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: **AUGUST 29, 2016**

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

ADDITIONS TO THE AR MEDICAID PREFERRED DRUG LIST (PDL): Preferred status added to the following drugs: OTIC: Ciprodex® otic, neomycin/polymyxin HC otic, ciprofloxacin otic, acetic acid 2% otic, acetic acid HC otic; PANCREATIC ENZYMES: CREON®, ZENPEP®; CF INHALED ANTIBIOTICS: BETHKIS®, KITABIS™; GROWTH HORMONES: GENOTROPIN®; HCV TREATMENT: ZEPATIER™, EPCLUSA®, ribavirin 200 mg tablets and capsules;

CHANGES TO EXISTING POINT OF SALE PRIOR AUTHORIZATION (PA) CRITERIA OR EDITS: Total daily dose 300 Morphine Milligram Equivalents (MME) for all short-acting opioid drugs, long-acting opioid drugs, or combination of both, for chronic pain patients;

NEW AND REVISED CLINICAL EDITS THROUGH THE MANUAL REVIEW PA PROCESS: NINLARO® (ixazomib); ENTRESTO™ (sacubitril and valsartan); VRAYLAR™ (cariprazine); VENCLEXTA™(venetoclax); NUPLAZID™ (pimavanserin); SERNIVO™ (betamethasone dipropionate); EMVERM™ (mebendazole); BRIVIACT® (brivaracetam)

CLAIM EDITS, INCLUDING DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS: loperamide 2 mg capsule

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.*

A. ADDITIONS TO THE PREFERRED DRUG LIST (PDL) from the August 10, 2016 PDL Review:

EFFECTIVE OCTOBER 1, 2016: PREFERRED STATUS FOR DRUGS IN THE FOLLOWING CATEGORIES: Otic, Pancreatic Enzymes, Inhaled Antibiotics For CF, Growth Hormone, And HCV Treatments:

1. OTIC ANTIBIOTICS DROPS AND ANTIBIOTIC/CORTICOSTEROID COMBINATION DROPS:
Preferred Status:

- CIPRODEX® (ciprofloxacin/dexamethasone) Otic Suspension
- Neomycin/polymyxin HC Otic Solution
- Ciprofloxacin Otic Drops
- Acetic Acid 2% Otic Drops
- Acetic Acid HC Otic Drops

Non-Preferred Status:

- CIPRO® HC Otic
- CORTISPORIN®-TC Otic
- COLY-MYCIN® S Otic
- OFLOXACIN Otic

2. PANCREATIC ENZYMES (pancrelipase):
Preferred Status:

- CREON®
- ZENPEP®

Non-Preferred Status:
- PANCREAZE®
- VIOKACE™
- ULTRESA®
- PERTZYE™

3. INHALED ANTIBIOTICS for CYSTIC FIBROSIS

Preferred Status With Point of Sale (POS) Criteria*:
- BETHKIS® (tobramycin solution) INHALATION 300 mg/4 ml
- KITABIS™ PAK (tobramycin solution) INHALATION 300 mg/5 ml
  *(*Current POS clinical criteria requires a diagnosis in Medicaid history of cystic fibrosis; drugs also have quantity edits for 28-day supply every other month; includes a POS edit to prevent therapeutic duplication)*

Non-Preferred Status:
- TOBI® (tobramycin solution)
- CAYSTON® (aztreonam)
- TOBI PODHALER® (tobramycin)

4. GROWTH HORMONE (somatropin):

Preferred Status, Manual Review PA**
- GENOTROPIN® (somatropin) CARTRIDGE INJECTION or SYRINGE INJECTION
  *(** All PA requests for GH treatment will continue with manual review PA on a case-by-case basis using current criteria; Current point-of-sale continuation criteria will remain.)*

Non-Preferred Status:
- SAIZEN®
- OMNITROPE®
- ZOMACTON™
- NORDITROPIN®
- NUTROPIN®
- SEROSTIM®
- HUMATROPE®
- ZORBTIVE®

5. CHRONIC HEPATITIS C VIRUS (HCV) TREATMENT

HCV PA criteria changes that support the PDL status are effective immediately. *A brief criteria summary is listed below as related to the PDL status. Please see the complete HCV PA criteria on the HCV PA form on the Medicaid Pharmacy Program website.*

Preferred Status, Manual Review PA:
- ZEPATIER™ (elbasvir and grazoprevir), With Or Without Ribavirin for Genotype-1a, & 1b, Genotype-4
- EPCLUSA® (velpatasvir and sofosbuvir), With Or Without Ribavirin for Genotype-2 and Genotype-3
- RIBAVIRIN (generic) Tablets or Capsules 200 mg

Non-Preferred Status, Manual Review PA:
- EPCLUSA® (velpatasvir and sofosbuvir), With Or Without Ribavirin for Genotype-5 and Genotype-6, and other genotypes with Child-Pugh B or Child-Pugh C;

Non-Preferred Status
- HARVONI® (ledipasvir and sofosbuvir)
- SOVALDI® (sofosbuvir)
- DAKLINZA™ (daclatasvir)
- OLYSIO® (simeprevir)
- TECHNIVIE® (ombitasvir and paritaprevir and ritonavir)
- VIEKIRA PAK® or VIEKIRA® XR (dasabuvir and ombitasvir and paritaprevir and ritonavir)
- Brand Name Ribavirin (e.g., REBETOL®, RIBASPHERE®, COPEGUS®, MODERIBA™, RIBAPAK®)
- peginterferon alfa-2a (PEGASYS®)
- peginterferon alfa-2B (PEGINTRON®, SYLATRON™)

PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800- 424-5739.**

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

1) Total Daily Morphine Milligram Equivalents (MME) of 300 MME/Day For Chronic Pain Patients (Includes short-acting opioid drugs, long-acting opioids agents, or combination of both)

Implementation Date Changed, *Now Effective* NOVEMBER 8, 2016, The Medicaid pharmacy program system will calculate the beneficiary's total daily opioid dose of short-acting opioids and long-acting opioids

based on the quantity dispensed and the days' supply submitted on the pharmacy drug claim, including a drug claim in history if the incoming opioid drug claim will have at least 3 days of overlap with a drug claim in history. The system will then convert each drug's daily opioid dose to Morphine Milligram Equivalents (MME) per day using the conversion factors from the Centers for Disease Control and Prevention (CDC) (http://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf) or from the GlobalRPh Calculator (http://www.globalrph.com/opioidconverter2.cgi). For beneficiaries receiving more than one opioid prescription per month, from same or different prescribers, that have at least 3 days of overlap in the days' supply, the MME will be calculated for each drug claim and will be additive for the total daily MME. The opioid drug claim, from same or different prescriber, that will cause the calculated total daily MME to exceed 300 MME per day will reject at point of sale.

Providers are encouraged to check the Prescription Drug Monitoring Program (PDMP) for the patient's complete list of opioid prescriptions, including prescriptions from other providers and prescriptions paid for with cash.

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Malignant or terminal cancer patients with appropriate diagnosis code in Medicaid history in the previous 365 days are exempt from the MME criteria.

The long advance notice of implementation is given to encourage prescribers to begin opioid downward titrations 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 beginning November 8, 2016.

PDL PA Call Center 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.**

THE FOLLOWING EDITS WILL BE EFFECTIVE IMMEDIATELY UNLESS OTHERWISE STATED

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

1) **NINLARO® (ixazomib) CAPSULE, 2.3 mg, 3 mg, 4 mg:** NINLARO® (ixazomib) is an antineoplastic agent that is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. The recommended starting dose of NINLARO is 4 mg administered orally once a week on Days 1, 8, and 15 of a 28-day treatment cycle. Please refer to the package insert for additional dosing information.

   The reimbursement rate for NINLARO® is the same for all 3 strengths, which is $2,982.48 for each capsule; 3 doses of 4 mg capsule = $8,947.44 per month (taken on days 1, 8, & 15 of a 28-day cycle).

   NINLARO® will require a manual review PA on a case-by-case basis. Each approved PA will to be for a short period of time (e.g., 3 months). Prescriber may request additional PAs as long as the disease is not progressing (e.g., spike in serum or urine monoclonal protein, increase in plasma cells in bone marrow, or other signs of progression such as new plasmacytoma, lytic bone lesion, hypercalcemia) or there is not unacceptable toxicity. For each PA request, the prescriber must submit documentation that the disease is not progressing. In addition, there is a quantity edit of 3 capsules per 28 days' 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.

2) **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 reimbursement rate for ENTRESTO™ is $12.90 per tablet; 30-day supply = $387.

   The criteria have been revised and the requirement has been removed that the patient must have left ventricular ejection fraction ≤ 35%. 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 before switching to ENTRESTO™. The Medicaid pharmacy profile will be reviewed for compliance. 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.

3) **VRAYLAR™ (cariprazine) capsule 1.5mg, 3mg, 4.5mg, 6mg, and VRAYLAR™ Dose Pack 1.5 - 3 mg:** VRAYLAR™ is an atypical antipsychotic indicated for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder. The clinical studies for VRAYLAR™ were very short, 6 weeks for schizophrenia and 3 weeks for bipolar disease. There are no comparative data between VRAYLAR™ and other antipsychotic drugs. VRAYLAR™ is given orally once daily. VRAYLAR™, and its active metabolites, have a very long half-life and changes in dose will not be fully reflected in plasma for several weeks. Adverse events may first appear several weeks after the initiation of VRAYLAR™ treatment, probably because plasma levels of cariprazine and its major metabolites accumulate over time. Prescribers should monitor patients for adverse reactions and treatment response for several weeks after starting VRAYLAR™ and after each dosage change. There is currently no data on concurrent therapy of VRAYLAR™ plus other antipsychotic agents. There are no clinical studies in children less than 18 years of age.

   The reimbursement rate for VRAYLAR™ is $34.61 for each capsule; a 30-day supply = $1,038.30.

   VRAYLAR™ will require a manual review PA. Prescribing providers will need to submit a letter explaining the medical necessity of receiving this antipsychotic drug and include all chart notes regarding other agents tried and failed. In addition, a quantity edit of 1 capsule per day will apply to all strengths.

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) **VENCLEXTA™ (venetoclax) tablet 10 mg, 50 mg, 100 mg, Starting Pack:**
   VENCLEXTA™ is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA approved test, who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate [see Clinical Studies (14)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in previously treated CLL patients with high tumor burden when treated with VENCLEXTA™. Administer the VENCLEXTA™ dose according to a weekly ramp-up schedule over 5 weeks to the recommended daily dose of 400 mg. See the package insert for complete dosing information.

   The reimbursement rate: 10 mg tablet = $8.22; 50 mg tablet = $41.11; 100 mg tablet = $82.21; 400 mg (4 x 100 mg tablet) daily dose = $328.84/day; 30-day supply @ 400 mg/day = $9,865.20; Starter Pack 10-50-100 (42 tablets) = $50.70 each tablet; and $2,129.40 for the starter pack

   VENCLEXTA™ will require a manual review PA on a case by case basis for patients with CLL with 17p deletion who have had at least one prior therapy. Due to risk of TLS, prescriber must provide risk assessment data and TLS prophylaxis and monitoring data with each PA request. For those with medium or high risk, the PA approval will be on a month-to-month basis. In addition, there are dose-optimization quantity limits on the tablet strengths based on the table in the package insert for modification for toxicity: 10 mg tablet = up to 2 tablets per day; 50 mg tablet = up to 1 tablet per day; 100 mg tablet = up to 4 tablets per day. The Starter Pack 10-50-100 (42 tablets) will be limited to 1 starter pack per 180 days.

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) **NUPLAZID™ (pimavanserin) tablet 17 mg:** NUPLAZID™ is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease (PD) psychosis. The recommended dose of NUPLAZID™ is 34 mg, taken orally as two 17 mg strength tablets once daily, without titration. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. NUPLAZID™ is not approved for the treatment of patients with dementia-

related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

The reimbursement rate for NUPLAZID™ is $33.54 each tablet; a 30-day supply (#60) = $2,012.40

NUPLAZID™ will require a manual review PA on a case-by-case basis and criteria will include but not be limited to the following: a diagnosis of Parkinson's Disease at least 1 year prior, and patient had psychotic symptoms of hallucinations and/or delusions that started after the PD diagnosis, and symptoms were severe and frequent enough to warrant treatment with an antipsychotic, and patient scored at least 21 on a mental state examination; and patient was stable for at least 30-days prior to the request for the drug, and prescriber must provide data on all other prior antipsychotic drugs tried and provide information regarding the failure of prior antipsychotic drug(s). Chart notes will be required to substantiate the clinical data. Additional criteria include no therapeutic duplication between NUPLAZID™ and other antipsychotics. A quantity limit of up to 2 tablets per day and 60 tablets per 30-days will apply.

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) **SERNIVO™ (betamethasone dipropionate) Pump Spray, 120 ml and 60 ml:** SERNIVO™ Spray is a corticosteroid indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older. Apply SERNIVO™ Spray to the affected skin areas twice daily and rub in gently. The spray is a slightly thickened, white to off-white, non-sterile emulsion. SERNIVO™ cannot be used longer than 4 weeks.

   The reimbursement rate for SERNIVO™ is $6.71 per ml, or $805.20 for the 120 ml spray pump.

   SERNIVO™ will require a manual review PA on a case-by-case basis. The criteria will require the prescriber to submit a letter explaining the medical necessity of the beneficiary receiving this drug over other topical corticosteroid drugs in the same potency category that do not require a prior approval. There are other topical corticosteroids in the same potency category that are available without a PA. For example, no PA is required for betamethasone dipropionate cream (reimbursement rate: MAC @$1.39/gm, 15 gm tube = $20.85 per tube) or betamethasone dipropionate lotion (reimbursement rate: MAC @ $0.19/ml, 60 ml = $11.46 per bottle).

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) **EMVERM™ (mebendazole) 100 mg chewable tablet:** The generic mebendazole and the previous brand name, Vermox®, were removed from the market several years ago (2011 and 2005, respectively). EMVERM™ received approval for an sNDA in January 2016. EMVERM™ is indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) in single or mixed infections. Dosage and administration is 1 tablet one time for Pinworm, 1 tablet twice daily for 3 days for Whipworm, Common roundworm, and Hookworm. If the patient is not cured three weeks after treatment, a second course of treatment is advised per the package insert.

   The reimbursement rate for EMVERM™ is now $354.24 for each tablet (compared to $4.22 in 2011 for the generic tablet). 6 tablets for twice daily dosing for 3 days for one treatment= $2,125.44; if a patient receives a 2nd course of treatment (for a total 12 tablets) the total reimbursement rate = $4,250.88.

   EMVERM™ will require a manual review PA on a case-by-case basis. Prescriber will need to submit a letter explaining the medical necessity of receiving EMVERM™ and identification of the type of parasitic worm(s) (helminths) being treated. Quantity edit limited to 1 tablet is also applied and will be adjusted as needed during the PA process.

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) **BRIVIACT® (brivaracetam) tablet 10 mg, 25 mg, 50 mg, 75 mg, 100 mg; oral solution 10 mg/ml:** BRIVIACT® is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients who

are age 16 years and older with epilepsy. The recommended starting dosage is 50 mg twice daily (100 mg per day). Based on individual patient tolerability and therapeutic response, the dosage may be adjusted down to 25 mg twice daily (50 mg per day) or up to 100 mg twice daily (200 mg per day). In the clinical studies BRIVIACT® provided no added benefit when it was added to levetiracetam. Because of increases in BRIVIACT® exposure, dosage adjustment is recommended for all stages of hepatic impairment. Please refer to the package insert for serious adverse reactions.

The reimbursement rate is $15.65 each tablet, or 31-days' supply is about $970. The oral solution 10 mg/ml, available in 300 ml bottle is about $935 for each bottle; dosed at the maximum dose requires 2 bottles (600 ml) is about $1,870 for 30 day supply.

BRIVIACT® will require a manual review PA on a case-by-case basis. In addition, an age-edit limiting the drug to 16 years and greater has been applied. A quantity edit of 2 tablets per day and a quantity limit of up to two- 300 ml bottles per 30 days have been applied.

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

EFFECTIVE SEPTEMBER 29, 2016

1) **LOPERAMIDE 2 mg capsule:** loperamide hydrochloride is indicated for the control and symptomatic relief of acute nonspecific diarrhea and of chronic diarrhea associated with inflammatory bowel disease.

The recommended initial dose is 4 mg (two capsules) followed by 2 mg (one capsule) after each unformed stool until diarrhea is controlled, after which the dosage of loperamide should be reduced to meet individual requirements. When the optimal daily dosage has been established, this amount may then be administered as a single dose or in divided doses. The average daily maintenance dosage in clinical trials was 4 to 8 mg (two to four capsules). A dosage of 16 mg (eight capsules) was rarely exceeded in the trials. If clinical improvement is not observed after treatment with 16 mg per day for at least 10 days, symptoms are unlikely to be controlled by further administration.

The antidiarrheal medicine Imodium (loperamide) is the subject of a recent US Food and Drug Administration (FDA) warning of serious heart problems that can be fatal. The FDA is warning health care professionals to be aware that use of higher than recommended doses of loperamide can result in serious cardiac adverse events. Specifically, it states that physicians should consider loperamide as a possible cause of unexplained cardiac events including QT interval prolongation, Torsades de Pointes or other ventricular arrhythmias, syncope, and cardiac arrest. According to the FDA statement: "The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria," the FDA said. "They are also combining loperamide with interacting drugs in attempts to increase these effects."

The reimbursement rate for loperamide is $0.15 each, #90 = $13.50.

The utilization report for loperamide 2 mg capsule showed very large quantities being dispensed monthly. The quantity limit has been set for loperamide 2 mg capsule for a quantity of 90 capsules per 30 days.

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. **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.

2. ***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.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS: Effective JULY 1, 2016**, Providers requesting a Prior Authorization (PA) for a drug on the PDL or calling to request a Prior Authorization (PA) for an antipsychotic medication should call the **PDL PA Call Center at 1-800-424-7895**. **The PDL FAX number is: 1-800- 424-5739**. Please include a letter explaining the medical necessity and include any

supporting documentation, the beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.

9. **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.

10. **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.

11. **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/.

12. **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.

13. **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.