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: Cynthia Neuhofel, Pharm.D. Division of Medical Services Pharmacy Program Cynthia Neuhofel

DATE: **NOVEMBER 30, 2018**

SUBJ: **AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board OCTOBER 17, 2018 meeting for the following:** Manual review criteria for asthma for non-preferred drug Spiriva Respimat; New drugs manual review criteria: ORILISSA™ (elagolix); DOPTELET® (avatrombopag); MULPLETA® (lusutrombopag); SIKLOS® (hydroxyurea); MEKTOVI® (binimetinib); BRAFTOVI™ (encorafenib); LOKELMA™ (sodium zirconium cyclosilicate);

Preferred Drug List (PDL) Drugs from the NOVEMBER 14, 2018 Drug Review Committee Meeting for the following: Beta Adrenergic Blocking agents, Bowel Prep Agents, 2nd Generation Antidepressants;

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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/ Select "Resources" tab at the top right, then select "Documents" from the drop-down box. All Provider Memos are under the "Pharmacy" tab at the top.

Medicaid Pharmacy Program drug reimbursement rate methodology changed April 1, 2017; reimbursement rates stated in this memo are informational only and are only current as of the date the memo was drafted; the rates stated are approximate as they may have been rounded.

REMINDER: Morphine Milligram Equivalents (MME) Final Reduction November 14, 2018:
The final MME was reduced to **≤90 MME/day** on **November 14, 2018**. This is an additive edit for all opioid drug claims with overlapping days' supply. The beneficiaries with certain cancer diagnoses in Medicaid medical diagnosis history are exempted from the MME edit.

EFFECTIVE JANUARY 1, 2019:

PREFERRED DRUG LIST (PDL) UPDATE:
The 2nd generation antidepressants, beta-blockers, drugs for treating neuropathic pain, and bowel prep kits were reviewed at the November 14, 2018 PDL meeting. The Preferred status and Non-preferred status drugs were selected based on a review of comparative effectiveness as well as cost-effectiveness for the state Medicaid program and are listed below. *Prior Authorization criteria* and quantity limits will remain in place for Preferred-status drugs unless otherwise noted below. Agents in **bold** font indicate a change in designation on the PDL.

BETA ADRENERGIC BLOCKING AGENTS

Preferred agents (PA criteria removed for preferred drugs)

- Atenolol
- Metoprolol tartrate
- Propranolol HCl immediate-release
- Bisoprolol fumarate
- Carvedilol tablet
- Metoprolol succinate extended-release
- **Timolol**
- **Acebutolol**
- **Pindolol**
- **Sotalol**
- **Betaxolol**
- **Labetalol**
- **Propranolol Solution**
- **Propranolol/HCTZ**
- **Bisoprolol/HCTZ**
- **Atenolol/Chlorthalidone**

Non-preferred agents

- Carvedilol ER
- Nadolol
- Nebivolol HCl (Bystolic)
- Penbutolol sulfate
- Propranolol HCl extended-release (Inderal LA, Innopran XL)
- Propranolol HCl solution (Hemangeol)
- Sotalol (Sotylize)
- **Nadolol/bendroflumethiazide**
- **Metoprolol/HCTZ**

BOWEL PREP (New to PDL)

Preferred agents

- **Colyte Solution, Colyte with flavor Packets, Gavilyte-C**
- **Nulytely, Gavilyte-N**
- **Golytely Solution, Gavilyte G**
- **Moviprep Powder Kit**
- **PEG-3350 and Electrolytes Solution**
- **PEG-3350 with Flavor Packs Solution**
- **Trilyte**

Non-preferred agents

- **Osmoprep Tablet**
- **Clenpiq**
- **Prepopik Powder Packet**
- **Suprep Bowel Prep Kit**
- **Plenvu**
- **Golytely Powder Pack**

2ND GENERATION ANTIDEPRESSANTS (PA criteria and dose edits remain in place)

Preferred agents

- Bupropion HCl regular-release (Wellbutrin)
- Bupropion HCl extended-release (Wellbutrin XL)
- Bupropion HCl sustained-release (Wellbutrin SR)
- Citalopram hydrobromide (Celexa)
- Escitalopram oxalate (Lexapro)
- Fluoxetine HCl 10mg, 20mg capsule, and 20mg/5ml solution (Prozac)
- Fluvoxamine maleate (Luvox)
- Mirtazapine 7.5mg, 15mg, 30mg, 45mg tablet (Remeron)
- Paroxetine HCl regular-release tablet (Paxil)
- Sertraline HCl (Zoloft)
- Venlafaxine HCl extended-release capsule (Effexor ER)
- Venlafaxine HCl regular-release tablet (Effexor)
- **Duloxetine (Cymbalta)**

Non-preferred agents

- Bupropion hydrobromide extended-release tablet (Aplenzin)
- Bupropion HCl exended-release tablet (Forfivo XL)
- Desvenlafaxine extended-release tablet (Khedezla ER)
- Desvenlafaxine fumarate extended-release tablet
- Desvenlafaxine succinate extended-release tablet (Pristiq ER)
- Duloxetine HCl (Irenka DR)
- Fluoxetine HCl 10mg, 15mg, 20mg Tablet; 40mg capsule; and 90mg weekly capsule (Prozac)
- Fluvoxamine maleate extended-release (Luvox CR)
- Milnacipran HCl (Savella)
- Levomilnacipran (Fetzima)
- Mirtazapine orally disintegrating tablet (Remeron SolTab)
- Nefazodone HCl (Serzone)
- Paroxetine HCl controlled-release tablet, and 10mg/5ml suspension (Paxil)
- Paroxetine mesylate (Pexeva)
- Paroxetine (Brisdelle)
- Vilazodone HCl (Viibryd)
- Vortioxetine HBr (Trintellix, Brintellix)
- Venlafaxine HCl extended-release tablet

PRIOR AUTHORIZATION DRUG CRITERIA, NEW OR REVISED, FOR THE FOLLOWING DRUGS:

EFFECTIVE IMMEDIATELY

1. **SPIRIVA® (tiotropium bromide) RESPIMAT® METERED INHALATION SPRAY 1.25 mcg/ACTUATION NON-PREFERRED drug for ASTHMA**

Medicaid estimated reimbursement rate for one SPIRIVA® RESPIMAT® 1.25 mcg/actuation inhaler is **$381.61**.
SPIRIVA® RESPIMAT® Inhalation Spray is *a NON-PREFERRED drug* on the PDL and all requests for SPIRIVA® RESPIMAT® 1.25 mcg/actuation *require a manual review prior authorization on a case-by-case basis*. SPIRIVA® RESPIMAT® was included in the GINA Asthma Guidelines 2018 at STEP 5, which is defined as a severe asthma patient who continues to have persistent symptoms or exacerbations despite appropriate dose and frequency of 2 or more controller meds and the patient requires a higher level of care and/or add-on treatment.

The following criteria were developed to serve as an outline for the PDL PA Call Center for manual review PA requests for SPIRIVA® RESPIMAT® 1.25 mcg/actuation inhaler for treating asthma.

SPIRIVA RESPIMAT 1.25 mcg INHALER ASTHMA APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING:

- The PA request is for SPIRIVA RESPIMAT 1.25 mcg/Actuation inhaler @ a dose of 2.5 mcg (2 actuations) once daily;
- Beneficiary is ≥6 years of age;
- Chart notes indicate the beneficiary has diagnosis of severe asthma or refractory asthma with persistent asthma symptoms despite use of appropriate controller drugs (per GINA guidelines) (e.g., @moderate/high-dose ICS/LABA) and beneficiary requires a higher level of care and/or add-on treatment;
- Beneficiary's asthma is poorly controlled despite correct inhaler technique;
- Beneficiary must be adherent with 2 or more asthma controller medications (e.g., moderate/high dose of ICS/LABA) as maintenance treatment plus use of an as-needed reliever medication; good adherence to controller inhaler(s) for purposes of this criteria is defined as the Medicaid drug profile history shows controller inhaler(s) filled monthly at least 4 months out of previous 6 months. A combination inhaler of ICS/LABA is considered as two asthma controller medications.
- Beneficiary is a non-smoker;
- Prior Authorization (PA) can be approved for 6 months at a time;

CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:

- Beneficiary must be adherent to all prescribed asthma controller medications with Medicaid drug history profile showing all controller inhalers (e.g., medium/high dose of ICS/LABA and Spiriva Respimat Inhaler) filled monthly for at least 4 months out of previous 6 months; and beneficiary is adherent to the prescribed dose and frequency for daily use;
- Beneficiary continues to have persistent asthma symptoms that require add-on treatment;
- PA for SPIRIVA® RESPIMAT® can be approved for 6 months at a time and prescriber must submit asthma re-assessment chart notes with every PA request.

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:

- The beneficiary does not have severe asthma (e.g., beneficiary has COPD);
- Beneficiary is not using a medium to high dose ICS/LABA controller drug and provider has not submitted documentation to substantiate medical justification for the severe asthma patient not using the higher dose;
- Beneficiary is non-adherent to standard asthma controller medication treatment (e.g., ICS/LABA) of at least 4 monthly inhalers in previous 6 months;
- Beneficiary is non-adherent to add-on treatment of SPIRIVA RESPIMAT 1.25 mcg/Actuation inhaler of at least 4 monthly inhalers in previous 6 months;

QUANTITY EDIT:

- SPIRIVA RESPIMAT MIST INHALER strength 1.25 mcg per actuation for asthma: Each inhaler contains 60 metered actuations for a 30-day supply, quantity limit will be set at 1 inhaler per 30 days' supply; and include the standard refill allowance set at 75%.

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

2. ORILISSA™ (elagolix) 150 mg and 200 mg Tablet:

Approximate Medicaid Reimbursement Rate:
150 mg, supplied as bottle of #28 tablets: $30.17 each tablet; **28 day supply = $844.76**
200 mg, supplied as bottle of #56 tablets: $15.09 each tablet; **28 day supply = $845.04**

ORILISSA™ will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING

- Beneficiary is > 18 years of age;
- Beneficiary is premenopausal;
- Beneficiary has moderate to severe pain associated with endometriosis;
- Provider must submit results of a transvaginal ultrasonography (TVS) or surgery report to substantiate endometriosis diagnosis;
- Provider must submit chart notes that substantiate that the pelvic pain is due to endometriosis, and that it is not due to other causes, such as pelvic inflammatory disease, pelvic adhesions, ovarian cysts or masses, leiomyomata, scar endometriomas, or adenomyosis, or non-gynecologic conditions and factors (such as, Irritable Bowel Syndrome (IBS), inflammatory bowel disease, interstitial cystitis, myofascial pain, depression, or a history of sexual abuse);
- Provider must provide chart notes providing background as to when endometriosis symptoms started;
- Beneficiary has drug claims in Medicaid drug history of at least 3 months of treatment with OTC acetaminophen and/or ibuprofen as these medications are covered by Medicaid Pharmacy Program with a prescription, or 3 months of legend NSAIDs as 1st line treatment;
- Beneficiary has tried at least 6 months of treatment with hormonal therapy (combined contraceptive pill or progestogen);
- Provider must provide chart notes for all previous treatments for endometriosis;
- Provider must provide chart notes documenting all pregnancies in history;
- Provider must submit liver function test results and a full lipid panel;
- Provider must submit calculated Child-Pugh score or tests necessary for calculation of Child-Pugh score;
- Beneficiary does not have severe liver impairment or Child Pugh Class C;
- Provider must submit current pregnancy test results and planned starting date of ORILISSA for within 7 days from the last onset of menses;
- Provider must submit beneficiary's agreement to use non-hormonal contraception during treatment (due to reduced efficacy with estrogen containing contraceptives);
- Provider must submit results of the beneficiary's central DXA bone mineral density (BMD) test performed within the previous 3 months;
- Beneficiary does not have a diagnosis of osteoporosis or osteopenia (i.e., T-score > -1.0 or Z-score > -2.0);
- Beneficiaries meeting approval criteria can be approved for up to 3 months for initial PA approval based on diagnosis, dose, and duration of therapy as stated in drug package insert:
    - Beneficiary who meets approval criteria for diagnosis of moderate to severe pain associated with endometriosis without a coexisting condition of dyspareunia will be limited to 150 mg once daily for a maximum treatment duration of 24 months;
    - Beneficiary who meets approval criteria for moderate to severe pain associated with endometriosis, with or without coexisting condition of dyspareunia, AND who has a Child-Pugh B score (moderate hepatic impairment) will be limited to 150 mg once daily for a maximum treatment duration of 6 months;
    - Beneficiary who meets approval criteria for moderate to severe pain associated with endometriosis AND who has coexisting condition of dyspareunia will be limited to 200 mg twice daily (BID dose) for a maximum treatment duration of 6 months;
- Prescriber shall provide patient specific measurable goals for treatment response outcomes for the pain associated with primary endometriosis;
- Initial PA can be approved for up to 3 months at a time;

CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:

- Beneficiary is adherent to prescribed dose;
- Documentation submitted to show beneficiary has a clinically meaningful positive treatment response per the patient specific measurable goals previously submitted;
- PA can be approved for 3 months at a time for ongoing therapy up to the maximum duration of therapy time limits set in the FDA approved doses listed in the package insert:
    - 150 mg once daily for maximum treatment duration of 24 months for beneficiary who meets approval diagnosis criteria and does not have coexisting condition of dyspareunia; OR
    - Up to 200 mg twice daily for maximum treatment duration of 6 months for beneficiary who meets approval diagnosis criteria AND has co-existing condition of dyspareunia; OR

  - 150 mg once daily for up to a maximum treatment duration of 6 months for beneficiary who meets approval diagnosis criteria AND also has moderate hepatic impairment (Child-Pugh Class B), regardless of coexisting condition of dyspareunia;
- Beneficiary does not have severe liver impairment or Child Pugh Class C;
- Beneficiary is not pregnant;
- Beneficiary is continuing to use non-hormonal contraception during treatment due to reduced efficacy with estrogen-containing contraceptives;

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:
- Beneficiary did not show a clinically meaningful positive treatment response of reduction of the pain associated with primary endometriosis;
- Drug claims not in Medicaid drug claim history and no documentation provided to substantiate the rationale for not using acetaminophen and/or NSAIDs;
- Drug claims not in Medicaid drug claim history and no documentation provided to substantiate the rationale for not using hormonal therapy;
- Beneficiary only has the symptom of dyspareunia without the additional diagnosis of moderate to severe pain associated due to endometriosis;
- Beneficiary does not have a definitive diagnosis of endometriosis based on transvaginal ultrasonography or surgery;
- Provider cannot make a definitive diagnosis that the moderate to severe pelvic pain is due to endometriosis and not due to another cause, i.e., beneficiary has chronic pelvic pain that may be due to other causes, such as pelvic inflammatory disease, pelvic adhesions, ovarian cysts or masses, leiomyomata, scar endometriomas, or adenomyosis, or non-gynecologic conditions and factors (such as Inflammatory Bowel Syndrome (IBS), inflammatory bowel disease, interstitial cystitis, myofascial pain, depression, or a history of sexual abuse);
- Request to exceed the FDA approved maximum treatment duration for either strength tablet, or request to exceed dose for treatment diagnosis as stated in the package insert, or request for additive lengths of treatment duration using a combination of the 2 tablet strengths;
- Beneficiary is pregnant or planning to become pregnant during therapy time;
- Beneficiary has a history of multiple (>2) pregnancies/child births;
- Beneficiary has diagnosis of osteoporosis or osteopenia (i.e., T-score < -1.0 or Z-score < -2.0);
- Beneficiary has Child Pugh C score (severe hepatic impairment);
- Beneficiary has suicidal ideation or mood disorder;
- Beneficiary is currently receiving medication treating depression;
- Beneficiary is currently receiving a strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (eg cyclosporine, gemfibrozil);
- Beneficiary is currently receiving therapy with leuprolide injection (LupronDepot® or Lupaneta Pack™);
- Beneficiary has a diagnosis of hyperlipidemia OR is currently receiving therapy for hyperlipidemia;

QUANTITY EDIT:
- The approved PA for the strength tablet based on diagnosis will be entered at time of PA approval; each PA approval duration not to exceed 3 months at a time;
- Quantity limit for the 150 mg strength tablet will not exceed 1 daily; the 150 mg strength tablet will not exceed a maximum duration of therapy of 24 months for a beneficiary who does not have moderate hepatic impairment (Child-Pugh B);
- Beneficiaries who have moderate hepatic disease (Child-Pugh B) will be limited to only receiving the 150 mg strength once daily for up to a maximum duration of therapy of 6 months;
- Quantity limit for the 200 mg strength tablet will not exceed 2 daily (BID dosing) for beneficiaries who have the additional coexisting condition of dyspareunia; the 200 mg strength tablet will not exceed a maximum duration of therapy of 6 months;
- No additive lengths of treatment duration using both tablet strengths will be approved;

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

3. ORAL THROMBOPOIETIN RECEPTOR AGONISTS INDICATED FOR THROMBOCYTOPENIA WITH CHRONIC LIVER DISEASE PRIOR TO AN INVASIVE PROCEDURE: DOPTELET® (avatrombopag) Tablet 20 mg and MULPLETA® (lusutrombopag) 3 mg Tablet, film coated

a) DOPTELET® (avatrombopag) Tablet 20 mg:

- **Medicaid Reimbursement Rate (WAC) is *$900 per tablet*; Packaged as package of 10 tablets or packaged as 15 tablets; *$9,000 for #10 tablets*; *$13,500 for #15 tablets*.**

b) MULPLETA® (lusutrombopag) 3 mg Tablet, film coated:

- **Medicaid reimbursement rate = $1,214.29 each tablet; package size is 7 tablets in blister pack; $8,500.00 for a 7-day supply for therapy.**

DOPTELET® and MULPLETA® will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA FOR EITHER DOPTELET® OR MULPLETA®, REQUIRE ALL OF THE FOLLOWING:

- Beneficiary has thrombocytopenia with baseline platelet count of <50,000/µL AND chronic liver disease AND beneficiary is scheduled to undergo an invasive procedure or operation that would otherwise require a platelet transfusion to address a risk of bleeding associated with the procedure unless there is a clinically significant increase in platelet count from baseline;
- Beneficiary is an adult ≥18 years of age;
- Prescriber must submit explanation and supporting documentation of medical necessity of beneficiary receiving requested drug over beneficiary receiving platelets;
- Prescriber must submit the target platelet count the beneficiary must reach during the pre-operative period in order for beneficiary to continue with the planned surgery or invasive procedure;
- Prescriber must submit all of the beneficiary's chart notes, including all previous blood counts;
- Prescriber must submit current hemoglobin levels with hematocrit;
- Prescriber must submit current platelet count at the time of the PA request.
- Approval dose and duration dependent on package insert dosing for drug requested:
    - DOPTELET®: The approved dose will follow the package insert dosing chart: if platelet count is <40,000/µL, the approved once daily dose is 60 mg daily for 5 days; if platelet count is ≥40,000/ µL to < 50,000/µL, the daily dose is 40 mg once daily for 5 days.
    - MULPLETA®: The approved dose is one 3 mg tablet once daily for 7 days.
- Prescriber must provide information as to whether or not he/she anticipates administering platelets at the time of surgery or invasive procedure;
- If beneficiary received Doptelet or Mulpleta previously for a previous invasive procedure, prescriber must provide chart notes and platelet count results to the drug therapy;
- Prescriber must submit the type of scheduled procedure;
- Prescriber must submit the date of the scheduled procedure;
    - DOPTELET® dosing must begin 10-13 days prior to the scheduled procedure, and dosing should end 5 to 8 days prior to the procedure;
    - MULPLETA® dosing must begin 8-14 days prior to the scheduled procedure, and dosing should end 2-8 days prior to the procedure;
- The PA for DOPTELET® will be NDC specific at the time of approval for the quantity required for the dose (using the NDC for 10 tablets or the NDC for 15 tablets).

CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:

- No continuation past 5 days for DOPTELET®; OR
- No continuation past 7 days for MULPLETA®;

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:

- Beneficiary's platelet count at time of PA request is ≥50,000/µL;
- If the beneficiary is scheduled for an invasive surgery or procedure and requires a platelet count of at least 75,000/µL;
- Request for either drug if beneficiary was a non-responder to previous therapy of either Doptelet or Mulpleta;
- Days supply requested is greater than 5 days for DOPTELET®;
- Days supply requested is greater than 7 days for MULPLETA®;
- Request is for a beneficiary with chronic liver disease in an attempt to normalize platelet counts;
- Planned procedure is paracentesis;
- Planned procedure is shunt procedure;
- Emergency procedure or trauma;
- Beneficiary has pseudothrombocytopenia;

- Beneficiary has Heparin-Induced-Thrombocytopenia (HIT);
- Doptelet will be denied for use in neurosurgical interventions, thoracotomy, laparotomy, or organ resection;
- Mulpleta will be denied for use in patients undergoing thoracotomy, laparotomy, organ resection, open-heart surgery, or craniotomy, history of splenectomy, partial splenic embolization, or thrombosis; Child-Pugh C;
- Beneficiary has a history of arterial or venous thrombosis, including partial or complete thrombosis;
- Concurrent use with thrombopoietic agent or Spleen Tyrosine Kinase Inhibitor (e.g., Promacta (eltrombopag), Nplate (romiplostim), or Tavalisse (fotamatinib));
- Beneficiary has history of hepatic encephalopathy uncontrolled by drugs;
- Beneficiary has current evidence of or a history of thrombosis (partial or complete) in the main portal vein, portal vein branches, or any part of the splenic mesenteric system, or a prothrombotic condition other than liver disease;
- Beneficiary has known portal vein blood flow velocity rate <10 cm/second or previous portal vein thrombosis at time of PA request;
- Beneficiary has absence of hepatopetal blood flow in the main trunk of the portal vein as demonstrated by Doppler ultrasonography within 28 days prior to PA request;
- Beneficiary has Hepatocellular carcinoma (HCC) with Barcelona Clinic Liver Cancer (BCLC) staging classification C or D;
- Beneficiary has current malignancy including solid tumors and hematologic malignancies (except HCC as stated above);
- Beneficiary has active infection requiring systemic antibiotic therapy within 7 days of PA request. However, prophylactic use of antibiotics is permitted;
- Beneficiary has history of alcohol abuse, alcohol dependence syndrome, drug abuse, or drug dependence within 6 months of PA request (unless participating in a controlled rehabilitation program) or acute alcoholic hepatitis (chronic alcoholic hepatitis is allowed) within 6 months of PA request;
- Beneficiary is human immunodeficiency virus positive;
- Beneficiary has any clinically significant acute or active bleeding (eg, gastrointestinal, central nervous system);
- Beneficiary has known history of any primary hematologic disorder (eg, immune thrombocytopenic purpura (ITP), myelodysplastic syndrome);
- Beneficiary has known medical history or evidence of any of the following diseases:
  - congenital thrombotic disease (eg, antithrombin deficiency, protein C deficiency, protein S deficiency, or coagulation factor [Factor V Leiden] mutation)
  - acquired thrombotic disease (eg, antiphospholipid antibody syndrome, paroxysmal nocturnal hemoglobinuria, hyperhomocysteinemia, or increased factor VIII)
  - Budd Chiari syndrome.
- Beneficiary has history or evidence of disease associated with a risk of bleeding (e.g., coagulation factor deficiency or von Willebrand factor deficiency);
- Beneficiary has a history of significant cardiovascular disease (eg, congestive heart failure New York Heart Association Grade III/IV, arrhythmia known to increase the risk of thromboembolic events [eg, atrial fibrillation], coronary artery stent placement, angioplasty, and coronary artery bypass grafting);
- Female beneficiary of childbearing potential who have had unprotected sexual intercourse within 30 days before PA request and who does not agree to use a highly effective method of contraception (eg, an intrauterine device, a double-barrier method [such as condom plus diaphragm with spermicide], a progesterone-only contraceptive implant/injection, or have a vasectomized partner with confirmed azoospermia) throughout the entire therapy and for 30 days after drug discontinuation. All females will be considered to be of childbearing potential unless they are postmenopausal (at least 12 months consecutive amenorrhea in the appropriate age group and without other known or suspected cause) or have been sterilized surgically (ie, bilateral tubal ligation, hysterectomy, or bilateral oophorectomy) at least 1 month before dosing of medication begins;
- Beneficiary is a post liver transplant patient;
- Male beneficiary has hemoglobin levels ≤ 8.0 or ≥ 18.0 g/dL with hematocrit ≥ 54% at time of PA request; Female beneficiary has hemoglobin level ≤ 8.0 or > 15 g/dL at PA request with hematocrit ≥ 45% for women;
- Beneficiary received blood products containing platelets within 7 days of the PA request;
- Beneficiary received heparin, warfarin, nonsteroidal anti-inflammatory drugs (NSAID), aspirin, verapamil, and antiplatelet therapy with ticlopidine or glycoprotein IIb/IIIa antagonists (eg, tirofiban) within 7 days of PA request;
- Beneficiary received interferon (IFN) use within 14 days of PA request;
- Beneficiary received estrogen-containing hormonal contraceptive or hormone replacement therapy use within 30 days of PA request;
- Beneficiary is pregnant or lactating;
- Beneficiary does not meet approval criteria;

QUANTITY EDIT:
- For DOPTELET®, the number of tablets required will be calculated based on the recommended dose chart in the package insert for the beneficiary's current platelet count and the approved prior authorization will be NDC specific for the 10 tablet package or the 15 tablet package and entered at the time of the PA approval; the duration of therapy will not exceed 5 days;
- For MULPLETA®, the approved quantity is 7 tablets and the duration of therapy will not exceed 7 days;

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

4. **SIKLOS® (hydroxyurea) 100 mg Film Coated Tablet**

Medicaid Estimated Reimbursement Rate: **Siklos 100 mg tablet = $5.00 each**; a **500 mg dose would = $25.00;**

Medicaid Reimbursement Rate Pricing Comparison to
- **Hyrea** (hydroxurea) **500 mg capsule**= **$0.298 each 500 mg capsule**;
- **Droxia** (hydroxurea) **200 mg, 300 mg, & 400 mg capsules** = **$0.756 each capsule**

SIKLOS® will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING:
- Beneficiary has diagnosis of Sickle cell anemia (SCA);
- Prescriber must submit explanation and supporting documentation of medical necessity of beneficiary receiving SIKLOS® (hydroxyurea) over HYDREA (hydroxyurea) 500 mg capsule or DROXIA (hydroxyurea) 200 mg, 300 mg, or 400 mg capsule that do not require prior authorization;
- Prescriber must submit blood counts at baseline;
- Prescriber must submit beneficiary's weight for weight-based dose calculation;
- Approval of PA can be for up to 3 months at a time;

CONTINUATION CRITERIA REQUIRE ALL OF THE FOLLOWING:
- Beneficiary must be adherent to prescribed dose;
- Prescriber must monitor blood counts every 2 weeks and submit all results of beneficiary's blood counts performed since previous PA approval;
- Prescriber must submit beneficiary's weight at every PA request and dose meets weight based dose;
- Prescriber must submit blood counts at every PA request and blood counts are in acceptable range for dose;

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:
- Prescriber did not substantiate use of SKILOS over other hydroxyurea brands that do not require prior authorization;
- Beneficiary is not adherent to prescribed dose;
- Blood counts are considered toxic levels or out of acceptable range;

QUANTITY EDIT:
- Dose is weight based and therefore prescriber must submit beneficiary's weight with every PA request, and quantity limit entered at time of PA approval

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

5. MEKTOVI® (binimetinib) 15 mg Tablet and BRAFTOVI™ (encorafenib) 50 mg and 75 mg Capsule:

MEDICAID Estimated Reimbursement Rate:
MEKTOVI Tablet: **$60.98 Each Tablet**; Bottle size is 180 tablets; Recommended dose is 45 mg every 12 hours; #180 tablets for **30-day supply = $10,976.40**

BRAFTOVI Capsule: 50 mg = $92.47 Each Capsule; bottle size is #60 capsules; 75 mg = $60.98 Each Capsule, bottle size is 90 capsules; Recommended dose is 450 mg orally once daily; 75 mg x 6 capsules = 450 mg; **450 mg daily (#180 of 75 mg) = $10,976.40; 300 mg daily (75 mg x 4) =$7317.60; 200 mg daily (50 mg x 4) = $11,096.40;**

MEKTOVI® (binimetinib) Tablet and BRAFTOVI™ (encorafenib) capsule will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING:
- Beneficiary is ≥18 years;
- Beneficiary has a diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test and results are submitted with PA request;
- Beneficiary does not have wild-type BRAF melanoma;
- Beneficiary ECOG score is 0 - 2;
- Both MEKTOVI® tablet and BRAFTOVI™ capsule are prescribed as concurrent therapy;
- Beneficiary is not pregnant;
- Female beneficiary must agree to effective contraception during treatment;
- PA approval for each drug will be month-to-month due to high adverse effect profile on both drugs and likelihood of dose reductions;
- Monitor Liver Function Tests (LFTs) at baseline prior to initiation of treatment;
- Beneficiary is not classified as moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment;
- Beneficiary does not have severe renal impairment (CLcr<30 mL/min);
- Provider must submit results of creatine phosphokinase (CPK) test at baseline;
- Provider must assess ejection fraction by ECG or MUGA scan prior to treatment initiation at baseline and submit results, reassess one month after initiation, and every 2-3 months during treatment. Monitor closely in patients with cardiovascular risk factors.
- Submit chart notes of monitoring visual symptoms at baseline.
- PA approval for both drugs will be on a month-to-month basis due to adverse effects that require dose adjustments; the required monthly quantity to make the daily dose requested at each PA will be entered at the time the approved PA is entered into the system.

CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:
- Provider to submit current chart notes and all test results since previous PA approval with every PA request;
- Provider must re-assess ejection fraction by ECG or MUGA scan one month after initiation, and every 2-3 months during treatment and submit test results with every PA request. Monitor closely in patients with cardiovascular risk factors.
- Beneficiary must be able to tolerate dose of BRAFTOVI 200 mg once daily or permanently discontinue BRAFTOVI;
- Beneficiary is not pregnant or lactating;
- Monitor LFTs monthly throughout treatment;
- Monitor visual symptoms each visit. Perform ophthalmologic exam at regular intervals and for new or worsening visual disturbances
- If MEKTOVI® (binimetinib) is temporarily withheld due to adverse effects, the PA for the BRAFTOVI (encorafenib) dose should be adjusted accordingly to a maximum dose of 300 mg once daily, if it has not already been reduced, until binimetinib is resumed;
- Beneficiary is adherent to prescribed dose of both drugs;
- Provider must state dose of each drug at every PA request;
- The PA review will follow dose modifications, dose reductions, and permanent discontinuation of either drug using the adverse event charts listed in the respective package inserts. If one drug is permanently discontinued, both drugs will be discontinued;
- Provider must monitor creatine phosphokinase (CPK) periodically [Board members, do you have a recommendation for monitoring CPK “periodically”? No frequency given in pkg insert]
- PA approval for both drugs will be on a month-to-month basis due to adverse effects that require dose adjustments; the required monthly quantity to make the daily dose requested at each PA will be entered at the time the approved PA is entered into the system.

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:

- Disease progression on MEKTOVI® (binimetinib) Tablet and BRAFTOVI™ (encorafenib) capsule;
- Disease progress with prior therapy on a BRAF inhibitor and/or a MEK- inhibitor;
- Beneficiary has wild-type BRAF melanoma;
- Beneficiary has ECOG score of 3 or 4
- Uncontrolled arterial hypertension despite medical treatment;
- HIV positive or active Hepatitis B, and/or active Hepatitis C;
- Impairment of gastrointestinal function;
- Patients with neuromuscular disorders that are associated with elevated CK;
- History of leptomeningeal metastases;
- Beneficiary is pregnant or lactating;
- If Beneficiary received YERVOY® (ipilimumab) as adjuvant therapy or other immunotherapy treatment, it must have ended at least 6 weeks prior to PA request;
- If beneficiary is unable to tolerate one drug and it is permanently discontinued, the PA for the 2nd drug will be denied;
- Beneficiary has specific adverse reactions listed in package insert that requires discontinuation of BRAFTOVI;
- Beneficiary is classified as moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment;
- Beneficiary has severe renal impairment (CLcr<30 mL/min);
- Beneficiary has prolonged QTc (>480 msec);
- Beneficiary has uncontrolled hypertension;
- Beneficiary has Gilbert's syndrome (constitutional hepatic dysfunction and familial nonhemolytic jaundice);
- Beneficiary has abnormal left ventricular ejection fraction;
- Beneficiary has history or current evidence of retinal vein occlusion;

QUANTITY EDITS:

- Dose modifications for adverse reactions for either drug will follow the recommendations outlined in the respective drug package inserts;
- MEKTOVI® (binimetinib) is a 15 mg tablet and the bottle size is 180 tablets. The recommended dose is 45 mg twice daily 12 hours apart. Dose is reduced for adverse reactions. Prescriber must state dose with each PA request and the required monthly quantity limit will be entered at the time of the PA approval. Discontinue MEKTOVI if beneficiary is unable to tolerate 30 mg twice daily. If BRAFTOVI™ (encorafenib) is discontinued, the MEKTOVI will be discontinued.
- MEKTOVI and patients with moderate to severe hepatic impairment: For patients with moderate (total bilirubin greater than 1.5 and less than or equal to 3 × ULN and any AST) or severe (total bilirubin levels greater than 3 × ULN and any AST) hepatic impairment, the recommended dosage is 30 mg orally taken twice daily;
- BRAFTOVI™ capsule is available as a 50 mg capsule (bottle size 60 capsules) and a 75 mg capsule (bottle size 90 capsules). The recommended dose is 450 mg once daily. The 1st reduction is to 300 mg daily; 2nd reduction is to 200 mg daily; discontinue if 200 mg once daily is not tolerated. Prescriber must state dose with each PA request and strength and quantity will be entered at the time of PA approval. (The most economical strength to make the 450 mg dose and the 300 mg dose is using the 75 mg capsule; the 50 mg capsule will be entered for the PA for the 200 mg dose.)
- If MEKTOVI® (binimetinib) is temporarily withheld, the BRAFTOVI dose should be reduced to a maximum dose of 300 mg once daily until binimetinib is resumed;
- If either drug is permanently discontinued, the PA for the other drug will be denied;

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

6. LOKELMA™ (sodium zirconium cyclosilicate) 5 gm and 10 gm Powder Pack

MEDICAID REIMBURSEMENT RATE:
LOKELMA 5 gm and 10 gm powder pack are same price as the billing unit is per packet not per gm; each packet is = $21.833 each packet; carton size 30 packets= $654.99;

Medicaid Reimbursement Rate Pricing Compared to

- VELTASSA® (patiromer calcium sorbitex), 8.4 gm packet, 16.8 gm packet, 25.2 gm packet; all packet sizes = $27.36 each packet. VELTASSA also requires manual review PA.

LOKELMA™ (sodium zirconium cyclosilicate) will require manual review PA on a case-by-case basis using all of the following:

APPROVAL CRITERIA, REQUIRE ALL OF THE FOLLOWING:
- Beneficiary is ≥18 years of age;
- Beneficiary has diagnosis of hyperkalemia with clinically significant potassium values at the time the prior authorization for LOKELMA is requested;
- Provider must submit letter explaining medical necessity of beneficiary receiving LOKELMA;
- LOKELMA is not for emergent life-threatening use and provider must submit chart notes and provide treatment plan for determining the underlying cause of hyperkalemia, and include other treatments used for treating hyperkalemia to determine length of treatment with LOKELMA;
- Female beneficiary of childbearing potential is not pregnant and must be practicing highly effective method of birth control;
- PA approval length of time, quantity, dose will be determined during the PA review;

CONTINUATION CRITERIA, REQUIRE ALL OF THE FOLLOWING:
- Provider must submit current serum potassium levels at the time of each PA request;
- Beneficiary must be adherent to prescribed dose as well as other treatment measures;
- PA approval length of time, quantity, dose will be determined during the PA review;

DENIAL CRITERIA, ANY ONE OF THE FOLLOWING:
- Prescribing for an emergent life-threatening condition;
- Pseudohyperkalemia;
- Female beneficiary is pregnant, lactating, or planning to become pregnant;

QUANTITY EDIT:
- The system quantity limit for the 5 gm packet and the 10 gm packet will be limited to 1 packet per day and a quantity override can be entered as medically necessary at the time of PA approval (e.g., system edit would prevent use of two 5 gm packets to make the 10 gm dose; or an approval override could be entered for a maintenance dose for 15 gm (e.g., 3 x 5 gm packets per day);
- Recommended dose is 10 gm three times a day for up to 48 hours, then 10 gm once daily for continued treatment to reduce serum potassium;
- Each PA length of therapy will be determined at the time of the PA approval;

Magellan Medicaid Administration (MMA) Help Desk 1-800-424-7895; 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. **Effective January 1, 2019,** Arkansas Medicaid will implement **PASSE** (**Provider-Led Arkansas Shared Savings Entity**), a new Medicaid program to address the needs of individuals who have intensive behavioral health and intellectual and developmental disabilities service needs. The PASSE organizations will administer all medical needs *and all pharmacy prescription drug needs* for all PASSE members. **Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member.** For more information about PASSE, please refer to the website: https://humanservices.arkansas.gov/about-dhs/dms/passe. For questions about each PASSE organization, please refer to this website for contact information: https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us

2. **MAT (Medication Assisted Treatment) with Buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: "**Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care.** As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. **Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own**

practices or through referrals to reputable behavioral health practitioners in their communities. In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such patients for appropriate counseling and other nonpharmacological therapies." http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

Per ASAM National Practice Guideline, in Part 5: Buprenorphine, Summary of Recommendations, # (5) "**Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder**." https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

3. **Chronic Pain Patients Who Do *Not* Need Treatment for Addiction**: Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*: *Treatment Improvement Protocol (TIP) Series 40*: "Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. *They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids in the course of their medical treatment*." Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment. http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

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

5. **Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the **FDA approved dose** for treating opioid addiction is **prescribing the total daily dose as one *single daily dose***. "After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day **as a single daily dose**. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage."

Per ASAM National Practice Guidelines, the bold and italics were added for emphasis, but the following statement is pulled from the "At Induction" section of "Part 5: Buprenorphine", under Dosing, "Once it has been established that the initial dose is well tolerated, the buprenorphine dose can be increased fairly rapidly to **a dose *that provides stable effects for 24 hours* and is clinically effective**". https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

6. **CIRCUMVENTING MEDICAID LIMITS FOR OPIOIDS AND BENZODIAZEPINES:**
Beneficiaries who pay *cash* for opioids to avoid Medicaid dose and quantity limits *or* pay cash *in addition to* the opioids paid for by Medicaid, result in a much higher daily MME than what is calculated in the Medicaid system edits, are above the CDC recommendations, and could *put the patient at risk for overdose*. **According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.**

7. **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on NOVEMBER 14, 2018 to ≤ 90 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that cause the total MME/day to exceed the existing limit of ≤ 90 MME/day will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).

8. **REGARDING MANUAL REVIEW PA REQUESTS:** Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, require a prior authorization request for a drug as an *exception* to established point of sale prior approval criteria algorithm, or require a request for non-preferred drugs on the

PDL, are all reviewed on a *case-by-case basis* through a manual review process. All manual review requests for prior authorization *require, at a minimum, the prescriber to provide a letter explaining the medical necessity* for the requested drug *along with all written documentation to substantiate* the medical necessity, e.g., chart notes, pharmacy printouts for cash, printout of private insurance paid drugs, lab results, etc. ***Please note that starting the requested drug, <u>including long-acting injectable antipsychotic agents</u>, through either inpatient use, the use of office "samples", or by any other means, prior to a Prior Authorization request being reviewed and approved by the Medicaid Pharmacy Program does <u>not</u> necessitate Medicaid Pharmacy Program approval of the requested drug.***

9. **<u>"CLAIM EDITS"</u>** referred to in this memo include quantity edits, cumulative quantity edits, monthly quantity edits, age edits, gender edits, accumulation quantity edits, and daily dose edits.

10. **<u>CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017</u>:** Medicaid currently requires a manual review PA of any antipsychotic agent prescribed for children less than 10 years of age (i.e., age 9 years and under) **for all new starts on an antipsychotic agent, including a change in the chemical entity for children currently on an antipsychotic agent.** All documentation, chart notes, signed informed consent, and required lab work must be submitted and the manual review will be performed by the Medicaid Pharmacy Program board certified child & adolescent psychiatrist.

11. **<u>SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE, *EFFECTIVE MARCH 8, 2017*</u>:** The current point of sale (POS) prior approval (PA) criteria for the second generation antidepressants, including Trazodone, were developed based on utilization for adults, and the minimum and maximum therapeutic doses were based on adult doses. ***Second Generation Antidepressants, Trazodone, or Tricyclic Antidepressants for Children ≤ 3 years of age will require manual review prior approval (PA) by the Medicaid Pharmacy Program child psychiatrist.*** The prescriber must submit the request in writing, explain the medical necessity for the child to receive the drug requested, and include chart notes and any other documentation that will substantiate the request and the dose. Each request will be reviewed on a case-by-case basis.

12. **<u>REGARDING EMERGENCY OVERRIDE</u>**: In an emergency, for those drugs for which a five-day supply can be dispensed, an Arkansas Medicaid enrolled pharmacy provider may dispense *up to* a five-day supply of a drug that requires prior authorization e.g., a drug that requires a clinical PA or requires a PA for a non-preferred drug. **This provision applies *only* <u>in an emergency situation</u> when the MMA Prescription Drug Help Desk and the State Medicaid Pharmacy Program offices are closed, *and* the pharmacist is not able to contact the prescribing provider to change the prescription.** The Emergency Supply Policy does not apply to drugs that are not covered by the State. Frequency of the emergency override is limited to once per year per drug class for non-LTC beneficiaries and once per 60 days per drug class for LTC beneficiaries.

    To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. 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, <u>https://arkansas.magellanrx.com/provider/documents/</u>.

13. **<u>HARD EDIT ON EARLY REFILL FOR CONTROLLED AND NON-CONTROLLED DRUGS</u>:** 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 than expected/calculated. 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 <u>*not*</u> be approved.

14. **<u>REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:</u>** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-controlled drug or a 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.

Effective August 8, 2018, the RTS logic with Early Refill Accumulation Limited edit was revised for the **non-controlled drugs** which now **allow** an **accumulation of 12 days' supply during the previous 180 day period**.

Effective February 14, 2018, the RTS logic with Early Refill Accumulation Limit edit is **revised for the controlled drugs**. The revised edit for *controlled drugs* will only allow an extra 7-days' supply accumulation through early fills in previous 180 day period rather than an accumulation of an extra 15-days' supply. The RTS logic with Early Refill Accumulation Limit edit for non-controlled drugs will remain as is. Early refills for both controlled drugs and non-controlled drugs will continue to be monitored and may be adjusted in the future to reduce misuse.

15. **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.

16. **ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN < 18 YEARS OF AGE have an ongoing requirement for labs** for metabolic monitoring every 6 months. When any provider sends a patient who is less than 18 years of age for the required metabolic labs 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.

17. **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.

18. **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 fax a letter explaining the medical necessity and include any supporting documentation, the beneficiary ID number, beneficiary name, and Medicaid Provider ID with your request.

19. **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.

20. **THE AR MEDICAID PHARMACY PROGRAM REIMBURSES ENROLLED PHARMACY PROVIDERS 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. If medications are needed to treat remaining family members, each prescription must be billed accordingly to each family member's Medicaid ID number. 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.

21. **ANY REIMBURSEMENT RATES STATED IN THIS MEMORANDUM (OR ANY PREVIOUS MEMORANDUMS) ARE FOR REFERENCE PURPOSES ONLY AND SUBJECT TO CHANGE:** AR Medicaid Pharmacy Program reimbursement methodology changed based on the requirements in the Affordable Care Act (ACA) and requirements of §447.502 of the final regulation, and based on the CMS imposed final implementation date of April 1, 2017. The pricing methodology is lesser of methodology that applies to all brand or generic drugs for

usual and customary charge, or NADAC, or ACA FUL, or SAAC. If the NADAC is not available, the allowed ingredient cost shall be WAC + 0%, SAAC, or ACA FUL. The Professional Dispensing Fee has been increased to $9 for Brand Drugs and $10.50 for Preferred Brand Drugs and all Generics. Reimbursement rates stated in this memo are in no way a contractual obligation by Arkansas Medicaid. NADAC pricing is subject to change and any pricing stated is only current as of the date this memo was drafted. 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/ A coversheet for the NADAC Help Desk Request for Medicaid Reimbursement Review form can be found on the Arkansas Medicaid website: https://arkansas.magellanrx.com/client/docs/rxinfo/ARRx_NADAC_Request_Medicaid_Reimbursement_Review_Form.pdf

22. **AR MEDICAID PHARMACY PROGRAM IS ON FACEBOOK:** The Arkansas Medicaid Pharmacy Program is now on Facebook. Please join our group page titled "AR Medicaid Pharmacy Provider Help Group". This is a closed group for providers of Arkansas Medicaid services or those who work for a provider of Arkansas Medicaid services and join requests will be verified. The group is administered by a State of Arkansas employee and a Magellan Medicaid Administration employee on his/her own time. The purpose of the group page is to help the provider community with any issues that involve billing or prescribing covered outpatient drugs through the Arkansas Medicaid Pharmacy Program. We will not disclose any PHI and will delete any posts that contain PHI. Want to know what criteria is needed for a drug? Don't know who to call to handle your issue? Just post your questions and we will answer.

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.