) is a long-acting basal human insulin analog for subcutaneous injection.

EAC TRESIBA: Only available in a pen.
U-100 = $30.54/ml; 3 ml pen = $91.62 per pen; 5 pens /pack = $458.10
U-200 = $61.07/ ml; 3 ml pen =$183.21 per pen; 3 pens/pack = $549.63

EAC Lantus (insulin glargine) 10 ML vial = $256.50/ 10-ml vial; No PA required;
EAC Levemir 10 ml vial = $277.61; No PA required;
EAC Humulin N 10 ml vial = $132.41; No PA required;
EAC Humulin N 10 ml vial = $132.41; No PA required;

TRESIBA will require manual review PA on a case-by-case basis for medical necessity of this long-acting basal insulin over other long-acting basal insulins. In addition, there is a quantity limit of one pack of the insulin strength per 31-days' supply: U-100 TRESIBA® insulin is limited to 15 ml (5 pens x 3 ml each) and U-200 is limited to 9 ml (3 pens x 3 ml each).

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.

12) GLEEVEC® (imatinib) TABLET 100 mg and 400 mg:

Put very simply, after a brand name drug's patent has expired there may be a company producing a generic drug that meets the FDA's criteria for the "180-day generic drug exclusivity", which means it is protected from competition from other generic versions of the same drug product for 180 days. After the expiration of the 180-day exclusivity period, other generic companies may be poised to enter the market and as more generic drugs are available, the price begins to fall.

Brand name GLEEVEC® 100 mg TABLET will not require a PA. Brand name GLEEVEC® 400 mg tablet and the generic imatinib 100 mg tablet and imatinib 400 mg tablets will 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.

THE FOLLOWING EDITS WILL BE <u>EFFECTIVE JULY 13, 2016,</u> UNLESS OTHERWISE STATED

C. <u>CLAIM EDITS, INCLUDING DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS:</u>

1) COUGH AND COLD PRODUCTS WITH CODEINE:

Cough and Cold products fall under the optional coverage section in Social Security Act §1927 that Medicaid Pharmacy Programs may elect to cover or not cover. Per the Social Security Act §1927, "agents when used for the symptomatic relief of cough and colds" may be excluded from coverage. AR Medicaid Pharmacy Program covers a small limited number of cough and cold products that contain codeine, and this benefit is limited to beneficiaries < 21 years of age or Long-Term-Care (LTC) beneficiaries. A DEA diversion investigator recently indicated to Medicaid that the abuse of the cough and cold products containing codeine is high.

The quantity edit for cough and cold products with codeine is limited to 1 claim of 120 ml per month.

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. **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. 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:** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-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. The limits for the "Refill Too Soon Accumulation Logic" are currently the same for controlled drugs and non-controlled drugs. Early refills for both controlled drugs and non-controlled drugs will continue to be monitored and may be adjusted in the future.

3. **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.

4. **INCARCERATED PERSONS:** The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid beneficiaries who, on the date the prescription is filled, 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.

5. **ANTIPSYCHOTIC AGENTS CRITERIA FOR CHILDREN < 18 YEARS OF AGE 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.

6. **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.

7. **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. 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.

8. **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.

9. **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.

10. **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 PDL PA Call Center is unavailable, the state Medicaid Pharmacy Program office is closed, and the pharmacist is not able to contact the prescribing provider 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.

11. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** Reimbursement rates stated in this memo 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.

12. **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 for the requested drug along with all written documentation, e.g., chart notes, cash pharmacy print out, etc., to substantiate the medical necessity of the request. The request may be faxed to **Magellan Medicaid Administration (MMA) 1-800-424-7976.**

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.