ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

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MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: **MARCH 1, 2018**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board JANUARY 17, 2018 meeting** for BAXDELA, BENZNIDAZOLE, CALQUENCE, ENDARI, HEMLIBRA, LUPRON DEPOT-PED, SYNAREL, NOXAFIL SUSP., PREVYMIS, TIZANIDINE, BACLOFEN, VABOMERE, VERZENIO, XARELTO**; PDL changes approved by the PDL Drug Review Committee meeting FEBRUARY 14, 2018** for Anticoagulants, Antihistamines, Antihyperuricemics, Chronic GI Motility Agents, HCV, ICS

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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/ *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.

ANNOUNCEMENT REGARDING PRICING CHANGES: Tazorac 0.1% cream, Tamiflu, Tikosyn
EFFECTIVE IMMEDIATELY: **TAZORAC® (tazarotene) 0.1% CREAM, TAMIFLU® (oseltamivir) capsule and suspension, and TIKOSYN® (dofetilide) capsule will no longer be State Supported Brand required status**. *The AR Medicaid Pharmacy Program will continue to pay for the brand version of* TAZORAC 0.1% CREAM, TAMIFLU, and TIKOSYN® *at the Brand NADAC rate through 04/30/2018*. Generic versions are payable currently and will reimburse off the lesser of Generic NADAC/ACA FUL rates on file. A pharmacy will be able to submit a claim for the brand OR generic version and will be paid off the corresponding NADAC (or ACA FUL if generic) rate of the brand or generic version being dispensed. ***BEGINNING 05/01/2018, BRAND* TAZORAC® 0.1% CREAM, TAMIFLU® capsules and suspension, and TIKOSYN® *dispensed WILL PAY AT THE DEFAULT PAYMENTMETHODOLOGY, WHICH IS THE LESSER OF NADAC GENERIC OR ACA FUL.***

ANNOUNCEMENT: Future Medicaid Pharmacy Program Provider Memos:
To reduce paper waste, future *mailed* Provider Memos regarding new Prior Authorizations for drugs and other announcements will only contain the Table of Contents page listing the drugs and announcements contained in the memo as an alert message of upcoming changes. In addition, an electronic RA message will be sent to all providers as an additional alert message when the complete Provider Memo is posted on the Medicaid Pharmacy Program website at https://arkansas.magellanrx.com/provider/documents/. The memorandums are posted under the "Pharmacy" tab at the top of the page. The new online version will contain active hyperlinks in the Table of Contents: hover the mouse over the Table of Contents, press Ctrl on the computer keyboard until the mouse "hand" appears, then place the "hand" on the item and click the mouse. The hyperlink will move directly to that item.

CORRECTION to next MME Change Date:
The date in the October 2017 Provider memo incorrectly stated the next MME decrease date as "EFFECTIVE MAY 8, 201**7**" to decrease the MME to 150 MME/day. The correct implementation date for the next MME decrease should have stated **May 8, 201<u>8</u>** is the **decrease to a maximum of 150 MME/day**.

BENEFICIARIES WHO PAY CASH FOR OPIOIDS, 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.

CUSTOMIZED RETURN MESSAGES:
For those Pharmacy Providers that have software programs that allow messages to be seen after a claim is submitted, the Medicaid Pharmacy Program is adding customized return messages to some drugs so you may provide additional information to the prescriber if a drug claim denies at point of sale and you are informing the prescriber the drug will require a prior authorization for the beneficiary. For example, if an opioid claim denies at point of sale because the beneficiary has a *poisoning diagnosis* in recent history, the return message will read "PA denied because of poisoning diagnosis in history"; if montelukast 10 mg tablet denies because the child is less than 15 years of age, the return message will read "Dose Exceeds FDA approved dose for age". Input from some prescribers is that this would be helpful additional information for them to receive from a pharmacy on a faxed notation about PA required.

DELAYED IMPLEMENTATION FOR 3 SPECIFIC OPIOID-RELATED CRITERIA:
Please refer to the criteria amendment memo mailed January 31, 2018 for additional information. The implementation date was *changed from February 14, 2018* ***to March 14, 2018*** for the following PA criteria related to the opioid drugs:

- The PA criteria that identifies a "new start" to a opioid therapy is defined as there are no claims for any opioid drugs for pain in the beneficiary's Medicaid drug profile in the previous 60 days.

The following "new start to opioid therapy" criteria will exclude beneficiaries who meet the cancer diagnosis criteria rule.

- The maximum MME/DAY is decreased to a **maximum of 50 MME/day**; AND
- The initial prescription for the "New Start to opioid therapy" beneficiary for the short-acting opioid is limited to a **7-day supply** with the corresponding quantity limit of **up to 6 tablets or capsules per day**;

- If the Medicaid beneficiary has been paying *CASH* for opioid prescriptions *OR* has been filling *opioid prescriptions through a third-party insurance prescription drug plan (TPL)* in the previous 60 days rather than filling opioid prescriptions through the Medicaid Pharmacy Program, then there will be no Medicaid claims history to indicate that the beneficiary has been receiving opioid claims and is an opioid tolerant beneficiary. The prescribing provider may request an override (PA) to this "new start to opioid therapy" criterion and must provide prescription opioid drug claim documentation to the Medicaid Pharmacy Program to substantiate that his/her patient is opioid tolerant and may receive up to the current MME limit as part of the exception to the established criteria.

- The PA criteria that identifies a new start to **long-acting (LA) Opioid therapy** is defined as there are **no LA opioid claims in the beneficiary's Medicaid drug profile in the previous 60 days.** If there are no LA Opioid claims in previous 60-days, the incoming LA Opioid claim will reject at the point of sale. *This LA opioid criteria rule will exclude beneficiaries who meet the cancer diagnosis criteria, current LTC-eligible beneficiaries, and beneficiaries who met the NPO diagnosis criteria*.
  - If the beneficiary has been paying *CASH* or using a *third-party insurance prescription drug plan (TPL)* for previous claims of a LA opioid rather than filling LA opioid prescriptions through the Medicaid Pharmacy Program in the previous 60 days, then there will be no Medicaid claims history to indicate the beneficiary has been receiving a LA opioid. The prescriber may request an override (PA) for a LA opioid approval through a manual review PA request for an opioid tolerant beneficiary. To request the prior authorization, the prescriber must submit documentation that the beneficiary is opioid tolerant and is being *switched* to LA opioid therapy or documentation that the beneficiary has already been receiving a LA opioid. The LA opioid rule will include a beneficiary new to LA opioid therapy and is being *switched* from chronic use of a short-acting opioid to a LA opioid, OR a beneficiary who has been receiving a LA opioid but there is not a LA opioid prescription drug claim in Medicaid history in previous 60 days.

- The "**Edits To Assist In Safe Prescribing Of Opioids And Benzodiazepines After Non-Fatal Poisoning Or Overdose**" implementation date is also changed to **March 14, 2018.** This criteria rule will **deny all opioid claims and benzodiazepine claims if the beneficiary has a "poisoning" or overdose diagnosis in his/her medical history in previous 90 days. This rule is designed to ensure that prescribers are informed about their patients who suffered a recent non-fatal poisoning or overdose incident at a medical facility.** The clinical team at the Medicaid Pharmacy Program will work with the prescriber to safely taper the opioid and benzodiazepine doses to prevent future poisonings. Please see the Provider Memo dated November 22, 2017 for the complete criteria.

PDL CHANGES for Entresto®, Anticoagulants and LMWH, Antihistamines, Antihyperuricemics, Chronic GI Motility Agents, HCV Agents, Inhaled Corticosteroids (ICS)

EFFECTIVE IMMEDIATELY, **ENTRESTO®** (sacubitril and valsartan) is **removed from the PDL and *is no longer preferred status***. The drug will continue to have manual review on a case-by-case basis prior authorization approval criteria.

EFFECTIVE APRIL 1, 2018, Preferred Drug List (PDL) changes and additions approved at the FEBRUARY 14, 2018 PDL Drug Review Committee (DRC) meeting:

***ONLY CHANGES* are shown below to the PREFERRED status or the NON-PREFERRED status of the PDL.** Prior authorization criteria and other edits remain in place for referred-status drugs. Please refer to the Medicaid Pharmacy Program website for the complete list of preferred or non-preferred status drugs in each drug category https://arkansas.magellanrx.com/provider/docs/rxinfo/PDL.pdf/

ANTICOAGULANTS (Oral and LMWH)—*ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
enoxaparin-generic only, vial or syringe
warfarin—generic only
PRADAXA® capsule (dabigatran)
ELIQUIS® tablet (apixiban)
XARELTO® tablet (rivaroxaban)

NONPREFERRED AGENTS
dalteparin injection (Fragmin®)
fondaparinux injection (Arixtra®)
edoxaban tablet (Savaysa®)
Coumadin® (brand only)
Lovenox® (brand only)

ANTIHISTAMINE NASAL SPRAY and ORAL MINIMALLY SEDATING ANTIHISTAMINES
PREFERRED AGENTS
Added ASELASTINE NASAL SPRAY to PREFERRED status;
Removed Olopatadine from preferred status;
Remaining Preferred status oral drugs—no change;

NON-PREFERRED AGENTS
Moved Olopatadine (e.g., Patanase®) Nasal Spray *to NON-PREFERRED* status;
Remaining Non-Preferred drugs—no change;

ANTIHYPERURICEMICS—*ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
MITIGARE® capsule-BRAND ONLY
allopurinol
probenecid
probenecid/colchicine

NONPREFERRED AGENTS
colchicine tablet (Colcrys®)
colchicine capsule-generic
febuxostat (Uloric®)
lesinurad/allopurinol (Duzallo®)
lesinurad (Zurampic®)

CHRONIC GI MOTILITY AGENTS—*ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
Lubiprostone capsule (e.g., Amitiza®)

NONPREFERRED AGENTS
alosetron tablet (Lotronex®)
eluxadoline (Viberzi™)
plecanatide tablet (Trulance™)
methylnaltrexone tablet and injection (Relistor®)
naldemedine tablet (Symproic®)
linaclotide capsule (Linzess™)

naloxegol tablet (Movantik®)

CHRONIC HEPATITIS C ANTIVIRAL (HCV) AGENTS
PREFERRED AGENTS with Criteria*
Added MAVYRET™ tablet (glecaprevir and pibrentasvir)
Remaining Preferred HCV agents --no change to existing preferred drugs Epclusa®, Zepatier®, & ribavirin except PA criteria slightly revised;

NON-PREFERRED AGENTS
Added sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)
Remaining non-preferred agents—no change
PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800-424-5739.**

**The HCV PA form has been updated to reflect the PDL changes noted above. The revised HCV PA form will be posted on the Medicaid Pharmacy Program website and available for use beginning 4/1/2018. The URL for the revised form is https://arkansas.magellanrx.com/provider/docs/rxinfo/HepCTreatmntForm.pdf.*

INHALED CORTICOSTEROIDS (ICS)—CONTROLLER MEDS FOR ASTHMA:
PREFERRED AGENTS:
Removed QVAR HFA Inhaler from Preferred status;
Remaining Preferred status drugs—no change;

NON-PREFERRED AGENTS:
QVAR® HFA Inhaler *is on long-term backorder or is discontinued by the manufacturer and is moved to Non-Preferred status;*
QVAR® RediHaler™ (beclomethasone dipropionate HFA) inhalation aerosol is *Non-Preferred status*;
Remaining Non-preferred status drugs—no change;

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

EFFECTIVE IMMEDIATELY:
1) BAXDELA™ (delafloxacin meglumine) 450 mg tablet and 300 mg vial**:**

Reimbursement rate 450 mg tablet > $67 each tablet; twice daily dosing for 5 to 14 days; **Oral 14 day therapy or 28 tablets > $1,880**; Supplied as bottle of 20 tablets;
Reimbursement rate: 300 mg vial > $132 each vial; twice daily dosing for 5 to 14 days; 14 day IVPB therapy > **$3,700**; Supplied as single dose vials, packaged in cartons of 10;

BAXDELA™ (delafloxacin) will require a **manual review prior authorization on a case-by-case basis**.
Approval criteria will require all of the following:

- The prescriber must submit a letter explaining the medical necessity for why BAXDELA™ is required rather than one of the many other available antibiotics that do not require prior authorization and that successfully treat acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria.
- Approval only for age ≥ 18 years;

Quantity limit

- 2 per day; maximum of 28 for a 14 days' supply.

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.

EFFECTIVE IMMEDIATELY:
2) BENZNIDAZOLE 12.5 mg and 100 mg tablets:
Reimbursement rate: 12.5 mg tablet > $2 each tablet; 100 mg approximately $3.00 each tablet;

Example: a 40kg child at 8 mg/kg/day = 320mg/day; the closest dose would be 325 mg; 2 tablets of 12.5 mg + 3 tablets of 100 mg = $5 + $9 = $14/day x 30-days approximately $420; 60-days of treatment approximately $840;

BENZNIDAZOLE tablet will require a **manual review prior authorization on a case-by-case basis**. Approval Criteria will require all of the following:

- Prescriber must first submit request to the CDC to receive **BENZNIDAZOLE** from the CDC. If requesting the drug through Medicaid Pharmacy Program, the request for prior authorization must include copy of the request submitted to CDC and the CDC denial response along with a letter explaining the medical necessity of receiving the drug.
- Approval will be limited to the **FDA approved indication for pediatric patients 2 to 12 years of age** for the **treatment of Chagas disease** (American trypanosomiasis) unless the official compendia provides support, as opposed to just listing, for a requested off-label use.
- Prescriber must submit current weight. Weight-based dose will be calculated and **monthly quantity entered at the time the PA is approved**;
- Length of PA shall not exceed 60 days;

Continuation criteria:

- PA Approval will not exceed 60-days;

Denial Criteria, any one of the following will deny:

- Prescriber did not contact CDC;
- Other treatment subgroups that do not fall within the FDA approved indication;
- Dose or duration of therapy that exceeds FDA approved dose and duration;

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.

EFFECTIVE IMMEDIATELY:

3) **CALQUENCE®** (acalabrutinib) 100 mg capsule:
Reimbursement rate > $234 each capsule; Supplied as 60-count bottle for every 12 hour dosing; **30-day supply > $14,055**

CALQUENCE® capsule will **require manual review prior authorization on a case-by-case basis.** Approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving CALQUENCE along with all required chart notes and documentation to substantiate the request;
- Beneficiary must be an adult age ≥18 years;
- Beneficiary has diagnosis of pathologically confirmed **mantle cell lymphoma (MCL),** with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1;
- Beneficiary **has received at least one prior therapy**;
- Beneficiary was not previously treated with other BTK inhibitors (e.g., Imbruvica® (ibrutinib));
- Beneficiary **does not have significant cardiovascular disease,** such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of PA request, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification;
- The prescriber **must submit a current QTc interval measurement for the beneficiary**, either manually measured or using an automated ECG machine, with the initial Prior Authorization (PA) request prior to start treatment with CALQUENCE;
- Beneficiary does not have corrected QT interval (QTc) > 480 msec.;
- Beneficiary must not meet any of the exclusion criteria in the clinical trials;

- Beneficiary must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2;
- Prescriber must submit **Child Pugh score**;
- **Prior Authorization Approval will be month to month** due to high incidence of adverse effects that may require a dose modification;
- Beneficiary must use contraception while receiving the drug if sexually active and able to bear or beget children;

Continuation Criteria require all of the following:

- Beneficiary is not at increased risk for QTc prolongation;
- Beneficiary must be adherent to prescribed dose;
- Beneficiary must not have disease progression;

Quantity Limit:

- **2 capsules per day; 60 per 30 days' supply**

Denial Criteria, any one of the following is cause for denial:

- Beneficiary has disease progression;
- Beneficiary has unacceptable toxicity;
- Beneficiary is pregnant;
- Beneficiary is breastfeeding;
- Beneficiary has severe hepatic impairment classified as Child Pugh C;
- Beneficiary has a life-threatening illness, medical condition or organ system dysfunction;
- Beneficiary was previously treated with other BTK inhibitors (e.g., Imbruvica® (ibrutinib));
- Beneficiary has **significant cardiovascular disease** such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of PA request, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification;
- **Beneficiary has a higher risk for QTc prolongation**, such as beneficiary has congenital QTc prolongation, has a history of QTc-interval prolongation, is using co-medication which can prolong the QTc interval, or has electrolyte disorders;
- Beneficiary **has corrected QT interval (QTc) > 480 msec**.;
- Beneficiary has malabsorption syndrome, disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel or ulcerative colitis, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction;

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.

EFFECTIVE IMMEDIATELY:

4) **ENDARI™** (glutamine) powder, for solution:

ENDARI Reimbursement rate > **$18 EACH PACKET**; max dose is 6 packets per day, **30-day supply at max dose approximately $3,330**

DROXIA (hydroxyurea) Capsule: Reimbursement rate for 200 mg, & 300 mg capsule approximately $0.75 each capsule; 400 mg capsule approximately $0.81 each capsule

ENDARI™ will **require manual review prior authorization on a case-by-case basis**.

Approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving ENDARI along with all required chart notes and documentation to substantiate the request;
- Beneficiary must be **≥ 5 years** of age;
- Prescriber **must provide documentation** (e.g., hemoglobin electrophoresis) that **beneficiary has HbSS or HbSβ^0-thalassemia for Sickle Cell Anemia**;
- Prescriber must submit beneficiary's current prothrombin time (INR);

- Prescriber must submit beneficiary's current serum albumin;
- Prescriber must **provide all documentation** and all medical records and any data regarding all hospitalizations, ER visits, or admission of **≥3 painful Sickle Cell Crises in the previous 12 months** *while receiving hydroxyurea*; for purposes of these criteria, Sickle Cell Crises is defined as admission to an emergency room (ER) department or medical facility for Sickle Cell Crises -related pain that was treated with a parenterally-administered narcotic or parenterally-administered ketorolac in the previous year;
- Prescriber must **submit current prescribed dose of hydroxyurea** and treatment plan for use of hydroxyurea along with baseline fetal hemoglobin (HbF) level prior to starting Hydroxyurea and current HbF level while on hydroxyurea (i.e., hydroxyurea therapy should be consistent with Consensus Treatment Protocol for hydroxyurea therapy for managing sickle cell disease) ;
- Beneficiary **must be adherent on prescribed daily dose of hydroxyurea** for a minimum of 6 months (180 days) prior to the PA request for ENDARI;
- If beneficiary is currently not receiving hydroxyurea, provide documentation as to why not? Was the hydroxyurea *discontinued* by prescriber? Provide all documentation of failed response to hydroxyurea, including treatment plan for hematologic toxicity due to hydroxyurea (e.g. temporary hold of hydroxyurea, a dose reduction, or drug discontinuation); documentation must include baseline HbF level prior to starting hydroxyurea, HbF level while receiving hydroxyurea;
- If beneficiary is non-adherent to prescribed hydroxyurea, provide treatment plan for patient to be adherent to hydroxyurea in order to reduce the painful crises of SCD, the need for blood transfusions, and hospitalizations;
- Prescriber must submit patient's current weight at every ENDARI PA request;
- Prescriber must submit treatment plan for how patient is to handle acute complications of sickle cell disease if ENDARI is approved, including dose modifications and adherence to hydroxyurea, and dose modifications of opioid medications;
- Initial approval shall not exceed 3 months for those with adherence to prescribed hydroxyurea and stable weight; PA approval for a child not to exceed 3 months due to potential need to increase dose with weight gain;

Quantity Limit:

- The **dose is a weight-based dose**. Prescriber must submit patient's *current* weight with every PA request and the specific quantity required for the beneficiary's weight based dose will be entered with each approved PA; **max dose is 6 packets per day**;

Continuation Criteria, requires all of the following:

- Prescriber must submit patient's current weight at every PA request;
- **Beneficiary must be adherent to hydroxyurea** prescribed dose while receiving ENDARI;
- Beneficiary **must be adherent to ENDARI** prescribed dose;
- By 6 months from start of ENDARI therapy, the **beneficiary must show a positive response to ENDARI**, defined in this criteria as ***documented improvement*** is submitted to show the following: decreased chronic pain and decreased opioid use, or beneficiary had a significant reduction of painful sickle cell crises compared with prior to starting ENDARI, or fewer ER admissions or in-patient hospitalizations or admissions to ER/medical facility for sickle cell anemia-related pain that was treated with a parenterally administered narcotic or parenterally administered ketorolac, or fewer occurrence of Acute Chest Syndrome or fewer cumulative days as in-patient in a hospital;
- **By 1 year from start of ENDARI therapy**, prescriber must submit all documentation, chart notes, and all medical records and any data regarding all hospitalizations, ER visits, or admission for **painful Sickle Cell Crises.** The documentation from most recent 12 months will be compared to the 12 months of data submitted with initial PA request, as well as the data in the beneficiary's electronic Medicaid profile, to determine if ENDARI was effective in reducing painful crises and the beneficiary showed a positive response to the drug;
- **PA approval shall not exceed 3 months at a time** for those with stable weight who meet criteria; PA approval for a child not to exceed 3 months due to potential need to increase dose with weight gain; the specific quantity required for the beneficiary's weight based dose will be entered with each approved PA

Denial Criteria, any one of the following will cause denial:

- Documentation of reduction of painful sickle cell crises, i.e., positive response to ENDARI, not submitted;
- Beneficiary meets any of the exclusion criteria from the ENDARI drug trial;
- Beneficiary does not meet approval criteria;
- Beneficiary is **not adherent to prescribed dose of hydroxyurea** for a minimum of 6 months prior to ENDARI request, or has not been prescribed hydroxyurea to reduce the frequency of painful crises and to reduce the need for blood transfusions;
- Beneficiary was not adherent to prescribed dose of ENDARI;
- History of renal impairment;
- History of hepatic impairment;
- Beneficiary is pregnant or planning pregnancy or breastfeeding;
- Multisystem Organ Failure;
- Beneficiary has an increased prothrombin time INR > 2.0 (normal INR is 0.8 to 1.1);
- Serum albumin < 3.0 g/dL;

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.

EFFECTIVE IMMEDIATELY:

5) HEMLIBRA® (emicizumab) SQ syringes:

30 mg/1 mL; 60 mg/0.4 mL; 105 mg/0.7 mL; 150 mg/1 mL syringe

Reimbursement rate: 30 mg > $2,975 each syringe; 60 mg > $5,920 each syringe; 105 mg > $10,415 each syringe; 150 mg >$14,875 each syringe;

Initial Dose: 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks; subsequent doses are 1.5 mg/kg once weekly;

Example for 100 kg person @ 3 mg/kg = 300 mg per week; using 2 x 150 mg syringes per week, or 8 syringes for **4 weeks' supply, the reimbursement rate > $119,000**;

Reduced dose of 1.5mg/kg per week for 100 kg person = 150 mg syringe per week, or 4 syringes for **4 week supply is > $59,500;**

HEMLIBRA will **require manual review prior authorization on a case-by-case basis.**

Initial approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of changing his/her patient from the patient's existing therapy to HEMLIBRA and include chart notes and other documentation to substantiate the request. Prescriber should include documentation of previously prescribed treatment with episodic and/or prophylactic bypassing agents, FVIII, FIX, or alternative bypassing agents such as recombinant factor VIIa (rFVIIa) and prothrombin complex concentrates (PCC), including the activated forms (APCC), for at least the previous 24 weeks;
- Beneficiary has diagnosis of congenital hemophilia A (congenital factor VIII deficiency) with Factor VIII inhibitors and ≥5 Bethesda units per 1 ml plasma;
- Prescriber must provide documentation that beneficiary had ≥ 6 bleeds in the previous 24 weeks prior to request for HEMLIBRA (if on an episodic or PRN bypassing agent regimen) or ≥2 bleeds in the previous 24 weeks prior to request for HEMLIBRA (if on a prophylactic or scheduled agent regimen); documentation should include number of breakthrough bleeds per month if the PRN bypassing agents was shipped monthly, drug/dose/frequency of dose for treating breakthrough bleed(s), and how many days to resolve each of breakthrough bleed(s);
- Prescriber must submit liver function tests to show beneficiary does not have severe hepatic impairment;
- Prescriber will discontinue all other *scheduled* prophylaxis; HEMLIBRA will not be approved as conjunctive therapy with other *scheduled* factor products or bypassing agents;

- If beneficiary is to remain on episodic (PRN) agent therapy to treat breakthrough bleeds, prescriber must submit documentation of drug, dose, frequency of dose, and PRN instructions;
- Prescriber must submit treatment plan and how the beneficiary's bleeds are documented and tracked and use of the PRN bypassing agents are tracked;
- Prescriber to provide *current* body weight for beneficiary at every HEMLIBRA PA request;
- The initial approved dose will follow the FDA approved dose of 3 mg/kg once weekly for the first 4 weeks;
    - Initial PA request: Approval will be for 1 month for the FDA-approved dose of 3 mg/kg once weekly for the first 4 weeks. 2nd PA will be at the reduced dose, see below.
- All approved PAs for any beneficiary will be entered for the specific syringe strengths (30 mg, 60 mg, 105 mg, and 150 mg) required to make the specific dose for the beneficiary's weight using syringe strengths that will provide the least amount of waste;

Continuation Criteria will require all of the following:

- Every PA request requires the beneficiary's *current weight* since this drug has a weight-based dose;
- **Month-2 and Month-3** will be for **one month at a time** and the Medicaid drug profile will be reviewed for other hemophilia drugs dispensed for PRN use for breakthrough bleeds. **Prescriber must submit all documentation regarding use of the PRN bypassing agents for every breakthrough bleed** (for example prescriber must provide documentation of bleed, dose, frequency of dose, length of therapy to resolve breakthrough bleed, etc.) **to substantiate PRN dose dispensed if the pharmacy is dispensing the PRN product monthly**.
- For **Month-2 and Month-3 PA requests**, drug profile will be checked for **adherence to HEMLIBRA prescribed dose**;
    - **Month-2** PA: a one-month PA at reduced dose;
        - Prescriber must provide beneficiary's weight. The dose will be reduced to 1.5 mg/kg once weekly for 4 weeks per the FDA approved dose; doses higher than 1.5 mg/kg once weekly will not be approved; no "PRN" HEMLIBRA doses will be approved;
    - **Month-3** PA: prescriber must provide beneficiary's weight; dose will continue at reduced dose; no "PRN" HEMLIBRA doses will be approved;
- **For the Month-4 PA,** Beneficiary must show a positive response to HEMLIBRA during previous 3 months, i.e., bleeding episodes have been reduced. Prescriber must submit documentation to support improvement; if PRN bypassing agents are being dispensed every month prescriber must submit documentation on all breakthrough bleeds (drug/dose/frequency of dose for treating breakthrough bleed(s), and how many days to resolve each of breakthrough bleed(s), etc.) to substantiate PRN dose(s) dispensed;
- If documentation for the 1st 3 months of HEMLIBRA supports positive response, defined as decreased breakthrough bleeds and less PRN factor product dispensed, *or* if beneficiary has the same number of breakthrough bleeds occurring per documentation then the positive response will be defined as less overall cost to Medicaid compared to the 3 months prior to starting HEMLIBRA, and approval may be for up to a 3 month Prior Authorization approval;
- At every PA request, Prescriber must submit all documentation for breakthrough bleeds to account for all PRN products dispensed; positive response is required for continued approval for HEMLIBRA;
- All approved PAs for any beneficiary will be for the specific syringe strengths (30 mg, 60 mg, 105 mg, and 150 mg) that are required to make the specific dose for the beneficiary's weight with the least amount of waste;

Denial Criteria, any one of the following will cause denial:

- Beneficiary has inherited or acquired bleeding disorder other than hemophilia A;
- Beneficiary continues to receive *prophylactic doses* (scheduled doses) FVIII, FIX, or any other alternative bypassing agents products;
- Beneficiaries who are non-adherent with prescribed HEMLIBRA weekly dose;
- Doses exceeding the FDA approved dose or frequency;
- Requests for "PRN" doses of HEMLIBRA;
- Beneficiaries who do not meet the approval criteria;

- Beneficiaries who meet the exclusion criteria used in the HEMLIBRA drug trial;
- Beneficiary does not have a positive response to HEMLIBRA; i.e., breakthrough bleeding episodes have not been reduced to fewer than before starting HEMLIBRA, *or* if the breakthrough bleeds remain the same and the overall cost to Medicaid for hemophilia products for the beneficiary costs more with HEMLIBRA + PRN bypassing agents than with previous drug regimen the HEMLIBRA request will be denied, *or* the beneficiary is having more breakthrough bleeds than with previous therapy.
  For example, during the PA request review, the Medicaid drug history will be checked for monthly bypassing agents dispensed while receiving HEMLIBRA and prescriber must provide documentation to substantiate PRN dose(s) dispensed. (i.e., prescriber must submit documentation to support improvement, and if PRN bypassing agents are being dispensed every month by the pharmacy provider then the prescriber must submit documentation on all breakthrough bleeds (drug/dose/frequency of dose for treating breakthrough bleed(s), and how many days to resolve each of breakthrough bleed(s), etc.) If the number of breakthrough bleeds is the same, and the overall costs of HEMLIBRA + PRN bypassing agents is higher than previous therapy then there is no justification to continue HEMLIBRA therapy.

  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.

EFFECTIVE: APRIL 1, 2018

6) **LUPRON DEPOT-PED®** (leuprolide) and **SYNAREL®** (nafarelin) Nasal Spray:

For treating CENTRAL PRECOCIOUS PUBERTY (CPP)

LUPRON-DEPOT PED 7.5 MG 1 MONTH:	AR CAP: $1,081.88
LUPRON-DEPOT PED 11.25 MG 1 MONTH:	AR CAP: $2,246.13
LUPRON-DEPOT PED 15 MG 1 MONTH:	AR CAP: $2,598.43
LUPRON-DEPOT PED 11.25 MG 3 MONTH:	AR CAP $7,018.295
LUPRON-DEPOT PED 30 MG 3 MONTH:	AR CAP $7,755.045
SYNAREL NASAL SPRAY, 8 mL container:	reimbursement rate is >$323 per mL, or **>$2,631 per 8 mL container;**

Point of Sale approval criteria for LUPRON-DEPOT PED® or SYNAREL® Nasal Spray are removed from the Pharmacy Program system.

Requests for LUPRON-DEPOT PED®, SYNAREL® Nasal Spray, or other gonadotropin-releasing hormone (GnRH) agonist drugs, for treating CPP, will require **manual review prior authorization on a case-by-case basis**.

Initial approval criteria for CPP will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving requested drug for treating CPP along with all required chart notes and documentation;
- Full activation of the hypothalamus-pituitary-gonadal (HPG) axis before 8 years of age in females and before 9 years of age in males;
- Female shall be less than 8 years of age or male less than 9 years of age when initiating treatment with LUPRON-DEPOT PED or any other GnRH agonist for treatment of Central Precocious Puberty (CPP);
- Prescriber to submit documentation of growth rate acceleration above normal growth rate for age;
- Prescriber to submit all chart notes, testing, and documentation used to determine CPP (e.g., including notes on Tanner stage of development, progressive female breast development confirmed by palpitation before 8 years of age, progressive penis and testicular enlargement, etc.);
- During the manual review, the following may be requested if not initially provided with the request:
  - A bone age determination and predicted adult height;
  - Submission of all baseline laboratory tests for luteinizing hormone (LH), and either estradiol or testosterone, and follicle stimulating hormone (FSH); e.g., an LH of >0.3 IU/L is the most reliable screening test for CPP on a random blood sample;

  - If LH is <0.3 and CPP is suspected, a stimulation test with a gonadotrophin-releasing hormone (GnRH) analog may be necessary;
- TSH test for hypothyroidism if the growth velocity is slow instead of rapid; (to exclude hypothyroidism as the cause of CPP);
- Pelvic ultrasonography if LH is suppressed and estradiol is high; (increased ovarian and uterine volumes relative to age are diagnostic of CPP; if LH is suppressed and estradiol is high the CPP symptoms could be caused by ovarian cyst or ovarian tumor);

Continuation criteria will require all of the following:

- Female < 11 years of age or male < 12 years of age for continuation of GnRH therapy previously initiated for treatment of CPP;
- Prescriber to provide data that child shows positive response to the drug therapy (e.g., slowing of the growth velocity to <7cm/year, shrinkage or softening of the glandular breast tissue or the testes, or documentation of suppression of the HPG axis);

Denial criteria: any one of the following will cause denial

- Treatment of premature Adrenarche (PA) associated with normal rate of growth and no evidence of clitoromegaly, penile growth or testicular enlargement;
- Treatment of premature menarche in the young girl with vaginal bleeding but no or little breast development and no evidence of endocrinopathy on the basis of pelvic ultrasonography or concentrations of LH, FSH, and estradiol;
- There is no activation of the HPG axis, and FSH, LH, and estradiol or testosterone concentrations are at prepubertal levels;
- Treatment of premature thelarche (PT) in very young females (e.g., age <2 years) without additional indicators of CPP;
- In females, lipomastia and palpation fails to disclose firm glandular tissue and nipples and areola show no estrogenic stimulation;
- If the only signs of sexual development are pubic and/or axillary hair and/or axillary odor;
- When child's predicted adult height is within the normal range;
- Using pubertal suppression to increase linear growth;
- Female age ≥11 years; male age ≥12 years;

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.

EFFECTIVE APRIL 1, 2018

7) NOXAFIL® (posaconazole) SUSPENSION 200 mg/5 mL:
Packaged as a 105 mL of suspension in a 4-oz bottle;
NADAC Brand $12.24/mL; 105 mL = $1,285.20; **630 ml = $7,711.20**;

Point of Sale approval criteria for NOXAFIL suspension will be removed from the Pharmacy Program system. Noxafil tablets and Noxafil vial already require manual review prior authorization.
Requests for NOXAFIL suspension will require manual review prior authorization on a case by case basis using FDA approved label indications and dosage information. Noxafil delayed-release tablets and oral suspension are not to be used interchangeably due to the differences in the dosing of each formulation.

Approval criteria for NOXAFIL suspension will require all of the following for the initial request and continuation requests.

- Prescriber must submit a letter explaining the medical necessity of receiving NOXAFIL suspension along with chart notes and all required documentation;
- Prescriber must submit the beneficiary's diagnosis to be treated with NOXAFIL suspension;
- Length of PA will be entered at the time the PA is entered;

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.

EFFECTIVE IMMEDIATELY:

8) PREVYMIS™ (letermovir) tablet or vial:

240 mg tablets, 480 mg tablets and Injection vials 240 mg/12 mL and 480 mg/24mL.
Reimbursement rate: both strengths of tablet approximately $195 each tablet; both vials approximately $270 for vial; If beneficiary receives **100 days of therapy, TABLETS approximately $19,500 and VIALS approximately $27,000;**

PREVYMIS will require manual review prior authorization on a case-by-case basis.

Initial approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving PREVYMIS along with chart notes and all required documentation;
- Prescriber to provide documentation that **beneficiary is a recipient of an adult CMV-seropositive [R+] allogeneic hematopoietic stem cell transplant (HSCT)**;
- Prescriber to **provide transplant date** with the initial PA request. PREVYMIS must be **started between Day 0 post-transplant and Day 28 post-transplant**, and **continued *through* Day 100 post-transplantation** (*not* necessarily 100 days of drug therapy). The PA termination date will be entered into the system for after Day 100 post transplant to ensure patient will have medication (use Day 103 post-transplantation) to ensure the full "through Day 100 post-transplantation";
- Beneficiary must be an adult age ≥18 years;
- Beneficiary must not meet any of the *exclusion criteria* in the clinical trials;
- Prescriber to provide documentation that **beneficiary does not have CMV viremia prior to initiation** of PREVYMIS;
- Beneficiary shall not be receiving Pimozide or ergot alkaloids;
- Beneficiary shall not be receiving cyclosporine with pitavastatin or simvastatin;
- Approved dose shall not exceed the FDA approved dose or FDA approved length of therapy for the diagnosis of prophylaxis of cytomegalovirus (CMV) infection and disease;
- If IV vial requested, prescriber to submit documentation that it will be administered in beneficiary's home, *and* prescriber **must submit documentation as to the medical necessity of beneficiary requiring the IV vials over the oral tablets**;
- PA for the dosage will be entered at the time of the approved PA; 480 mg tablet is the recommended daily dose and it will be adjusted to the 240 mg tablet if patient receiving cyclosporine concurrently;
- **PA will be approved month to month** in the event cyclosporine is initiated after starting PREVYMIS;
- Prescriber must **provide beneficiary's creatinine clearance**; no dose adjustment necessary for severe renal impairment of CLcr>10 mL/min; no approval for CLcr<10 mL/min;
- Prescriber to **provide Child-Pugh score**; beneficiary must not have severe hepatic impairment (Child-Pugh C);

Continuation Criteria, all of the following apply:

- Drug will only be continued "through Day 100 post-transplant";
- If cyclosporine initiated after starting PREVYMIS, the next PA will be entered for 240 mg strength

Quantity limit:

- Quantity limit of 1 tablet or vial per day for all strengths and formulations;
- Length of therapy will be approved through and including **Day 100 post-transplantation** (not necessarily 100 days of therapy; # of days approved will depend on if drug started in the hospital and the start date using Medicaid Pharmacy Program);

Denial Criteria, any one of the following will cause denial:

- Requests to start PREVYMIS after Day 28 post-transplant;
- Beneficiary has CMV viremia prior to initiation of PREVYMIS;
- Patient receiving cyclosporine and pitavastatin concurrently or receiving cyclosporine and simvastatin concurrently;
- End stage renal disease or CLcr<10 mL/min
- Child Pugh C;
- Beneficiary does not meet approval criteria;
- If beneficiary meets any of the exclusion criteria from the drug trial (e.g., requires mechanical ventilation, hemodynamically unstable, positive for HIV, positive for HCV, positive for HBV, has active solid tumor malignancies, pregnant, breastfeeding, history of alcohol abuse or dependence, user of recreational or illicit drugs, etc.);

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.

EFFECTIVE APRIL 26, 2018

9) SKELETAL MUSCLE RELAXANTS: **TIZANIDINE** and **BACLOFEN:**

NADAC Generic: TIZANIDINE tablet 2 mg = $0.11355 ea; 4 mg = $0.10893 ea
NADAC Generic: BACLOFEN tablet 10 mg = $0.11880; 20 mg = $0.23212 ea
NADAC Generic: CYCLOBENZAPRINE tablet 10 mg = $0.02355 ea
NADAC Generic: METHOCARBAMOL tablet 500 mg = $0.06010; 750 mg = $0.07728;
Reimbursement rate: CHLORZOXAZONE tablet 500 mg approximately $0.22 each

In the PDL skeletal muscle relaxant drug category, the point of sale approval criteria for the "preferred with criteria" agents, tizanidine tablet and baclofen tablet, will be removed. The preferred drugs in this category are cyclobenzaprine 10 mg tablet, methocarbamol 500 mg and 750 mg tablet, chlorzoxazone 500 mg tablet, tizanidine 2 mg and 4 mg tablet, and baclofen 10 mg and 20 mg tablet.

- THERAPEUTIC DUPLICATION CRITERIA will be added to all preferred agents in the skeletal muscle relaxant drug category to prevent therapeutic duplication among the various agents and/or strengths;
- For consistency, QUANTITY EDITS have been added to the preferred muscle relaxants that did not have quantity edits.
    - QUANTITY EDITS were added to the following:
        - Tizanidine, both strengths, up to 3 tablets/24 hours; #93/31 days' supply;
        - Baclofen, both strengths, up to 4 tablets/24 hours; #124/31 days' supply;
        - Methocarbamol, both strengths, up to 8 tablets/24 hours; #248/31 days' supply;

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.

EFFECTIVE IMMEDIATELY:

10) VABOMERE™ (meropenem-vaborbactam) injection:
2 gm (1 gm meropenem and 1 gm vaborbactam) vial;
Reimbursement rate approximately: $165 EACH 2 gm VIAL;

- Recommended dose is 4 gm administered Q8H IV infusion over 3 hours each infusion for patients with eGFR ≥50 mL/min/1.73m2; Dose should be adjusted for patients with renal impairment as follows:
    - eGFR 30-49, 2 gm Q8H
    - eGFR 15-29, 2 gm Q12H
    - eGFR <15, 1 gm (0.5 gm meropenem and 0.5 gm vaborbactam) Q12H
- 4 gm Q8H, approximately **$990 per day**; **14-day treatment approximately $13,860**

VABOMERE will require **manual review prior authorization on a case-by-case basis**.

Approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving VABOMERE along with chart notes and all required documentation;
- Prescriber must provide estimated glomerular filtration rate (eGFR) as the drug is dose dependent on the eGFR;
- Beneficiary must be **≥18 years** of age;
- **Prescriber to provide start date of VABOMERE in hospital**; If drug *not* started in the hospital, prescriber must submit documentation of why this specific antibiotic is needed (example, allergic to Zosyn, resistant to single agent meropenem, etc.,)

QUANTITY LIMIT not to exceed 6 vials per day for 4 gm q8h dose; Quantity to be entered at time of PA approval if dose is less than recommended dose (4 gm Q8H) due to reduced eGFR;

- **Total Duration of therapy** not to exceed 14 days (max dose would require 84 vials for a 14 days' supply); **calculate duration based on start date in hospital;** remaining quantity for PA will be entered at the time the PA is 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.

EFFECTIVE IMMEDIATELY:

11) VERZENIO™ (abemaciclib) tablet:
50 mg, 100 mg, 150 mg, 200 mg tablets
Reimbursement rate all strengths > $195 each tablet. Packaged as 14 tablets, or a 7-day supply, in a dose pack. Recommended dose is 150 mg or 200 mg twice daily;
#56 tablets for a **28 day supply >$10,945**

VERZENIO will require **manual review prior authorization on a case-by-case basis**.
Approval criteria will require all of the following:

- Prescriber must submit a letter explaining the medical necessity of receiving VERZENIO along with chart notes and all required documentation;
- Beneficiary must have a diagnosis that matches an FDA approved indication for the drug: 1) In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; *or* 2) As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting;
- Beneficiary must be an adult **age ≥18 years**;
- **Prescribed dose must be submitted with every PA request**;
- Approved **dose shall not exceed the FDA approved dose** for each diagnosis: 1) When used in combination with fulvestrant, the recommended dose of VERZENIO is 150 mg taken orally twice daily; 2) When used as monotherapy, the recommended dose of VERZENIO is 200 mg taken orally twice daily
- **PA will be approved on a month-to-month basis** due to high incidence of adverse effects (AE) and high incidence of dose reductions; quantity & dose entered at PA approval;
- **Prescriber must submit results for baseline liver function tests** prior to the start of VERZENIO, and every 2 weeks for the first 2 months, then monthly for 2 months, then as needed. Results must be submitted with every PA request;
- Prescriber must **provide beneficiary's creatinine clearance**; beneficiary must not have severe renal impairment (CLcr<30mL/min), end-stage renal disease, or on dialysis;
- Prescriber to provide Child-Pugh score; if beneficiary has severe hepatic impairment (Child-Pugh C), dose must be reduced to once daily;
- Beneficiary must not meet any of the exclusion criteria in the clinical trials;

Quantity Limit:
- 2 tablets/day for all strengths; packaging is available as 14 tablets (7-day supply) per package in all strengths; cumulative quantity allowed up to 56 tablets per 28 days; Quantity & dose entered at PA approval;
- If beneficiary has Child-Pugh C, quantity limit is 1 per day; cumulative quantity up to 28 per 28 day supply;

Continuation criteria requires all of the following must be met;
- Beneficiary must not have disease progression or unacceptable toxicity;
- Beneficiary must be able to tolerate at least a minimum of 50 mg BID dosing and be adherent to prescribed dose;
- Prescriber must submit required labs with each PA request;
- Prescriber must submit daily dose with each PA request;

Denial criteria: any one of the following will cause denial;
- Does not meet approval criteria;
- Disease progression;
- If beneficiary cannot tolerate a dose of 50 mg twice daily;
- If beneficiary has severe renal impairment (CLcr<30mL/min), end-stage renal disease, or on dialysis;
- History of central nervous system (CNS) metastasis or evidence of CNS metastasis on the magnetic resonance image of brain obtained at baseline.
- Beneficiary meets any one of the exclusion criteria from the VERZENIO drug trial;

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.

EFFECTIVE APRIL 1, 2018

12) **XARELTO®** (rivaroxaban) 10 mg tablet:
Final pricing dependent upon bottle packaging size.
NADAC Brand: $12.38350 per tablet if dispensed from bottle packaged as 30 tablets or 100 tablets; 30 days' supply = **$371.40**
Reimbursement rate> $12.90 per tablet if dispensed from bottle packaged as 90 tablets; a 30 days' supply > **$388**

The existing point of sale approval criteria that was specific for the XARELTO 10 mg strength tablet that allowed only one claim of 10 mg in a 6-month time period will be removed.

The XARELTO 10 mg tablet will be added to the point of sale approval criteria with the other XARELTO strengths (15 mg, 20 mg, and starter pack) to prevent therapeutic duplication. The point of sale approval criteria is outlined below:
- No therapeutic duplication allowed between different strengths of Xarelto with overlapping days' supply;
- One (1) therapeutic duplication with overlapping days' supply will be allowed once per 186 days for inferred change in therapy between a Xarelto® claim and any of the following: a Pradaxa® claim, a warfarin claim, Savaysa® claim, OR an Eliquis® claim; AND
- The Xarelto® claim and the warfarin claim, the Pradaxa® claim, the Savaysa® claim, or the Eliquis® claim cannot have the same date of service.

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. **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

2. **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

3. **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on NOVEMBER 8, 2017 to ≤ 200 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that will cause the total MME/day to exceed the existing limit of ≤200 MME/day (>200 MME/day) will deny at point of sale whether prescription is from same prescriber or different prescribers.

   The next reduction is scheduled for May 8, 2018 with a reduction to a maximum of 150 MME/day.

   BENEFICIARIES WHO PAY CASH FOR OPIOIDS, 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 INCREASED RISK FOR OVERDOSE.

   The Medicaid Pharmacy Program will continue reducing the maximum allowed Morphine Milligram Equivalent (MME) daily dose for chronic non-cancer pain patients by 50 MME approximately every 6 months to reduce the risk for overdose or poisoning. The ultimate Medicaid goal is to reduce the TOTAL MME PER DAY for chronic non-cancer pain patients to meet the CDC recommendations.

4. **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, by using 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.

5. **<u>Chronic Pain Patients Who Do *Not* Need Treatment for Addiction</u>**: 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 <u>not</u> 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*." http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

6. **<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.

7. **<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.

8. **<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.

9. **<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, https://arkansas.magellanrx.com/provider/documents/.

10. **<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 a Medicaid beneficiaries who, ***<u>on the date the prescription is filled</u>, 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, <u>including beneficiaries in a juvenile correctional facility</u>, the medications <u>cannot be billed to Medicaid Pharmacy Program</u> 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.

11. **<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 ***not*** be approved.

12. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** 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. The limits for the "Refill Too Soon Accumulation Logic" are currently the same for non-controlled drugs and controlled drugs, including opioids.

    Effective February 14, 2018, the RTS logic with Early Refill Accumulation Limit edit is **revised for the controlled drugs only**. 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.

13. **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.

14. **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.

15. **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.

16. **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.

17. **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.

18. **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.

19. **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

20. **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.