ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

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MEMORANDUM

TO: Arkansas Medicaid Prescribers and Interested Parties

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

DATE: Aug. 14, 2015

SUBJ: **AR Medicaid DUR Board edits approved at the July 15, 2015 meeting:**

Changes To Existing Prior Authorization (PA) Criteria Or Edits: Viekira Pak™ (dasabuvir and ombitasvir and paritaprevir and ritonavir); Oral anticoagulant drugs; Protopic® (tacrolimus) ointment, Elidel® (pimecromlimus) cream, Dovonex® (calcipotriene) cream; Evista® (raloxifene hydrochloride) tablet; Regranex® (becaplemin) gel; Movantik™ (naloxegol) tablet; Constipation drugs including Linzess® (linaclotide), Amitiza® (lubiprostone), Movantik™ (naloxegol), and Relistor® (methylnaltrexone bromide); Xarelto® (rivaroxaban) 10 mg; Long-acting opioid agents;

Clinical edits through the Manual Review PA Process: Cholbam™ (cholic acid); Natpara® (parathyroid hormone); Sandostatin® (octreotide acetate) LAR Depot Injection; Invega Trinza™ (paliperidone palmitate) injection; Namzaric™ (memantine/donepezil) capsule;

Point-of-Sale (POS) Clinical Edits with or without Claim Edits: Avycaz™ (ceftazidime-avibactam) inj.; Cresemba® (isavuconazonium sulfate) capsule and vial;

All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at https://arkansas.magellanrx.com/provider/documents

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

REMINDER REGARDING INCARCERATED PERSONS: The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for Medicaid beneficiaries who, ***on the date the prescription is filled, are incarcerated in a correctional or holding facility for individuals who are prisoners, including juvenile correctional facilities***, are detained pending disposition of charges, or are held under court order as material witnesses. ***If medications are requested for incarcerated Medicaid beneficiaries, including beneficiaries in a juvenile correctional facility, the medications cannot be billed to Medicaid Pharmacy Program and are subject to recoupment.*** Pharmacists should contact the correctional facility regarding the facility's reimbursement procedures for the requested medications.

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

To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. Frequency of the emergency override is limited to *once per year per class of drugs* for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website.

1. CHANGES TO EXISTING PRIOR AUTHORIZATION (PA) CRITERIA OR EDITS:

A. VIEKIRA PAK™ (dasabuvir and ombitasvir and paritaprevir and ritonavir) CRITERIA CHANGES

Effective immediately, the following will apply to all Hepatitis C Virus (HCV) PA requests:

i) The HCV Statement of Medical Necessity form must be completed and faxed to the Medicaid Pharmacy Program, along with all additional chart information that is needed, such as biopsy results, lab test results, genotype, subtype (e.g., 1a or 1b), and chart data to support exception requests; AND
ii) Liver biopsy is required for all requests; AND
iii) HCV PA requests will be approved for advanced fibrosis (Metavir F3), compensated cirrhosis (Metavir F4), or pre-liver transplant beneficiaries (see chart below); AND
iv) All other PA requests for patients who do not meet the Metavir F3 or Metavir F4 category who are at higher risk for severe liver-related complications and severe extrahepatic hepatitis C complications will be reviewed on a case-by-case basis; AND
v) The following drugs and length of therapy will be approved for HCV PA requests that meet the criteria outlined above:

NOTE: Advanced fibrosis (Metavir F3); Compensated cirrhosis (Metavir F4)	**DRUGS FOR PA APPROVAL**
GT-1 TN w/o cirrhosis (Metavir F3) *who have pre-treatment HCV RNA less than 6 million IU/ml:*	HARVONI® X **8** WEEKS
GT-1a TN or TE w/o cirrhosis (Metavir F3)	VIEKIRA PAK™ + RBV X 12 WEEKS
GT-1a TN with cirrhosis (Metavir F4)	VIEKIRA PAK™ + RBV X **12**** WEEKS
GT-1a TE with cirrhosis (Metavir F4)	VIEKIRA PAK™ + RBV X 24 WEEKS
GT-1b TN or TE w/o cirrhosis (Metavir F3)	VIEKIRA PAK™ X 12 WEEKS
GT-1b TN or TE with cirrhosis (Metavir F4)	VIEKIRA PAK™ + RBV X 12 WEEKS
GT-2 TN or TE with cirrhosis (Metavir F4) or w/o cirrhosis (Metavir F3)	SOVALDI®+ RBV x 12 weeks
GT-3 TN or TE with (F4) cirrhosis or w/o (F3) cirrhosis	SOVALDI® + RBV x 24 weeks
GT-4 TN or TE with cirrhosis (Metavir F4) or w/o cirrhosis (Metavir F3)	SOVALDI®+ PR x 12 weeks
GT=GENOTYPE; TN=TREATMENT NAÏVE; TE=TREATMENT EXPERIENCED; RBV=RIBAVIRIN; PR=PEGALATED INTERFERON+RIBAVIRIN	
** "VIEKIRA PAK administered with ribavirin for **12** weeks may be considered for some patients based on prior treatment history". In *GT-1a TN infected subjects with cirrhosis*, there was not a significant clinical difference in the SVR12 rates between 24 and 12 weeks of treatment with VIEKIRA PAK™ plus RBV.	

The EAC, or reimbursement rates, are as follows:
Viekira Pak™, $255.91 each tablet in packages with 112 tablets per Pak, =12 weeks treatment= $85,985.76; 24 weeks treatment= $171,971.52.

Harvoni® 90/400 mg: $1,161 each tablet; 8 weeks treatment = $65,016; 12 weeks treatment = $97,524; 24 weeks treatment = $195,048

Sovaldi® 400 mg: $1,032; 12 weeks treatment= $86,688; 24 weeks treatment = $173,376

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

B. ORAL ANTICOAGULANT CRITERIA: warfarin; ELIQUIS® (apixaban) 2.5 mg, 5 mg tablet; PRADAXA® (dabigatran etexilate mesylate) 75 mg, 150 mg capsules; XARELTO® (Rivaroxaban) 10 mg, 15 mg, 20 mg tablets, and XARELTO® Starter Pack; SAVAYSA™ (edoxaban tosylate) tablet 15 mg, 30 mg, 60 mg:

The point-of-sale denial criteria that included therapeutic duplication edits between Low Molecular Weight Heparin (LMWH) products and oral anticoagulant agents have been removed. The implementation date for the oral anticoagulant criteria was moved to **Aug. 19, 2015** to accomplish this change. See the provider memo dated June 15, 2015 for further information regarding the anticoagulant criteria.

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 Sept. 30, 2015 unless otherwise stated.

C. PROTOPIC® (tacrolimus) OINTMENT 0.1% and 0.03%, ELIDEL® (pimecromlimus) CREAM 1%, DOVONEX® (calcipotriene) CREAM:

The point of sale criteria for Protopic® ointment, Elidel® cream, and Dovonex® cream, have been revised to include a denial for the diagnosis of vitiligo in Medicaid history in the previous 2 years. Vitiligo is an off-label use for the above agents.

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

D. EVISTA® (raloxifene hydrochloride) TABLET:

EVISTA® is indicated for

- the treatment and prevention of osteoporosis in postmenopausal women,
- the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis, and
- the reduction in risk of invasive breast cancer in postmenopausal women at high risk of invasive breast cancer.

The clinical point-of-sale approval criteria have been revised to the following:

- Diagnosis of post-menopause in the previous 2 years, AND
  - Diagnosis of carcinoma in situ of breast in the previous 2 years, OR
  - Diagnosis of atypical hyperplasia of breast in the previous 2 years, OR
  - Diagnosis of Family History of Malignant Neoplasm of Breast in previous 2 years;

  OR
- Diagnosis of post-menopause in the previous 2 years, AND
- Diagnosis of osteoporosis in the previous 2 years, AND
  - Diagnosis of esophageal strictures in the previous 2 years , OR
  - Diagnosis of esophageal achalasia in the previous 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.

E. REGRANEX® (becaplermin) GEL:

REGRANEX® Gel contains becaplermin, a human platelet-derived growth factor that is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. REGRANEX® Gel is indicated as an adjunct to, and not a substitute for, good ulcer care practices.

Limitations of use:

- The efficacy of REGRANEX® Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers.
- The effects of REGRANEX® Gel on exposed joints, tendons, ligaments, and bone have not been established in humans.
- REGRANEX® Gel is a non-sterile, low bioburden preserved product. Therefore, it should not be used in wounds that close by primary intention.

The EAC is $63.33 per gm; a 15 gm tube is $949.95.

The clinical point-of-sale approval criteria have been revised to the following:

- Diagnoses of diabetes, type I or type II, with neurological manifestations in the previous 365 days, AND
- Non-pressure Skin Ulcer (neuropathic ulcer) of lower extremities in the previous 180 days.

The quantity edit is 1 tube per 30 days, and the cumulative quantity is limited to two- 15 gm tubes per 180 days.

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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 October 14, 2015 unless otherwise stated:

F. MOVANTIK™ (naloxegol) TABLET 12.5 mg, 25 mg:

MOVANTIK™ is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

The clinical point-of-sale approval criteria have been revised to the following

- At least one paid Medicaid drug claim for an opioid in the past 30 days; AND
- At least one paid Medicaid drug claim for polyethylene glycol 3350 (Miralax, Glycolax) or lactulose in the previous 7 to 30 days, AND
- No therapeutic duplication with overlapping days' supply greater than 25% between a different strength of Movantik™ (naloxegol), Relistor® (methylnaltrexone bromide), or Amitiza® (lubiprostone), AND
- Must be ≥ 18 years;
- Continuation of Movantik™ will require 1 paid claim of Movantik™ in previous 30 days.

A quantity edit of one tablet daily and a maximum cumulative quantity edit of 31 tablets per 31 days are applied to both strengths of Movantik™.

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.

G. CONSTIPATION DRUGS INCLUDING LINZESS® (linaclotide), AMITIZA® (lubiprostone), MOVANTIK™ (naloxegol), RELISTOR® (methylnaltrexone bromide):

The point of sale denial criteria edits for these medications include looking for a diagnoses that causes GI Mechanical Obstruction in Medicaid history.

The clinical point-of-sale denial criteria have been revised to the following:
If there is a diagnosis that causes GI Mechanical Obstruction in Medicaid history in the previous 30 days, the incoming claim will deny at point of sale. The former requirement was a 2 year history check.

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

H. XARELTO® (rivaroxaban) 10 mg TABLET:

Xarelto® 10 mg is indicated for prophylaxis of DVT following hip or knee replacement surgery.

The clinical point-of-sale approval criteria have been revised to the following:

- One claim of up to 31 tablets of Xarelto® 10 mg is allowed at POS for inferred hip or knee replacement surgery prophylaxis, AND
- One paid claim for Xarelto® 10 mg is allowed once every 186 days for inferred surgery prophylaxis, AND
- There are no therapeutic duplication claims for any oral anticoagulants in the previous 30 days of Medicaid drug history.

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

I. LONG-ACTING OPIOID AGENTS:

The long-acting opioid drug class is part of the Medicaid Preferred Drug List (PDL).

The clinical point-of-sale approval criteria have been revised to the following:
The criteria have been revised to allow for an inferred change in therapy for beneficiaries with a malignant cancer diagnosis in Medicaid history in the previous 365 days. This change will allow one therapeutic duplication with overlapping days' supply between two long-acting opioid agents once per 93 days. The two drug claims must have different dates of service for the inferred change of therapy rule to apply.

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

2. NEW CLINICAL EDITS THROUGH MANUAL REVIEW PRIOR APPROVAL (PA) PROCESS:

A. CHOLBAM™ (cholic acid) CAPSULE:

CHOLBAM™ is indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs), and for adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.

Limitation of Use:
The safety and effectiveness of CHOLBAM™ on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.

The recommended dosage of CHOLBAM™ is 10 to 15 mg/kg administered orally once daily, or in two divided doses, in pediatric patients and in adults.

The EAC for the 50 mg capsule= $284.66 each; the EAC for the 250 mg capsule= $856.56 each. An example of the reimbursement rate for a 50 kg person @ 10 mg/kg is 2 x 250 mg capsules per day = $51,393.60 per 30 day supply; an example of a 50 kg person @ 15 mg/kg is 3 x 250 mg capsules per day = $77,090.40 per 30 day supply.

Cholbam™ will require manual review PA on a case-by-case basis using the FDA approved indications, dose, and clinical trial criteria, including package insert information on response to treatment. Prescribers must supply all appropriate lab data, chart notes, and patient weights to show response to therapy for continued PA.

Maximum daily quantity limit not to exceed 4 capsules per day for either strength, as well as a maximum cumulative quantity edit of 124 capsules per 31 days for either strength.

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

B. NATPARA® (parathyroid hormone) INJECTION FOR SUBCUTANEOUS USE 25 mcg, 50 mcg, 75 mcg, 100 mcg:

NATPARA® is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Limitations of Use:

- Because of the potential risk of osteosarcoma, NATPARA is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.
- NATPARA® was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
- NATPARA® was not studied in patients with acute post-surgical hypoparathyroidism.

The dose of NATPARA® should be individualized based on total serum calcium (albumin-corrected) and 24-hour urinary calcium excretion. The recommended NATPARA dose is the minimum dose required to prevent both hypocalcemia and hypercalciuria. This dose will generally be the dose that maintains total serum calcium (albumin-corrected) within the lower half of the normal range (i.e., between 8 and 9 mg/dL) without the need for active forms of vitamin D and with calcium supplementation sufficient and individualized to meet the patient's daily requirements.

Doses of active forms of vitamin D and calcium supplements will need to be adjusted when using NATPARA®.

The EAC for each cartridge is $4,085; 2 cartridges = 28 days therapy=$8,170 reimbursement rate.

NATPARA® will require a manual review PA on a case-by-case basis using the FDA approved indications, dose, and clinical trial criteria, including response to treatment and approval guidance information. Prescribers must supply all appropriate lab data and chart notes to show response to therapy for continued PA.
A maximum quantity edit of 2 cartridges per claim and a cumulative quantity of 2 cartridges per 28 days' supply applies.

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. SANDOSTATIN® (octreotide acetate) LAR DEPOT INJECTION 10 mg, 20 mg, and 30 mg:

SANDOSTATIN® LAR Depot is indicated in patients in whom initial treatment with Sandostatin® Injection has been shown to be effective and tolerated. SANDOSTATIN® LAR Depot is indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option; long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors; long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.

Patients should be maintained on SANDOSTATIN® Injection subcutaneous (SQ) solution for at least 2 weeks to determine tolerance to octreotide. Patients who are considered to be "responders" to the drug, and who tolerate the drug can then be switched to SANDOSTATIN® LAR Depot. The SANDOSTATIN® Injection subcutaneous solution does not require a PA.

EAC for SANDOSTATIN® SQ solution: 50 mcg/1 ml = $13.60; 100 mcg/1 ml = 26.38; 200 mcg/5 ml = $54.40/1ml, = $272 per 5 ml vial; 500 mcg/1 ml = $127.26; 1,000 mcg/5 ml vial = $267.68/ml, = $1,338.40 per 5 ml vial. Acromegaly dosed TID; Carcinoid Tumors and VIPomas dosed in 2-4 divided doses.

EAC for SANDOSTATIN® LAR DEPOT vial: 10 mg LAR vial = $2,432.00 each vial; 20 mg LAR vial= $3,186.35 each vial; 30 mg LAR vial= $4,771.33 each vial. The LAR DEPOT is dosed every 4 weeks.

SANDOSTATIN® LAR Depot injection will require a manual review PA reviewed on a case-by-case basis. In addition, per the recommendation in the package insert, the SQ formulation must be used for approximately 2 weeks to ensure tolerability and response to therapy before switching to the LAR formulation. In addition, prescribers may be required to submit chart notes. The SANDOSTATIN® subcutaneous injection solution is 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.

D. INVEGA TRINZA™ (paliperidone palmitate) 273 mg, 410 mg, 546 mg, 819 mg INJECTION:

Invega Trinza™, a 3-month injection, is an atypical antipsychotic indicated for adults for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna® for at least four months. INVEGA TRINZA™ is not approved for use in patients with dementia-related psychosis.

The EAC for INVEGA TRINZA™ dosage form is calculated per ml, which varies for the syringe strength. The EAC, or reimbursement rate, below is calculated for the ml size of the syringe strength:

273 mg/ 0.875 ml = $2,073.80
410 mg/ 1.315 ml = $3,110.69
546 mg/ 1.75 ml = $4,147.73
819 mg/ 2.625 ml = $6,221.47

Invega Trinza™ will require a manual review PA on a case-by-case basis for adults age 18 years and older. Each PA request, if approved, will be limited to 1 injection (3 months) at a time. Prescribers are required to complete the Invega Trinza™ Statement of Medical Necessity form that is available on the Medicaid website and submit chart notes with each request.
https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_PA_Request_Form_invega_trinza.pdf

Fax a letter of medical necessity along with the Invega Trinza™ Statement of Medical Necessity Form and chart notes to the AR Medicaid Pharmacy Program at 1-800-424-5851.

E. NAMZARIC™ CAPSULE 14 mg/10 mg, 28 mg/10 mg (memantine/ donepezil):

NAMZARIC™ is a combination of memantine hydrochloride extended-release, a NMDA receptor antagonist, and donepezil hydrochloride, an acetylcholinesterase inhibitor, indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on memantine hydrochloride (10 mg twice daily or 28 mg extended-release once daily) and donepezil hydrochloride 10 mg, or memantine hydrochloride (5 mg twice daily or 14 mg extended-release once daily) and donepezil hydrochloride 10 mg (in patients with severe renal impairment).

Safety and effectiveness of NAMZARIC™ in pediatric patients have not been established. Memantine failed to demonstrate efficacy in two 12-week controlled clinical studies of 578 pediatric patients aged 6-12 years with autism spectrum disorders (ASD), including autism, Asperger's disorder and Pervasive Development Disorder - Not Otherwise Specified (PDD-NOS).

Namzaric™ capsule will require a manual review PA on a case-by-case basis.

Quantity edits apply of a maximum of 1 capsule per day and a cumulative quantity of 31 capsules per 31 days.

For adult patients age 50 years and older, memantine and donepezil do not require a PA although quantity edits 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.

3. NEW CLAIM EDITS, INCLUDING DOSE-OP OR QUANTITY EDITS:

A. AVYCAZ™ (ceftazidime-avibactam) 2 gm/0.5 gm vial

AVYCAZ™ (ceftazidime-avibactam) is a combination of a cephalosporin and a beta-lactamase inhibitor indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:

- Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole
- Complicated Urinary Tract Infections (cUTI), including Pyelonephritis

The recommended dosage of AVYCAZ™ is 2.5 grams (2 grams ceftazidime and 0.5 grams avibactam) administered every 8 hours by intravenous (IV) infusion over 2 hours in patients 18 years of age and older.

As only limited clinical safety and efficacy data for AVYCAZ are currently available, reserve AVYCAZ for use in patients who have limited or no alternative treatment options. To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVYCAZ and other antibacterial drugs, AVYCAZ should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

The EAC is $294.12 per vial, or $882.36/day. 14 days of therapy = $12,353.04.

The follow edits apply:

- Age edit of ≥ 18 years of age;
- Maximum daily dose of 3 vials per day, and a maximum quantity limit per claim of 42 vials for 14 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.

B. CRESEMBA® (isavuconazonium sulfate) CAPSULE 186 mg, CRESEMBA® VIAL 372 mg:

CRESEMBA® is an azole antifungal indicated for patients 18 years of age and older for the treatment of invasive aspergillosis and for the treatment of invasive mucormycosis.

Co-administration of strong CYP3A4 inhibitors or co-administration of strong CYP3A4 inducers with CRESEMBA® is contraindicated. Please refer to the package insert for complete list of drug-drug contraindications. CRESEMBA® is contraindicated in patients with familial short QT syndrome.

The EAC per capsule = $72.24; loading dose = $866.88; 31 day supply = $4,478.88
Per vial = $246.13 each vial; loading dose = $1,476.78; 31 day supply = $7,630.03;

The following edits apply:

- Age edit of ≥ 18 years of age;
- Quantity edits:
  - Capsules: 2 per day; #62 caps per 31 days;
  - Vials: 1 vial per day; #31 vials per 31 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:

The CMS ICD-10 implementation is scheduled for to Oct. 1, 2015. Will you be ready?

1. **INCARCERATED PERSONS:** The Medicaid Pharmacy Program is prohibited by federal regulations, 42 C.F.R. §435.1009 and §435.1010, from paying for drug claims for 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.

2. **ANTIPSYCHOTIC AGENTS CRITERIA FOR CHILDREN < 18 YOA have an ongoing requirement for labs** for metabolic monitoring. When any provider sends a patient who is less than 18 years of age for the metabolic labs that are required for the antipsychotic agents, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.

3. **INFORMED CONSENT FORM FOR ANTIPSYCHOTIC AGENT PA FOR CHILDREN < 18 YOA:**
For those providers who have not had their own version of the Informed Consent form approved for use with Medicaid PA requests and who use the Medicaid Informed Consent form for antipsychotic agents, the form has been updated (v072914) and is posted on the Medicaid website. As the form is updated and posted on the Medicaid website, providers are required to use the most current form. Effective, Dec. 10, 2013, the old versions will no longer be accepted.

4. **FOR PDL REQUESTS AND FOR REQUESTS FOR ANTIPSYCHOTIC DRUGS**: Providers requesting a Prior Authorization (PA) for a drug on the PDL or calling to request a Prior Authorization (PA) for an antipsychotic medication should call the Evidence-based Prescription Drug Program (EBRx) PA Call Center at (Toll Free) 1-866-250-2518 or Local 501-526-4200. **The NEW EBRx FAX number is: (800) 424-5739**. If faxing the request, please include any supporting documentation for the request with the fax, and include beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.

5. **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.

6. **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.

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

   To file a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. Frequency of the emergency override is limited to *once per year per class* of drugs for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website.

8. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE,** and are in no way a contractual obligation by Arkansas Medicaid. Current Generic Upper Limits (GUL) or Maximum Allowable Cost (MAC) that have been issued at the State and or Federal level, along with State issued Capped Upper Limits (CAP), can be found on the Arkansas Medicaid website: https://arkansas.magellanrx.com/provider/documents. EAC is Estimated Acquisition Cost and, in the absence of a federal or state GUL or MAC, this reimbursement methodology is calculated using AWP-14% for brand agents and AWP-20% for generic agents.

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

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

This advance notice is to provide you the opportunity to contact, counsel, and change patients' prescriptions.
If you need this material in an alternative format, such as large print, please contact the Program Development and Quality Assurance Unit at 501-320-6429.

If you have questions regarding this transmittal, or you need this material in an alternative format such as large print, please contact the Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895. For copies of past Remittance Advices (RA) or Arkansas Medicaid Provider Manuals (including update transmittals), please contact the HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and out-of-state at 1-501-376-2211.

ONGOING REMINDER ABOUT ANTIPSYCHOTIC AGENTS FOR CHILDREN FROM PREVIOUS COMMUNICATIONS:

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

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

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

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

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

Group-2 (lipid codes)

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

Please Note: When any provider sends a patient who is less than 18 years of age for the metabolic labs required for the antipsychotic agents*, the provider must include* the PCP's name and Medicaid ID number *in the lab order request form*. *It does not have to be the PCP ordering the labs.* Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, section II, 245.000 B for detailed information, pasted below:

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

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