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: **MAY 31, 2018**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board APRIL 18, 2018 meeting** for the following: Changes to prescriber requirements for MAT drugs, MME/day changes for opioids, Refill Too Soon Accumulation Limits, Diphenoxylate/Atropine tablets, ERLEADA™, HUMIRA®, NARCAN® NASAL SPRAY, naloxone vial and pre-filled syringe, NERLYNX™, SOLOSEC™

NEW PDL DRUG CATEGORIES approved at the MAY 9, 2018 PDL meeting: C-III stimulants, phosphate binders for CKD, ESA agents, colony stimulating factors, platelet aggregation inhibitors, lipotropic

Table of Contents

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.

ANNOUNCEMENT REGARDING PRICING CHANGES

EFFECTIVE 7/1/18, The drugs listed below will be removed from the State Supported Brand Medication list:

NILANDRON® (nilutamide), ASACOL® HD (mesalamine delayed release), VALCYTE® (valganciclovir HCl) for Oral Solution, NITROSTAT® (nitroglycerin) SL tablet, AZILECT® (rasagiline mesylate) tablet, EFFIENT® (prasugrel) tablet.

ANNOUNCEMENT: Future Medicaid Pharmacy Program Provider Memos

To reduce paper waste, in the 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.

CHANGE IN MEDICAID WEBSITE LINK

The *new* Arkansas Medicaid website link is https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx. To find the Medicaid Pharmacy Program section, select the "**Other Links**" arrow at the top left, then select "**Magellan Medicaid Administration**" from the drop-down list. Then select the "**PROVIDER**" picture, then select the **RESOURCES** tab at the top, then select **DOCUMENTS** for the full Medicaid Pharmacy Program website area. The memorandums are posted under the "Pharmacy" tab at the top of the page. Beginning with the January 2018 memo, the online version for Provider Memos 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 desired and click the mouse. The hyperlink will move directly to that item.

EFFECTUVE JULY 1, 2018, PDL (PREFERRED DRUG LIST) ADDITIONS: C-III STIMULANTS, PHOSPHATE BINDERS FOR CKD, ESA AGENTS, COLONY STIMULATING FACTORS, PLATELET AGGREGATION INHIBITORS, LIPOTROPICS

The Preferred status and Non-preferred status drugs selected at the May 9, 2018 meeting are listed below. *Current Prior Authorization criteria* and other edits **will remain** in place for Preferred-status drugs as noted below.

C-III STIMULANTS—*ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
NUVIGIL® (armodafinil) (BRAND ONLY) – existing manual review PA criteria remain;

NONPREFERRED AGENTS
PROVIGIL® (modafinil)
modafinil
armodafinil (generic only)

PHOSPHATE BINDERS for CKD-- *ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
RENAGEL® (sevelamer HCl) tablet
RENVELA® (sevelamer carbonate) TABLET (BRAND ONLY)
calcium acetate capsule and tablet

NON-PREFERRED AGENTS
AURYXIA® (ferric citrate) tablet
FOSRENOL® (lanthanum carbonate) chewable tablet
PHOSLYRA® (calcium acetate) 667 mg/5 ml oral solution
RENVELA® (sevelamer carbonate) Powder Pack
sevelamer carbonate tablet (generic only)
VELPHORO® (sucroferric oxyhydroxide) chewable tablet

ERYTHROPOIESIS STIMULATING AGENTS-- *ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
EPOGEN® (epoetin alfa) vial -- existing manual review PA criteria remain
PROCRIT® (epoetin alfa) vial

NONPREFERRED AGENTS
ARANESP® (darbepoetin alfa in polysorbat) vial and syringe
MIRCERA® (methoxy peg-epoetin beta) syringe

COLONY STIMULATING FACTORS-- *ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
NEUPOGEN® (filgrastim) vial and syringe
GRANIX® (tbo-filgrastim) syringe
NEULASTA® (pegfilgrastim) syringe

NONPREFERRED AGENTS
LEUKINE® (sargramostim) vial
NEULASTA® ONPRO® KIT (pegfilgrastim)
ZARXIO® (filgrastim-sndz) syringe

PLATELET AGGREGATION INHIBITORS-- *ADDING NEW DRUG CATEGORY TO PDL*
PREFERRED AGENTS
AGGRENOX (aspirin/dipyridamole) (BRAND ONLY)
dipyridamole
prasugrel
clopidogrel
BRILINTA® (ticagrelor) tablet

NONPREFERRED AGENTS
aspirin/dipyridamole (generic only)
ticlopidine
EFFIENT® (prasugrel) (Brand Only)
PLAVIX® (clopidogrel bisulfate) (Brand Only)
ZONTIVITY® (vorapaxar sulfate)

LIPOTROPICS-- *ADDING NEW DRUG CATEGORY TO PDL*
Fibric Acid Agents
PREFERRED AGENTS:
gemfibrozil
fenofibrate tablet 48 mg, 54 mg, 145 mg, 154 mg

NONPREFERRED AGENTS
fenofibrate capsule (e.g., Antara®, Lipogen®, Lofibra®) 30 mg, 67 mg, 90 mg, 134 mg, 200 mg
fenofibrate tablet (e.g., Fenoglide®, Triglide®) 40 mg, 120 mg, 160 mg
fenofibric acid (e.g., Fibricor®) tablet 35 mg, 105 mg
fenofibric acid (e.g.,Trilipix®) delayed-release capsule 45 mg, 135 mg

Bile Acid Sequestrant Agents
PREFERRED AGENTS:
colestipol tablet
colestipol granules
cholestyramine light powder for oral suspension
cholestyramine powder for oral suspension

NONPREFERRED AGENTS
WELCHOL® (colesevelam) powder pack and tablet

A. CHANGES TO PRIOR AUTHORIZATION CRITERIA OR RULES

EFFECTIVE IMMEDIATELY:

1) CHANGES TO PRESCRIBER QUALIFICATIONS for Buprenorphine-containing Agents for Treating Opioid Addiction in An Office Based Setting

- Regarding the AR Medicaid Pharmacy Program, the prescribing provider for a SL buprenorphine-containing agent may be a qualifying physician, a qualifying nurse practitioner (NP), or a qualifying physician assistant (PA). The addition of a qualifying nurse practitioner and a qualifying physician assistant will be allowed until Oct. 1, 2021, which is the expiration date set in the CARA Act for these two prescriber types[1];
- All qualifying prescribers who met the Buprenorphine Waiver requirements through SAMPHA must submit his/her copy of his/her X-DEA that is required for prescribing these buprenorphine-containing agents when treating opioid addiction and a copy of his/her prescribing waiver from SAMHSA the first time the prescriber requests a PA through the Medicaid Pharmacy Program. These documents will be kept on file and the prescriber will not be required to submit these documents with every patient PA request.

[1] CARA Act July 22, 2016, Qualifying Nurse Practitioners and Physician Assistants Waiver, https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/qualify-np-pa-waivers, accessed 03/21/2018.

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 NOVEMBER 7, 2018

2) MME/DAY CHANGES FOR OPIOID DRUGS:

The Arkansas Medicaid Drug Utilization Review (DUR) Board approved reducing the Total Daily MME/day limit on November 14, 2018 to ≤ 90 MME/day. The DUR Board requested that the Medicaid Pharmacy Program monitor the opioid utilization and prescribing for six months after the November 7, 2018 dose reduction implementation and present the findings to the DUR Board to determine if further reductions are necessary.

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 AUGUST 8, 2018

3) CHANGES TO REFILL TOO SOON (RTS) LOGIC WITH ACCUMULATION LIMIT for NON-CONTROLLED DRUGS

- For *non-controlled drugs*, the allowed *accumulated* quantity from early refills is reduced from an *accumulated 15 days' supply* ***to*** an *accumulated* ***12 days' supply*** during previous 180 day period.
- **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.**

B. PRIOR AUTHORIZATION CRITERIA (NEW OR REVISED CRITERIA) FOR THE FOLLOWING DRUGS:

EFFECTIVE JULY 10, 2018

4) DIPHENOXYLATE HYDROCHLORIDE AND ATROPINE SULFATE (e.g., Lomotil®) 2.5 mg/0.025 mg TABLET

An **age edit** has been implemented for the diphenoxylate/atropine **tablets** that will **deny** an incoming claim if the child is under 13 years of age.

Per the drug package insert, "In children under 13 years of age, use the oral solution. Do not use the tablets for this age group." For children *less than 13 years of age down to 2 years of age*, prescriber should refer to the age and weight-based dose chart detailed in the **diphenoxylate/atropine oral solution** package insert. These pediatric schedules are the best approximation of an average dose recommendation which may be adjusted downward according to the overall nutritional status and degree of dehydration encountered in the sick child.

Per the drug package insert, "Diphenoxylate hydrochloride and atropine sulfate is *not* an innocuous drug and dosage recommendations should be strictly adhered to, especially in children. Diphenoxylate hydrochloride and atropine sulfate is *not recommended for children under 2 years of age*. Overdosage may result in severe respiratory depression and coma, possibly leading to permanent brain damage or death. Therefore, keep this medication out of the reach of children." See the Overdose information in the drug package insert.

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

1) ERLEADA™ (apalutamide) Tablet, 60 mg

Reimbursement rate for a 30-day supply @ 4 tablets per day is approximately **$10,900**.

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

- Beneficiary is ≥ 18 years of age;
- Beneficiary has high risk **non-metastatic** castration-resistant prostate cancer demonstrated during continuous ADT, defined as 3 PSA rises, at least 1 week apart, with the last PSA greater than (>) 2 nanogram per milliliter (ng/mL);
- Beneficiary has histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features with high risk for development of metastases, defined as prostate-specific antigen doubling time (PSADT) less than or equal to (≤) 10 months. PSADT is calculated using at least 3 prostate-specific antigen (PSA) values obtained during continuous ADT (androgen deprivation therapy);
- Beneficiary **must be receiving gonadotropin-releasing hormone (GnRH) analog concurrently, *OR* the beneficiary has had a bilateral orchiectomy**. If the beneficiary's Medicaid profile does not provide documentation of either of these, the prescriber must submit the documentation;
- Beneficiary must maintain **castrate levels of testosterone of < 50 ng/dL** within 4 weeks of the PA request for ERLEADA™;
- Patients who received a first generation anti-androgen (for example, bicalutamide, flutamide, nilutamide) must have at least a 4-week washout prior to PA request AND must show continuing disease (PSA) progression (an increase in PSA) after washout;
- At least 4 weeks must have elapsed from the use of 5-alpha reductase inhibitors (finasteride or dutasteride), estrogens, and any other anti-cancer therapy prior to request to start ERLEADA™;
- At least 4 weeks must have elapsed from major surgery or radiation therapy prior to request to start ERLEADA™;
- Beneficiary has Eastern Cooperative Oncology Group Performance Status 0 or 1;
- Beneficiary must be currently receiving bone loss prevention treatment with bone-sparing agents must be on stable doses for at least 4 weeks prior to PA request for ERLEADA™.
- PA approval will be month-to-month due to high incidence of adverse reactions requiring dose interruption or modification;

Quantity edit:

- Daily dose not to exceed 4 x 60 mg (240 mg) once daily;
- ERLEADA™ is available as a bottle of 120 tablets. However, due to the high incidence of adverse events requiring dose reduction, the approved quantity will be entered at the time of each PA approval in the event of a dose reduction;

Continuation Criteria:

- Prescriber must include the beneficiary's current dose with each PA request due to high rate of adverse effects that require dose modifications;
- The approved quantity for the reduced dose will be entered at the time the PA is approved;
- Prescriber must test TSH level every 4 months and submit test results with the PA request to monitor effects of drug on hypothyroidism;

Denial Criteria:

- Presence of confirmed distant metastases, including central nervous system and vertebral or meningeal involvement;
- Symptomatic local or regional disease requiring medical intervention;
- Prior treatment with second generation anti-androgens;
- Prior treatment with CYP17 inhibitors;
- Prior treatment with radiopharmaceutical agents, or any other investigational agent for non-metastatic castration-resistant prostate cancer;
- Prior chemotherapy for prostate cancer except if administered in the adjuvant/neoadjuvant setting;
- History of seizure or condition that may pre-dispose to seizure;

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 SEPTEMBER 25, 2018

2) HUMIRA®: Criteria Change for Adult Crohn's Disease and Adult Ulcerative Colitis:

Reimbursement rate for the 10 mg, 20 mg, or 40 mg syringe is approximately $2,436 each;
Reimbursement rate for the 80 mg syringe is approximately $4,872 each;
HUMIRA® is the preferred status drug in the TIMS category on the Medicaid PDL that is indicated for Adult Crohn's Disease and Adult Ulcerative Colitis. The HUMIRA point of sale approval criteria was revised for Adult Crohn's disease and for Adult Ulcerative Colitis as follows below.

❖ **POS HUMIRA® Approval criteria for Adult Crohn's disease with fistula or abscess require *all* of the following**:

- Age ≥ 18 years,
  AND
- One diagnosis code in Medicaid history in the previous two years from Revised Table 5;
  OR
  One diagnosis code in Medicaid medical history in previous 2 years from Revised **Table 5A** + one diagnosis code in Medicaid medical history in previous 2 years from **Revised Table 5B** (see list below);

REVISED TABLE 5

K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.013	Crohn's disease of small intestine with fistula
K50.113	Crohn's disease of large intestine with fistula
K50.813	Crohn's disease of both small and large intestine with fistula
K50.913	Crohn's disease, unspecified, with fistula

REVISED TABLE 5A

K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications

REVISED TABLE 5B

K60.3	Anal fistula
K60.4	Rectal fistula
K60.5	Anorectal fistula
K65.1	Peritoneal abscess
K68.12	Psoas muscle abscess
K63.2	Fistula of intestine

- **POS Humira® Approval criteria for Adult Crohn's disease without fistula or abscess require all of the following:**
  - Age > 18 years;
    AND
  - Has Crohn's disease diagnosis in history in the previous two years (See **Table 6)**, *without* additional diagnosis code in history of fistula or abscess;
    AND
  - Beneficiary has ≥ 30 days of conventional drug therapy in the past 45 days treating Crohn's disease using one or more of the following drug regimens:
    - oral glucocorticoid or enteric coated budesonide capsule OR
    - methotrexate injection OR
    - 6-mercaptopurine OR
    - azathioprine

REVISED TABLE 6

K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications

- **POS HUMIRA® Approval criteria for Adult moderate to severe UC require all of the following:**
  - Age > 18 years,
    AND
  - Beneficiary has ULCERATIVE COLITIS diagnosis in history in the previous 2 years (diagnosis code from Table 7)
    AND
  - Beneficiary has ≥ 90 days of standard of care drug therapy in the past 120 days treating moderate to severe Ulcerative Colitis using one or more of the following drug regimens:
    - azathioprine
      OR
    - 6-mercaptopurine;

    OR
    Beneficiary has ≥ 30 days of drug therapy out of previous 45 days using an oral glucocorticoid or enteric coated budesonide tablet;

REVISED TABLE 7

K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications

- **HUMIRA® "Continuation" Criteria for Adult Crohn's disease and for Ulcerative Colitis:**
  The "continuation" criteria will be updated for the diagnoses in the corresponding tables as noted above, and will remain as requiring 1 Humira drug claim in previous 45 days (signifying previously met the approval criteria).

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 SEPTEMBER 18, 2018

3) NALOXONE 0.4 MG/ mL VIAL & PRE-FILLED SYRINGE, NALOXONE 2 mg/2 mL PRE-FILLED SYRINGE, AND NARCAN® NASAL SPRAY 4MG/0.1 MI; AND AFFECT ON OPIOID MEDICATION CLAIMS:

a) The Arkansas Medicaid Pharmacy Program will implement a naloxone quantity limit per claim as follows:
   - Naloxone 0.4 mg/1 mL syringe or 0.4 mg/1 mL vial: a quantity limit of up to 4 vials or syringes per claim is implemented. The billing unit is per mL; 4 vials or 4 syringes will equal 4 mLs billed;
   - Naloxone 1 mg/1 mL, 2 mL syringe: a quantity limit of up to 4 syringes per claim is implemented. The billing unit is per mL, 4 syringes will equal 8 mLs billed;
   - Naloxone 0.4 mg/1 ml, 10 mL multidose vial: a quantity limit of up to one-10 mL multidose vial per claim is implemented. The billing unit is per mL; one 10-mL vial will equal 10 mLs billed.
   - **NARCAN® (naloxone) Nasal Spray 4 mg/0.1mL**: *The PA criteria for the nasal spray has been removed*; a quantity limit of up to *two-cartons,* each containing two (2) blister packages (total of 4 blister packages), per claim is implemented. The billing unit is per "each", 4 blister packages dispensed (two cartons) will be billed as 4.

b) As long as the Medicaid beneficiary has Medicaid medication "slots" available during the month, there is no limit to the number of naloxone claims the beneficiary may fill/refill. *However*, when the 2nd naloxone claim is billed to Medicaid within a 90-day look-back period, ***the next incoming opioid claim(s) will deny at point of sale*** *for non-cancer patients* and **the opioid will require a manual review prior authorization** initiated by the opioid prescribing provider. ***This specific criterion will exclude terminal cancer patients who have an approved cancer diagnosis in the Medicaid medical history in the previous 365 days.*** The prescriber of the opioid must contact the Medicaid Pharmacy Program and provide specific information regarding the beneficiary's use of the naloxone dispensed, provide information on the overdose or poisoning for which the naloxone was used, provide a reduced opioid total daily dose, provide an opioid taper schedule, and agree not to provide opioid prescriptions for cash that circumvent the Medicaid opioid safe prescribing rules. The Medicaid Pharmacy Program clinical team will work with the prescriber to assist in safe prescribing of opioid prescriptions to prevent future opioid poisonings or overdose situations.

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) NERLYNX™ (neratinib) Tablet, 40 mg

Reimbursement rate for 30-day supply @ 6 tablets/day is approximately **$11,444.**

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

- Beneficiary has indication for the *extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy*;
- Beneficiary has histologically confirmed stage 2 through stage 3c HER-2/erbB-2 positive breast cancer with node positive disease;
- Beneficiary has been treated for early breast cancer with standard of care duration of trastuzumab or experienced side effects that results in early discontinuation of trastuzumab that have since resolved;
- The last dose of trastuzumab was given > 2 weeks and ≤ 1 year (365 days) from requested start time for NERLYNX™;
- Beneficiary is negative for local or regional recurrence of disease or metastatic disease at the time of the PA request using the following:
  - bone scan or PET scan if alkaline phosphatase (ALP) is ≥ 2 ULN and/or there are symptoms of metastatic done disease, and a confirmatory imagining study is required if the results from the bone scan are questionable; CT, MRI or ultrasound of the abdomen and chest is required only if AST , ALT, or ALP is ≥ 2x ULN;

  - chest radiograph;
- The beneficiary's left ventricular ejection fraction (LVEF) is ≥ 50%;
- Beneficiary is not pregnant; women of childbearing age must use a highly effective non-hormonal method of contraception (IUD, bilateral tubal ligation, vasectomized partner) from the time of informed consent to 28 days past last dose;
- The beneficiary's ECOG status is 0 to 1;
- Beneficiary is ≥ 18 years of age;
- **Prescriber has prescribed loperamide** to the beneficiary during the first 2 cycles (56 days) of NERLYNX™ treatment; prescriber shall follow the dose modifications required for diarrhea management;
- Prescriber is required to submit the beneficiary's Child-Pugh score; Child-Pugh C will receive dose reduction to 80 mg per day;
- Prescriber must submit results of liver function tests (ALT, AST, alkaline phosphatase, Fractionated bilirubin and prothrombin time) with initial PA request;
- Prescriber must submit the following screen assessments: absolute neutrophil count (ANC), platelet count, hemoglobin, total bilirubin, Creatinine Clearance;
- The dose and quantity limit is to be entered at the time of PA approval;
- PA approval will be month-to-month due to high rate of adverse effects that require dose modification;

Quantity Limit:

- Initial approval dose will not exceed 240 mg (6 tablets) once daily for the initial PA request;
- The package size is a bottle of 180 tablets. However, due to high incidence of adverse events requiring dose reduction, the approved quantity will be entered at the time of each PA approval in the event of a dose reduction;

Continuation Criteria:

- Prescriber must include the beneficiary's current dose with each PA request due to high rate of adverse effects that require dose modifications;
- Prescriber to provide date of all dose reductions that happened between NERLYNX fill dates;
- The NERLYNX™ tablet is packaged in bottles of 180 tablets; however, the approved quantity for the reduced dose will be entered at the time the PA is approved.
- Prescriber must provide **liver function test results (ALT, AST, alkaline phosphatase, Fractionated bilirubin and prothrombin time**) ***monthly*** **for the 1st 3 months**, **then *every 3 months while on treatment*** and as clinically indicated, Grade 3 diarrhea, or signs or symptoms of hepatotoxicity, such as worsening of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, or eosinophilia; Dose reductions due to hepatotoxicity as noted in the package insert will be followed and that quantity entered with an approved PA for one month;
- Each PA length of time shall not exceed 1 month;

Denial Criteria:

- Prior treatment with any pan-HER TKI (e.g., lapatinib, afatinib, dacomitinib);
- Clinical or radiologic evidence of local or regional recurrence of disease or metastatic disease prior to initial PA request or at each PA request;
- Currently receiving chemotherapy, radiation therapy, immunotherapy, or biotherapy for breast cancer;
- Screening laboratory assessments outside the following limits:
  - Absolute neutrophil count (ANC) < 1,000/µl (< 1.0 x 109/L) Platelet count < 100,000/µl (< 100 x 109/L) Hemoglobin < 9 g/dL Total bilirubin > 1.5 x institutional upper limit of normal (ULN) (In case of known Gilbert's syndrome, < 2 x ULN is allowed) Creatinine clearance < 30 mL/min (as calculated by Cockcroft-Gault formula or Modification of Diet in Renal Disease [MDRD] formula);
- Chronic gastrointestinal disorder with diarrhea as a major symptom (e.g., Crohn's disease, malabsorption, or Grade ≥ 2 NCI CTCAE v.4.0 diarrhea of any etiology at baseline;
- Clinically active infection with HBV or NCV;

- Disease progression;
- Unacceptable toxicity;
- Active uncontrolled cardiac disease, including cardiomyopathy, CHF NYHA functional classification of ≥ 2 and including individuals currently on digitalis, beta blockers, or calcium channel blockers, unstable angina, MI with 12 months of PA request, or ventricular arrhythmia;
- QTc interval > 0.450 seconds for males or > 0.470 for females, or known history of QTc prolongation or Torsade de Pointes (TdP);
- Currently pregnant or breast feeding;
- Beneficiary has secondary malignancy, other than adequately treated non-melanoma skin cancers, in situ melanoma or in situ cervical cancer, or if beneficiary had other non-mammary malignancies must be disease-free x 5 years
- Beneficiary will not receive NERLYNX past one year;
- Deny PA for NERLYNX™ for patients who fail to recover to Grade 0-1 from treatment-related toxicity or for Grade 4 toxicity;
- Deny PA for NERLYNX™ for toxicities that result in a treatment delay > 3 weeks,
- Deny PA request for patients that are unable to tolerate 120 mg;
- Deny quantity that exceeds the prescribed reduced dose;

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) SOLOSEC™ (secnidazole) 2-gm Granule Packet:

SOLOSEC: The Medicaid reimbursement rate is approximately **$271 for one dose of SOLOSEC**.

The Medicaid reimbursement rates for other treatment options for bacterial vaginosis in adult women:

- Metronidazole 500 mg oral tablet, twice daily for 7 days is approximately **$ 4.51;**
- Metronidazole 0.75% vaginal gel, 45 gm tube, is approximately **$56**
- Clindamycin 2% vaginal cream, 40 gm tube, is approximately **$73.61**
- Clindamycin 300 mg oral capsule, #14 is approximately **$3.09**
- Tinidazole 500 mg oral tablet #8 tablets is approximately **$22.24**
- Cleocin Vaginal Ovule 100 mg #3 ovules is approximately **$168.98**

SOLOSEC™ 2-gm granule packet will require manual review prior authorization on a case-by-case basis. Approval criteria will require all of the following:

- Beneficiary must be female;
- Beneficiary must be ≥ 18 years of age;
- Prescriber must submit documentation to substantiate the medial necessity of beneficiary receiving SOLOSEC™ over other more cost effective medications that do not require prior authorization and are indicated for treating bacterial vaginosis or the DrugDex information supports the effectiveness of treating bacterial vaginosis.

- Quantity Edit: SOLOSEC™ is packaged as a single 2-gm packet of granules taken once orally. The quantity limit is 1 dose per claim;

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. **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*.

4. **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on MAY 8, 2018 to ≤ 150 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that will cause the total MME/day to exceed the existing limit of ≤ 150 MME/day (> 150 MME/day) will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).

   The next reduction is scheduled for NOVEMBER 7, 2018 with a reduction to ≤ 90 MME/day.

5. **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, including long-acting injectable antipsychotic agents, 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 not necessitate Medicaid Pharmacy Program approval of the requested drug.***

6. **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*." http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

7. **"CLAIM EDITS"** 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.

8. **CHANGE IN MANUAL REVIEW PA FOR THE AGE OF CHILDREN PRESCRIBED ANTIPSYCHOTIC AGENTS, EFFECTIVE JANUARY 1, 2017:** 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.

9. **SECOND GENERATION ANTIDEPRESSANTS, TRAZODONE, AND TRICYCLIC ANTIDEPRESSANTS PRESCRIBED TO CHILDREN ≤ 3 YEARS OF AGE, *EFFECTIVE MARCH 8, 2017*:** 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.

10. **REGARDING EMERGENCY OVERRIDE**: 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* in an emergency situation 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/.

11. **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.

12. **HARD EDIT ON EARLY REFILL FOR CONTROLLED AND NON-CONTROLLED DRUGS:** The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner 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.

13. **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.

14. **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.

15. **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.

16. **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.

17. **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.

18. **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.

19. **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.

20. **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

21. **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.