

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: June 15, 2015

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

Changes To Existing Prior Authorization (PA) Criteria Or Edits: All Tramadol products; Clarifying look-back period for NPO/"swallow criteria"; Oral Anticoagulants: warfarin, ELIQUIS® (apixaban), PRADAXA® (dabigatran etexilate mesylate), XARELTO® (Rivaroxaban), and XARELTO® Starter Pack, SAVAYSA™ (edoxaban tosylate); SL Allergen Extracts: Grastek®, Ragwitek™; Amitiza® (lubiprostone), Linzess™ (linaclotide); Opioid–Induced Constipation (OIC): Relistor® (methylnaltrexone bromide) injection;

<u>Clinical edits through the Manual Review PA Process</u>: Neo-Synalar® cream <u>(neomycin sulfate/fluocinolone acetonide)</u>; Afrezza® Inhaled Insulin; Lynparza™ (olaparib); Ibrance® (palbociclib); Duopa (carbidopa/levodopa) enteral infusion suspension; Lenvima™ (lenvatinib) capsule; Sotylize™ (solalol) oral solution:

<u>Point-of-Sale (POS) Clinical Edits with or without Claim Edits:</u> Anticonvulsant oral liquids that are also available in solid oral dosage forms, example Vimpat® (lacosamide) and Trileptal® (oxcarbazepine); Opioid–Induced Constipation (OIC): Movantik™ (naloxegol) tablet; Uceris® (budesonide) Rectal Foam;

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., clinical PA criteria or is 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.

The following edits will be effective July 22, 2015 unless otherwise stated.

1. CHANGES TO EXISTING PRIOR AUTHORIZATION (PA) CRITERIA OR EDITS: A. Tramadol, Tramadol ER capsule and tablet, Tramadol/APAP, Tramadol ODT:

The safety and efficacy of tramadol products have not been studied in the pediatric population and is not recommended. Age edits have been added to all tramadol products based on statements in the package inserts regarding safety and efficacy or FDA approved indications. Quantity edits and accumulation quantity edits remain in place.

Claims will reject at point-of-sale for all children whose age is below the age edits as follows:

Tramadol IR: Claims for children below 17 years of age will reject at point of sale.

<u>Tramadol/APAP tablet</u>: Tramadol/APAP tablets are only indicated for the short-term (five days or less) for the management of acute pain. Claims for children <u>below 16 years</u> of age will reject at point of sale.

<u>Tramadol ER capsule, and Tramadol ER tablet</u>: Claims for children <u>below 18 years</u> of age will reject at point of sale.

<u>Tramadol ODT</u> (if available on the market again): Claims for children <u>below 16 years</u> of age will reject at point of sale.

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. NPO/"Swallow criteria": The Medicaid program uses point-of-sale (POS) prior authorization (PA) criteria for some oral liquids, oral suspensions, and oral dissolvable tablets (ODT) tablets when there is a solid oral dosage form available. This criteria includes an age edit of < 7 years and also includes certain ICD-9 diagnosis codes and CPT Procedure codes to determine patients who cannot swallow solid oral dosage forms ("NPO") for those who do not meet the age edit. The look-back period for the ICD-9 codes and CPT codes has been clarified for consistency for 1 year or 365 days. The ICD9 codes and CPT Procedure codes used in the "NPO" criteria are in the chart below:</p>

ICD-9/Procedure codes	Description
B4034, B4035, B4036	Enteral feeding supplies
B4149, B4150-B4156	Enteral formula
B4160-B4162	Enteral formula for pediatrics
43.11	PEG
46.32	PEJ tube
96.07	Nasogastric tube insertion
97.01	Nasogastric tube placement
432.46	PEG placement
432.60	PEG placement
437.52	Naso/Oro-gastric tube placement
437.6	Gastrostomy tube
437.61	G-tube repositioning
438.3	Gastrostomy tube
438.32	Gastrostomy tube
440.15	J-Tube
443.72	J-Tube
443.73	J-Tube
494.4	PEG placement

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C. 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 criteria have been revised as follows:

• ELIQUIS® and PRADAXA® indications have changed. The requirement of diagnosis of Atrial Fibrillation in Medicaid history has been removed from criteria for both drugs;

- For the inferred change in therapy criterion for the oral anticoagulant drugs ELIQUIS®, XARELTO®, PRADAXA®, SAVAYSA™, and WARFARIN: one (1) therapeutic duplication with overlapping days' supply and with different dates of service is allowed once per 186 days for inferred change in therapy between any of the 4 oral anticoagulants or warfarin;
- One (1) therapeutic duplication with same date of service is allowed once in 186 days between one claim for a low molecular weight (LMW) heparin and one claim of one of the oral anticoagulant drugs warfarin, Xarelto®, Pradaxa®, Eliquis®, Savaysa™;

No changes were made to the existing additional Xarelto 10 mg point-of-sale (POS) approval criteria:

- One claim of up to 31 tablets of XARELTO® 10 mg is allowed at POS for inferred surgery prophylaxis, AND
- One paid claim for Xarelto® 10 mg is allowed once every 186 days for inferred surgery prophylaxis, AND
- There are no other paid claims for other strengths of Xarelto® in the previous 6 months of Medicaid drug history;

The existing quantity edits will remain in place for Xarelto, Eliquis, and Pradaxa. Quantity edits will be added to SAVAYSA™ of 1 tablet/day for all strengths, and a cumulative quantity edit of 31 tablets per 31 days for all strengths.

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D. SL tablets of Allergen Extracts: GRASTEK® and RAGWITEK™:

GRASTEK® is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. GRASTEK is approved for use in persons 5 through 65 years of age.

GRASTEK® is not indicated for the immediate relief of allergic symptoms.

RAGWITEK™ is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. RAGWITEK is approved for use in adults 18 through 65 years of age.

RAGWITEK™ is not indicated for the immediate relief of allergic symptoms.

EAC: \$8.51 each tablet of either Grastek® or Ragwitek™. The dose is 1 tablet daily. 31-day supply = \$263.81

The DUR Board approved manual review PA for Grastek and Ragwitek in July 2014. The DUR Board provided the additional as a minimum guidance for review of requests:

- All PA requests for a SL allergen extract must include appropriate testing for the specific allergen (e.g., grass pollens or ragweed) for the drug requested. The testing can be either serum testing for the specific IqE or can be skin test; AND
- b) The skin test or IgE test for the specific allergen must test positive; AND
- The previous allergy season for either the ragweed or grass pollen will be reviewed for Medicaid drug claims used to treat allergy symptoms; AND
- d) At a minimum, the beneficiary must have filled drugs to treat allergy symptoms in at least 2 of the following categories during the previous allergy season and have at least 2 claims in consecutive months in each category:
 - i. Nasal inhaled steroid (must have at least 2 claims in consecutive months); OR
 - ii. Oral (systemic) antihistamine (must have at least 2 claims in consecutive months); OR
 - iii. Leukotriene modifier (e.g., montelukast) (must have at least 2 claims in consecutive months): OR
 - iv. Ophthalmic allergy drops (topical ocular mast cell stabilizers or antihistamines) for treating allergic conjunctivitis (must have at least 2 claims in consecutive months); AND
- e) The manual review will include checking for therapeutic duplication between allergy shots and the SL tablet and not allow both; AND
- f) The SL allergen extract drugs are contraindicated in persons classified as "severe asthma", whether "controlled" or "uncontrolled", on asthma controller medications or not, and requests will

- not be approved for persons with a diagnosis of "severe asthma". If an asthma patient is classified as less than severe asthma (e.g., moderate asthma) and using daily controller medications, the asthma diagnosis and asthma controller drug medications will not prevent approval.
- g) Once an approved PA is entered into the system, the continued approval of subsequent claims of the SL allergen extract will require that the beneficiary is adherent to therapy and the system must find the previous SL allergen extract claim within the previous 37 days of the incoming claim. Incoming claims that are more than 7 days late on a previous 30-day supply will reject at point-ofsale and the PA will not be renewed.

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E. AMITIZA® (lubiprostone) capsule, 8 mcg, 24 mcg and Linzess (linaclotide) 145 mg and 290 mg capsule:

EAC: 8 mcg or 24 mcg = \$5.41 each capsule

One change to existing criteria was made and all other criteria and edits to remain the same on each drug. The change clarifies the look-back period for use of other laxatives:

 At least one paid Medicaid drug claim 7 days to 30 days back for polyethylene glycol 3350 (Miralax, Glycolax) or lactulose.

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

F. OPIOID-INDUCED CONSTIPATION (OIC): RELISTOR® (methylnaltrexone bromide) 8 mg/0.4 ml, 12 mg/0.6 ml SQ injection: RELISTOR® is an opioid antagonist indicated for treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, and treatment of opioid-induced constipation in patients with advanced illnesses who are receiving palliative care, when response to laxative therapy has not been sufficient. Limitation of Use: Use beyond four months has not been studied. The recommended dosage of RELISTOR® is 12 mg subcutaneously once daily. Discontinue RELISTOR® if treatment with the opioid pain medication is also discontinued. The billing unit for Relistor® is per ml. The EAC for 12 mg/0.6 ml = \$123.94/ml; 8 mg/0.4 ml = 185.91/ml. Both the 12 mg vial or syringe and the 8 mg syringe calculate to be the same EAC of \$74.36 each. Using 1 daily, 30-day supply = \$2,230.80.

Relistor POS 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 7 days to 30 days back for polyethylene glycol 3350 (Miralax, Glycolax) or lactulose, AND
- No therapeutic duplication between different strengths of same drug or between Relistor and 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.

- 1. NEW CLINICAL EDITS THROUGH MANUAL REVIEW PRIOR APPROVAL (PA) PROCESS:
 - A. NEO-SYNALAR® 0.5%-0.025% (neomycin sulfate 0.5%, fluocinolone acetonide 0.025%) CREAM 60 gm: NEO-SYNALAR® cream is indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment. The reimbursement rate for Neo-Synalar cream is \$6.30 per gm, so a 60-gm tube is approximately \$378.

NEO-SYNALAR® cream will require a manual review PA on a case-by-case basis. Other products are available without a PA, such as Cortisporin® cream (NEOMYCIN/POLYMYXIN B SULF/HC) 7.5 gm (EAC \$70.74), and Cortisporin® ointment (NEOMYCIN/BACITRA/POLYMYXIN/HC) 15 gm (EAC \$96.73), as well as a triple antibiotic ointment (EAC approx. \$5.56 per tube) that a prescriber can prescribe in combination with other topical steroid products that do not require a prior authorization.

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. <u>AFREZZA® (REGULAR HUMAN INSULIN) INHALED INSULIN:</u> AFREZZA® is rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. The package insert stated several limitations of use: AFREZZA® is not a substitute for long-acting insulin. AFREZZA® must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus. AFREZZA® is not recommended for the treatment of diabetic ketoacidosis. The safety and efficacy of AFREZZA® in patients who smoke has not been established. The use of AFREZZA® is not recommended in patients who smoke or who have recently stopped smoking.

The product is packaged in different NDCs that are combinations of cartridges and strengths.

- 4 unit cartridge #90, EAC is \$2.59 each, or \$233.10
- 4 unit cartridge #30 plus 8 unit cartridge #60, EAC is \$3.20 each, or \$287.51
- 4 unit cartridge #60 plus 8 unit cartridge #30, EAC is \$2.89 each, or \$260.41
 COMPARED TO:

Regular Human Insulin 10 ml vial: \$11.32/ ml, or \$113.21for 10 ml vial; No PA required. Apidra (glulisine) is \$20.97/ml (\$209 per 10 ml vial); No PA required

Novalog (aspart) \$20.98/ml for 10 ml vial (\$209 per vial); No PA required

AFREZZA® Inhaled Insulin will require a manual review PA on a case-by-case basis. In addition, the beneficiary cannot be a smoker or past smoker. Although some consideration may be given for those who are unable to operate a syringe or a pen due to either manual dexterity or visual problems and if he/she does not have a care giver to assist in the insulin injection, the prescriber must address how the beneficiary will still be able to inject a long-acting insulin.

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. LYNPARZA™ (OLAPARIB) 50 MG CAPSULE: Lynparza™ is indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

The EAC is \$25.80 EACH CAPSULE; The recommended dose of 400 mg twice daily = 16 capsules per day = \$412.80 per day; the drug manufacturer packages the drug in 112 capsules per blister pack, or a 7 day supply. A 28-day supply = \$11,558.

Lynparza™ will require a manual review PA on a case-by-case basis using approved indications, dosage information, and data from clinical trials. In addition, a quantity edit not exceed 16 capsules per day, or 448 capsules for 28-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.

D. IBRANCE® (PALBOCICLIB) CAPSULE 75 MG, 100 MG, 125 MG: IBRANCE® is indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. The recommended dose of IBRANCE® is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. IBRANCE should be taken with food in combination with letrozole 2.5 mg once daily given continuously throughout the 28-day cycle. Patients should be encouraged to take their dose at approximately the same time each day. EAC of IBRANCE® for all 3 strengths is \$484.06 per each capsule; 21-day supply = \$10,165.26; EAC of letrozole (FEMARA®) 2.5 mg tablet is \$0.69317; 28-day supply = \$19.41

IBRANCE® will require a manual review PA on a case-by-case basis based on indications, dosage, and data from clinical studies. In addition, a quantity edit on each strength not to exceed 1 per day, or 21capsules for a 28 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.

E. <u>DUOPA (CARBIDOPA/LEVODOPA) ENTERAL INFUSION SUSPENSION (4.63 mg-20 mg/ml) cassettes:</u>
DUOPA is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.
DUOPA is administered over a 16-hour infusion period. Long-term administration of DUOPA requires

placement of a PEG-J outer transabdominal tube and inner jejunal tube by percutaneous endoscopic gastrostomy. DUOPA is dispensed from medication cassette reservoirs that are specifically designed to be connected to the CADD®-Legacy 1400 pump. PA authorization of the medication does not include any type of prior authorization that may be needed for the procedure or pump and prescribers are encouraged to check the appropriate provider manual.

The Duopa enteral infusion suspension is available in a 100 ml cassette. The cassettes are for single-use only and should not be used for longer than 16 hours, even if some drug product remains. EAC: \$2.083 per ml; 100 ml cassette = \$208.30; One cassette is used for 16 hours and removed and patient then switches to oral medication during the next 8 hours. One cassette daily or 30 cassettes per month = \$6,240/30-day supply.

Duopa enteral infusion suspension will require manual review PA on a case-by-case basis for those beneficiaries with advanced Parkinson's disease and the prescriber will be required to provide documentation of the medical necessity of using enteral infusion rather than oral form of carbidopa-levodopa tablets.

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

F. LENVIMA™ (lenvatinib) CAPSULE 10 MG, 14 MG, 20 MG, 24 MG: LENVIMA™ is indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). The recommended daily dose of LENVIMA™ is 24 mg. Continue LENVIMA™ until disease progression or until unacceptable toxicity occurs. There are only 2 strengths of capsules made, a 4 mg capsule and a 10 mg capsule. However, the capsules are packaged with 8 different NDCs in various quantities of 4 mg and/or 10 mg capsules to make a 5-day supply package and a 30-day supply package for each daily dose listed in the system, 10 mg, 14 mg, 20 mg, and 24 mg. There are 2 NDCs for 10 mg daily dose (5-day supply and 30-day supply), 2 NDCs for 14 mg daily dose (5-day supply and 30-day supply), 2 NDCs for 24 mg daily dose (5-day supply and 30-day supply) and 30-day supply) and 30-day supply).

EAC: NDCs for 10 mg daily dose= \$430.00 each capsule; \$2,150 for 5-day supply; \$12,900 for 30-day supply;

NDCs for 14 mg daily dose= \$215.00 each capsule; \$2,150 for 5 day supply; \$12,900 for 30-day supply; NDCs for 20 mg daily dose = \$239.94 each capsule; \$2,399.40 for 5-day supply; \$14,396 for 30-day supply; NDCs for 24 mg daily dose = \$159.96 each capsule; \$2,399.40 for 5-day supply; \$14,396 for 30-day supply.

LENVIMA™ will require a manual review PA on a case-by-case basis based on indication, dosage, and clinical trial data.

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. SOTYLIZE™ (SOTALOL) SOLUTION: SOTYLIZE™ (sotalol hydrochloride) oral solution is indicated for the treatment of ventricular arrhythmias, such as sustained ventricular tachycardia, that in the judgment of the physician are life-threatening.

SOTYLIZE™ EAC: The SOTYLIZE™ oral solution is available in 2 bottle sizes, 250 ml and 480 ml; the price per ml is different based on bottle size. The 250 ml bottle is \$1.49 per ml or \$372.50 for the bottle; the 480 ml bottle is \$1.29/ml or \$619.20 for the bottle.

Using the \$1.29/ml price, the 80 mg dose = \$20.64 per dose; using the \$1.49/ml price, the 80 mg dose is \$23.84 per dose; if dose is 80 mg once qd = 480 ml per 30 days, or \$619.20 using \$1.29/ml; if dose is 80 mg BID = 960 ml per 30 days, or \$1,238.40;

Using the \$1.29/ml price, the 320 mg dose = \$82.56 per dose; using the \$1.49/ml price, the 320 mg dose = \$95.36 per dose. If dose is 320 mg once qd = 1,920 ml per 30 days (4- pint bottles), or \$2,476.80; if dose is 320 mg BID = 3,840 ml per 30 days (8 pint bottles), or \$4,953.60.

SOTYLIZE™ requires a manual review PA on a case-by-case basis. The manual review will include beneficiary's history of filling solid oral dosage forms and NPO status and the need for sotalol oral solution in chart notes. Sotalol tablets 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.

2. NEW AUTOMATED CLINICAL POS EDITS WITH OR W/O ADDITIONAL CLAIMS' PROCESSING EDITS:

A. ANTICONVULSANT ORAL LIQUIDS THAT ALSO COME IN SOLID ORAL DOSAGE FORM, example Vimpat® (lacosamide) 10 mg/mL oral solution AND Trileptal® (oxcarbazepine) oral suspension 300 mg/5 ml:

Typically the oral solutions or suspensions are more expensive per dose than the solid Trileptal® oral dosage forms. Examples include Vimpat® (lacosamide) 10 mg/mL oral solution and Trileptal® (oxcarbazepine) 300 mg/5 ml oral suspension.

EAC Vimpat® oral solution 10mg/ml: comes in 2 size bottles, 200 ml, which is \$1.33/ml, and 465 ml, which is \$1.15 per ml. EAC Vimpat® tablets: 50 mg = \$7.56; 100 mg = \$11.83; 150 mg = \$12.53; 200 mg = \$12.53. Comparison of oral solution price by 200 ml bottle or 465 ml bottle for corresponding strengths: 50 mg solution = \$6.67 or \$5.74; 100 mg as solution = \$13.34 or \$11.48; 150 mg as solution = \$19.95 or \$17.25.

The EAC for oxcarbazepine oral suspension 300 mg/5 ml generic is \$0.87/ml and brand is \$1.20/ml. EAC for 300 mg as suspension = \$4.37 generic or \$6.00 for Trileptal® brand liquid. Comparison to tablets: 150 mg tablet = \$0.46 each, 300 mg tablet = \$0.54 each, 600 mg tablet = \$0.61 each.

Below is the complete list of anticonvulsant oral liquids that are also available in a solid oral dosage form. As new oral liquid anticonvulsants come to market they will be added to the list.

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General Description	
DEPAKENE 250 MG/5 ML SYRUP (valproate sodium)	
TEGRETOL 100 MG/5 ML SUSP (Carbamazepine)	
TRILEPTAL® 300 MG/5 ML SUSP (oxcarbazepine)	
CARBAMAZEPINE 200 MG/10 ML ORAL SUSP ORAL	
LACOSAMIDE (VIMPAT) 20MG/ML SOLUTION ORAL	
VALPROIC ACID (AS SODIUM SALT) 250MG/5MLSOLUTION ORAL	
VALPROIC ACID (AS SODIUM SALT) 500MG/10ML SOLUTION	
ORAL	
GABAPENTIN 300 MG/6 ML SOLN	

The automated "swallow criteria" will be implemented at point of sale of an upper age edit of < 7 years and certain ICD-9 diagnosis codes and CPT Procedure codes to determine "NPO" for those who do not meet the age edit. The look-back period for the 'NPO" ICD-9 codes and CPT codes is 1 year or 365 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.

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

MOVANTIK™ (naloxegol), is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. MOVANTIK™ is a peripherally acting opioid antagonist with no risk of abuse and with no risk of dependency. MOVANTIK™ has been shown to be efficacious in patients who have taken opioids for at least 4 weeks. Sustained exposure to opioids prior to starting MOVANTIK™ may increase the patient's sensitivity to the effects of MOVANTIK™. The recommended MOVANTIK™ dosage is 25 mg once daily in the morning. If patients are not able to tolerate MOVANTIK™, reduce the dosage to 12.5 mg once daily.

The EAC for the 12.5 mg and 25 mg tablets are both \$8.59 each tablet. 30-day supply = \$257.70

Movantik POS approval criteria are as follows:

- · At least one paid Medicaid drug claim for an opioid in the past 30 days; AND
- At least one paid Medicaid drug claim 7 days to 30 days back for polyethylene glycol 3350 (Miralax, Glycolax) or lactulose, AND
- No therapeutic duplication between different strengths of same drug or between Relistor and Movantik; In addition a quantity edit of one tablet daily and a maximum quantity edit of 31 tablets per 31 days is implemented for 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.

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

A. UCERIS® (BUDESONIDE) RECTAL FOAM:

UCERIS® rectal foam is indicated for the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge. UCERIS® rectal foam is formulated as an emulsion which is filled into an aluminum canister with an aerosol propellant. It is available as a metered dose of 2 mg budesonide.

The recommended dosage regimen is 1 metered dose administered rectally twice daily for 2 weeks followed by 1 metered dose administered rectally once daily for 4 weeks. UCERIS® rectal foam is supplied as a kit containing 2 aerosol canisters. Each canister is labeled with a net weight of 33.4g and contains 14 metered doses. Two canisters are needed for the first 2 weeks of therapy for twice daily dosing x 14 days, and then 2 canisters are needed for once daily dosing for the next 28 days.

EAC: \$7.91/gm; each canister = 33.4 gm = \$264.19 each canister; 1 kit (2 canisters) = \$528.39

A quantity edit of up to 4 canisters (2 kits) is allowed per claim, and an edit of up to 4 canisters (2 kits) allowed per year. No data was available on re-treatment. Requests for re-treatment sooner than 1 year 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.

FRIENDLY REMINDERS:

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

- 1. <u>INCARCERATED PERSONS</u>: 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. REVISED 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.
- 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, 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-LTCeligible 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.

- 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 along with written documentation, e.g., chart notes, to substantiate the medical necessity of the request. The request may be faxed to NEW MMA Pharmacy Unit Fax: (800) 424-7976.
- 10. 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 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
- 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.
- The reference facility retains the ordering physician's provider information with the client's medical record for the medical necessity audit trail.
- 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.