ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Pharmacy Program

P.O. Box 1437, Slot S415 · Little Rock, AR 72203-1437
Phone: 501-683-4120 · Fax: 1-800-424-5851

MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

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

DATE: **February 20, 2017**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board JANUARY 18, 2017 meeting and PDL changes approved by the PDL Drug Review Committee meeting FEBRUARY 1, 2017:**

ADDITIONS TO THE AR MEDICAID PREFERRED DRUG LIST (PDL): Please see the list below for the changes or additions to Preferred-status agents in the following categories: buprenorphine-containing agents for treating opiate dependence; Pulmonary Arterial Hypertension (PAH) Agents; Topical Pediculicide Agents for Treating Head Lice Infestations; Topical Antifungal Agents.

CHANGES TO EXISTING POINT OF SALE (POS) PRIOR AUTHORIZATION (PA) CRITERIA OR NEW POS PA CRITERIA OR EDITS: COPD drug criteria revised; Opioid MME Reduction to 250 MME/day; Enbrel® (etanercept) injection; Methadone Oral Solution for NAS; Sensipar® (cinacalcet) tablet;

CHANGES TO EXISTING MANUAL REVIEW PA CRITERIA OR NEW MANUAL REVIEW PA CRITERIA: Xolair® (omalizumab) injection; Humira® (adalimumab) injection; Cabometyx® (carbozantinib) tablet; Zinplava™ (bezlotoxumab) IV infusion; Orkambi® (lumacaftor/ivacaftor) tablet;

PLEASE NOTE:

The m*aximum Medicaid allowed quantity for a short-acting opioid was reduced on April 26, 2016 from 124 units to 93 units for a 31-day supply. Using a daily dose quantity of 6 units per day is only for short-term acute pain situations and not for chronic pain prescriptions that are dispensed monthly.* *Dispensing 93 units and shortening the days' supply to 16 days increases the calculated daily MME dose; shortening the days' supply on a submitted claim does not allow the next short-acting opioid prescription to be filled sooner because the quantity limit per prescription is also an accumulation quantity limit for all short-acting opioids the beneficiary received in the previous 31 days of the review and cannot be overridden.*

REGARDING MANUAL REVIEW PA REQUESTS: Drugs that require a clinical manual review PA, requests for a drug as an *exception* to established prior approval criteria algorithm, and requests for non-preferred drugs on the PDL, are reviewed on a case-by-case basis. Prescribers must provide a letter explaining the medical necessity for the requested drug or drug formulation along with all written documentation, e.g., chart notes, pharmacy printouts for cash and private insurance paid drugs, lab results, etc., to substantiate the medical necessity of the request. ***Please note that starting the requested drug, including long-acting injectable antipsychotic agents, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.***

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. Each request will be reviewed on a case-by-case basis.

All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at https://arkansas.magellanrx.com/provider/documents . *Reimbursement rates, (EAC or MAC), stated in this memo are informational only and are only current as of the writing of this memo; the EAC and MAC rates stated are approximate as they have been rounded.*

A. PDL CHANGES:

NOTATIONS ARE MADE BELOW FOR CHANGES TO THE PREFERRED DRUG LIST (PDL) PER THE FEBRUARY 1, 2017 PDL DRUG REVIEW COMMITTEE*
(**existing quantity edits and PA criteria for preferred drugs remain in place in all categories*)

EFFECTIVE APRIL 1, 2017

1) Buprenorphine-containing agents, *indicated as once daily dosing*, for treating opiate dependence:
NEW TO PDL

Preferred Agents with PA Criteria:
- buprenorphine sublingual tablets
- buprenorphine/naloxone sublingual film (Suboxone® SL Film)

Non-Preferred Agents:
- buprenorphine/naloxone buccal film (Bunavail®)
- buprenorphine/naloxone sublingual tablets (Zubsolv®)
- buprenorphine/naloxone sublingual tablets (generic)

2) Pulmonary Arterial Hypertension (PAH) agents:
NEW TO PDL

Preferred PAH Agents with PA Criteria:
- sildenafil tablets (Revatio®)
- tadalafil (Adcirca®)
- bosentan (Tracleer®)
- ambrisentan (Letairis®)

Non-Preferred Agents:
- sildenafil suspension (Revatio®)
- macitentan (Opsumit®)
- riociguat(Adempas®)
- Selexipag (Uptravi®)
- treprostinil (Orenitram®)
- iloprost (Ventavis®)
- treprostinil (Tyvaso®)

3) Topical Pediculicide Agents for Treating Head Lice Infestations:
NEW TO PDL

Preferred Pediculicide Agents with PA Criteria:
- permethrin 1% topical liquid OTC (e.g., Lice Killing liquid, Lice Treatment)
- piperonyl butoxide 4% /pyrethrum extract 0.33% OTC (e.g., Lice Killing Shampoo, Complete Lice Treatment, Lice Killing shampoo)
- permethrin 5% cream (Elimite™)

Non-Preferred Agents:
- benzyl alcohol lotion 5% (Ulesfia®) (Ulesfia® currently not payable in system due to manufacturer discontinuation of NDC)
- crotamiton cream 10% (Eurax®)
- ivermectin lotion 0.5% (Sklice®)
- lindane 1% lotion and shampoo
- malathion lotion 0.5% (Ovide®)
- spinosad suspension 0.9% (Natroba™)

4) Topical Antifungal Agents and Antifungal/Corticosteroid Agents:
NEW TO PDL

Preferred Topical Antifungal Agents:

- Tolnaftate 1% topical cream OTC
- Tolnaftate 1% topical powder OTC
- Tolnaftate 1% topical solution OTC
- Clotrimazole 1% Rx Cream
- Clotrimazole-Betamethasone Rx Cream
- Ketoconazole 2% Rx Shampoo
- Nystatin ointment, cream, powder

Non-Preferred Topical Antifungal Agents:

- Econazole 1% cream, foam
- Clotrimazole-Betamethasone Rx lotion
- Ketoconazole 2% cream, foam (Extina® Foam),
- Luliconazole cream 1% (Luzu™)
- Oxiconazole 1% cream, lotion (Oxistat®)
- Sertaconazole 2% cream (Ertaczo®)
- Sulconazole 1% solution, cream (Exelderm®)
- Miconazole 0.25%/zinc oxide 15%/white petrolatum ointment 81.35% (Vusion® OIntment)
- Naftifine cream and gel (Naftin®)
- Butenafine 1% cream (Mentax®)
- Nystatin emollient cream (Pediaderm® AF)
- Nystatin/triamcinolone ointment and cream

Non-Preferred Topical Antifungal Agents for Onychomycosis:

- ciclopirox 8% topical nail solution (Penlac® Nail Lacquer)
- efinaconazole 10% topical nail solution (Jublia®)
- tavaborole 5% topical nail solution (Kerydin®)

PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800- 424-5739.**

B. NEW POINT OF SALE (POS) PRIOR AUTHORIZATION (PA) CRITERIA OR CHANGES TO EXISTING POS PA CRITERIA:

EFFECTIVE: APRIL 18, 2017:

1) COPD POS Drug Criteria Changes:

The Global Initiative for Chronic Obstructive Lung Disease 2017 Report has changed some of its guideline recommendations from previous years. The Point of Sale (POS) criteria for the drugs used to treat COPD have been revised to be in agreement with the GOLD 2017 guidelines.

i) Definition of a COPD patient for POS PA criteria involving a COPD drug includes the following:
   (1) Beneficiary age of ≥ 40 years AND
   (2) ICD-9 diagnosis code 496 OR ICD-10 diagnosis code J44.9 found in Medicaid history in the past 2 years.

ii) Preferred Agents for Long-acting Antimuscarinic Antagonist (LAMA) or Long-acting $Beta_2$-agonist (LABA) POS Approval criteria (Spiriva® (tiotropium) and/or Serevent® (salmeterol)) in long-acting bronchodilator PDL category:
   (1) COPD diagnosis in history in previous 2 years AND
   (2) Beneficiary is ≥ 40 years of age, AND
   (3) No Therapeutic Duplication (TD) with overlapping days' supply between drugs in the same drug classification, e.g., patient cannot have 2 LAMA drugs, or 2 LABA drugs with overlapping days' supply.

POS Approval criteria will allow COPD patients to have one LAMA + one LABA per GOLD guidelines.

The denial criterion of a COPD patient with an asthma diagnosis in history in previous 2 years is removed from the preferred drugs in the long-acting bronchodilator PDL category (Spiriva and Serevent).

iii) Preferred Agents on PDL for ICS single entity drug now has Denial Criteria for COPD patient:
(a) COPD in diagnosis history in previous 2 years; AND
(b) Beneficiary is ≥ 40 years of age,
(c) ICS single entity agent DENIED at POS; ICS monotherapy is not first line for COPD:

COPD patients can use triple inhaled therapy LAMA + LABA + ICS per GOLD guidelines.

If COPD patient is already receiving LAMA + LABA therapy and therapy cannot be changed to a preferred fixed dose combination ICS/LABA, prescriber must request a preferred single entity ICS agent through a manual review PA request if requesting for triple inhaled therapy.

No therapeutic duplication of 2 ICS drugs.

iv) Preferred Agents on PDL for Fixed Dose Combination ICS/LABA (Symbicort®, Dulera®, or Advair Diskus®) POS Approval Criteria revised for COPD patients:
(1) COPD diagnosis in previous 2 years AND
(2) Beneficiary ≥ 40 years of age.

The requirement of use of other drugs (e.g., ICS, LAMA, LABA, or oral steroid claims) in history for the COPD patient is removed from the fixed dose ICS/LABA preferred agents. A fixed dose combination ICS/LABA can be used first line in a higher risk severe COPD patient with persistent exacerbations (GOLD Group C) although the GOLD guidelines recommend LABA-LAMA combination therapy as the primary choice.

v) Montelukast approval for COPD patient for *treating allergies only* is revised to the following:
(1) COPD diagnosis in previous 2 years AND
(2) Beneficiary is ≥ 40 years of age AND
(3) One of the following criteria below:
- > One claim for an inhaled nasal steroid from the 7th day to the 124th day in Medicaid history, OR
- > One claim for a second generation antihistamine from the 7th day to the 124th day in Medicaid history

vi) Daliresp (roflumilast) is a non-preferred drug on the PDL for COPD drugs.
Requests for roflumilast will be reviewed on a case-by-case basis. Internal review criteria for approval will require, at a minimum, ALL of the following:
1) The prescriber must submit the request in writing and explain the medical necessity of receiving roflumilast. The prescriber must also include documentation as required to support the request as outlined below:
2) The COPD patient must meet the assessment criteria for severe or very severe COPD Group D (FEV_1 is < 50% predicted) per the 2017 GOLD guidelines;
3) The COPD patient must also have diagnosis of chronic bronchitis; if chronic bronchitis diagnosis is not in Medicaid history, provider must provide chart notes for documentation;
4) COPD Group D patient must already be receiving "triple inhaled therapy" of LAMA + LABA + ICS at the time of the roflumilast request, using either fixed dose combination inhalers or single entity inhalers, AND
(i) Must be compliant on triple inhaled therapy for at least 3 months of claims for each drug in previous 4 months; if Medicaid drug profile does not document compliance (e.g., new to Medicaid), provider must submit a retail pharmacy drug profile documenting compliance with "triple inhaled therapy" for required time period;
5) COPD patient must also have a history of continued exacerbations while on triple inhaled therapy drugs, either frequent exacerbations (2 or more per year) or at least one hospitalization for an exacerbation in the previous year while on triple inhaled therapy.
6) Prescriber must submit smoking status for patient. If the COPD Group D patient is a current smoker, request for roflumilast is automatically denied.

PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800- 424-5739.**

EFFECTIVE MAY 9, 2017:

2) Morphine Milligram Equivalents (MME) Maximum Daily Dose Is *DECREASING*:
In 2013, AR had 319 drug overdose deaths; in 2014, AR had 356 drug overdose deaths. Per the CDC statistics, *Arkansas showed an 11.6% increase in drug overdose death* from 2013 to 2014. Although AR did

not rank high in the number of overdose deaths compared to other states, AR was included in the list of 13 states that have the *highest number of opioid prescriptions per person* when compared to the remaining other 37 states.

The ***current maximum daily dose limit of 300 Morphine Milligram Equivalents (MME)*** for all short-acting opioid drugs, long-acting opioid drugs, or a combination of both, for chronic pain non-cancer patients was implemented on November 8, 2016.

The Medicaid Pharmacy Program will continue reducing the maximum allowed Morphine Milligram Equivalent (MME) daily dose for chronic pain non-cancer patients by 50 MME approximately every 6 months to reduce the overdose risk and other risks associated with opioid use until the daily MME is closer to the recommendations from the CDC and CMS. The purpose of the imposed MME limits is to improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. ***The ultimate Medicaid goal is to reduce the total MME/day for chronic non-cancer pain patients to between 90 - 100 MME/day or less.***

Per the CDC, "Opioids are not first-line therapy" for chronic pain. Although opioids can reduce pain during *short-term use,* the clinical evidence review found *insufficient evidence* to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.

Per the CDC Guideline for Prescribing Opioid for Chronic Pain, 2016, the CDC recommendations regarding opioid MME daily dose include the following:

- The CDC considers *high opioid dosages ≥ 90 MME/day*.
- Benefits of high-dose opioids for chronic pain are not established.
- Risks for serious harms related to opioid therapy increase at higher opioid dosage.
- A single dosage threshold for safe opioid use could not be identified.
- Most experts agreed that, in general, increasing dosages to *50 or more MME/day increases overdose risk without* necessarily *adding benefits* for pain control or function.
- Most experts also agreed that opioid dosages *should not* be increased to ≥ 90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.
- Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks.
- *Dosages ≥ 100 MME/day are associated with increased risks of overdose 2.0–8.9 times* the risk at 1 to < 20 MME/day.
- A recent study of patients aged 15-64 years receiving opioids for chronic non-cancer pain and followed for 13 years revealed that *1 in 32 patients who escalated to opioid dosages > 200 MME/day died from opioid-related overdose*.
- *Concurrent use of benzodiazepines and opioids is likely to put patients at greater risk for potentially fatal overdose*, particularly if benzodiazepine(s) are combined with higher dosages of opioids ≥ 50 MME/day. Concurrent opioid and benzodiazepine prescribing should be avoided.

The Medicaid pharmacy program system converts the dose of all oral and transdermal opioid drug claims to morphine milligram equivalents (MME) per day *based on the quantity dispensed and the days' supply submitted* by the pharmacy provider on the opioid claim. The calculated MME *includes claims in history* if the incoming claim is being *filled early* and has 3 days or more overlapping with the days' supply of the claim(s) in history.

As a reminder, the maximum Medicaid allowed monthly quantity limit for a non-cancer chronic pain beneficiary for a short-acting (SA) opioid was **reduced** on April 26, 2016 from 124 units to **93** units for a 31-day supply. Using a daily dose quantity of 6 units per day is only for short-term acute pain situations and *not for chronic pain patients receiving the prescription monthly*. *Dispensing 90 units and shortening the days' supply to 15 days increases* the calculated daily MME dose, which *could cause* opioid claims to reject at point of sale due to calculated high MME/day. Shortening the days' supply on a submitted claim *does not* allow the next short-acting opioid prescription to be filled sooner because the quantity limit per prescription is also a SA opioid *accumulation limit* for all SA opioid dispensed in the previous 31 days.

As an additional reminder, therapeutic duplication of more than one long-acting opioid for concurrent therapy is not allowed in the POS PA criteria for any Medicaid beneficiary. The LA opioid criteria rule will allow for *an inferred change in therapy only* for beneficiaries with a malignant cancer diagnosis in Medicaid history in the previous 365 days. The inferred change in therapy rule will allow *one therapeutic duplication* with

overlapping days' supply between two different LA opioid agents once per 93 days. The two drug claims must have different dates of service for the inferred change of therapy rule to apply.

EFFECTIVE MAY 9, 2017, the Medicaid Pharmacy Program will *reduce the total daily MME dose to 250 MME/day* for chronic non-cancer pain patients receiving short-acting opioid, long-acting opioid, or both, whether from same prescriber or different prescribers. Incoming opioid claims that will cause the total MME/day to *exceed* 250 MME/day (>250 MME/day) will reject at point of sale.

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: MAY 23, 2017:

3) Methadone oral solution for NAS (Neonatal Abstinence Syndrome):

Methadone tablets and oral solution were changed to non-preferred status on August 8, 2016 for chronic non-cancer pain patients. *Beneficiaries receiving Methadone tablets or oral solution through point of sale criteria for malignant cancer continue to be audited through a manual review process.*

For infants with Neonatal Abstinence Syndrome (NAS) for whom methadone oral solution is prescribed for short-term use after discharge from the hospital, point of sale approval criteria has been developed as follows:

i) Infant has his / her own Medicaid ID in the Medicaid system and has prescription drug benefits; AND
ii) The infant's age is ≤ 90 days of age at the time the drug claim is submitted; AND
iii) The quantity of methadone oral solution dispensed is not more than 10 ml for a 30-day supply; AND
iv) The incoming claim and the claim in history will not make the accumulated quantity of methadone oral solution more than 10 ml for the previous 30-day supply; AND
v) Methadone oral solution for an infant older than 90-days who does not have malignant cancer diagnosis in the Medicaid diagnosis history, or the methadone oral solution accumulation quantity for a 30-day period will exceed 10 ml, will require manual review PA. The prescriber must send letter explaining medical necessity, quantity requested, dose, and taper plan schedule with the PA request.

PDL PA Call Center 1-800-424-7895; the PDL FAX number is 1-800- 424-5739.

4) ENBREL® (etanercept) INJECTION:

EAC $529 per syringe or pen

ENBREL® (etanercept) is FDA approved for use in patients 4 years and older with chronic moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy.

The POS approval criteria age has been changed as follows:

Criterion 1:

- Submitted diagnosis of psoriasis (Table 5) in the past two years,

AND

- Age ≥ 4 years old, AND
- Paid Drug claim for etanercept (Enbrel) in the past 45 days (signifying above criteria previously met)

ii) Criterion 2:

- Submitted diagnosis of psoriasis (Table 5) in the past two years, AND
- Age ≥ 4 years old, AND
- During days 180 to 395 days ago, a total of > 180 days of topical drug therapy with: anthralin, calcipotriene, corticosteroids, or tazarotene in past 395 days, AND
- During days 1 to 210 ago, a total of > 180 days of systemic drug therapy with: cyclosporine, methotrexate, or acitretin, AND
- Topical drug therapy trial occurred before systemic drug 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.

5) SENSIPAR® (cinacalcet) tablet 30 mg, 60 mg, 90 mg:

EAC 30 mg = $25.6968 each tablet
EAC 60 mg = $51.3936 each tablet
EAC 90 mg = $77.0904 each tablet

SENSIPAR® is indicated for the treatment of Secondary Hyperparathyroidism (HPT) in Adult Patients with Chronic Kidney Disease on Dialysis. *Limitations of Use: SENSIPAR® is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia*. The recommended starting oral dose of SENSIPAR® is 30 mg once daily. Serum calcium and serum phosphorus should be measured within 1 week and intact parathyroid hormone (iPTH) should be measured 1 to 4 weeks after initiation or dose adjustment of SENSIPAR®. SENSIPAR® should be titrated no more frequently than every 2 to 4 weeks through sequential doses of 30, 60, 90, 120, and 180 mg once daily to target iPTH levels of 150 to 300 pg/mL. Serum iPTH levels should be assessed no earlier than 12 hours after dosing with SENSIPAR®.

SENSIPAR® is indicated for Parathyroid Carcinoma and Primary Hyperparathyroidism. The recommended starting oral dose of SENSIPAR® is 30 mg twice daily. The dose of SENSIPAR® should be titrated every 2 to 4 weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, and 90 mg twice daily, and 90 mg 3 or 4 times daily as necessary to normalize serum calcium levels. Serum calcium should be measured within 1 week after initiation or dose adjustment of SENSIPAR®.

SENSIPAR® is indicated for the treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

Clinical POS approval criteria or manual review PA criteria will apply as follows:
Criterion 1: **POS PA approval criteria** for Treatment of Secondary Hyperparathyroidism (HPT) In Adult Patients with Chronic Kidney Disease (CKD) On Dialysis,

- Diagnosis in Medicaid medical history in previous 2 years of BOTH diagnoses codes for:
  - "Secondary HTP of renal origin" (ICD-9 code 588.81, or ICD-10 code N25.81),

AND

  - "ESRD CKD requiring Chronic Dialysis" (ICD-9 code 585.6 or ICD-10 code N18.6).

Manual review PA will be on a case-by-case basis if either diagnoses code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 2: **POS PA approval criteria** for Treatment of Hypercalcemia in Adult Patients with Parathyroid Carcinoma.

- Diagnosis in Medicaid medical history in previous 2 years of BOTH diagnoses codes for:
  - Cancer of the parathyroid gland, ICD-9 code 194.1, or ICD-10 code C75.0

AND

  - Hypercalcemia, ICD-9 code 275.41, or ICD-10 code E83.52

Manual review PA will be on a case-by-case basis if either diagnoses code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 3: **Manual review PA criteria** will be on a case-by-case basis for treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy:

- Manual review on a case-by-case basis. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis.

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

C. NEW MANUAL REVIEW PRIOR AUTHORIZATION CRITERIA OR CHANGES TO MANUAL REVIEW PA CRITERIA:

EFFECTIVE IMMEDIATELY:

1) XOLAIR® (omalizumab) INJECTION 150 mg vial:
EAC: 150 MG VIAL = $1,014.62 per each vial

XOLAIR® is indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

XOLAIR® has been shown to decrease the incidence of asthma exacerbations in these patients.
Limitations of Use:
XOLAIR® is not indicated for the relief of acute bronchospasm or status asthmaticus.
XOLAIR® is not indicated for treatment of other allergic conditions.

The dosage methodology for asthma has not changed; the dose is calculated using the IgE level and body weight and comparing that to the allowed dose in the chart included in the package insert. Calculated doses that would fall in the "Do Not Dose" area of the dosage chart will not be approved.

The manual review PA criteria for XOLAIR® remains the same for the asthma diagnosis for patients with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids, and the approval age has been changed to age 6 years and older (≥ 6 years). The PA form available on the Medicaid website does not need revision as it only requests the DOB on the form and does not make reference to "age" as part of 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.

2) HUMIRA® (adalimumab) SYRINGE OR PEN:
EAC = $2,114 per syringe or pen.

HUMIRA® has a new FDA approved indication, which is the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

The use of Humira for treating of non-infectious intermediate, posterior and panuveitis in adult patients is not first line or second line treatment. The manual review PA request will be reviewed on a case-by-case basis. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis, chart notes, and include data on all previous drugs tried for the treatment and explanation of failure, and treatment plan. The clinical reviewers will use data included in the package insert, data from treatment guidelines, and data from the expert panel recommendations during the clinical review of the PA request.

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

3) CABOMETYX ® (cabozantinib) tablets 20 mg, 40 mg, and 60 mg:
EAC: 20 mg tablet, 40 mg tablet, or 60 mg tablet = $496.65 each tablet

CABOMETYX TABLET is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. Do not substitute CABOMETYX tablets with cabozantinib *capsules*; cabozantinib *capsules* (COMETRIQ), is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC) and the recommended daily dose of COMETRIQ is 140 mg (one 80-mg and three 20-mg capsules).

The recommended daily dose of CABOMETYX is 60 mg. Do not administer CABOMETYX with food. Instruct patients not to eat for at least 2 hours before and at least 1 hour after taking CABOMETYX. Continue treatment until patient no longer experiences clinical benefit or experiences unacceptable toxicity. See package insert for dosage adjustments for adverse reactions and drug-drug conflicts.

CABOMETYX tablet will require manual review PA on a case-by-case basis for advance renal cell carcinoma, and patient must have received prior anti-angiogenic therapy with everolimus. A quantity edit of 1 tablet per day will be applied to each strength tablet, or 31 tablets for a 31 days' supply, and the standard refill allowance rate will apply.

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

4) ZINPLAVA™ (bezlotoxumab) solution, injection for IV infusion; available as 1,000 mg/40 mL (25 mg/mL):

EAC: pricing is per ml @ $98.04 per ml, 40 ml vial = $3,921.60 per vial; 1-40 ml vial will dose a person up to 100 kg.

ZINPLAVA™ injection is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence. "High risk for CDI recurrence" is defined as patients aged 65 years and older, or with a history of CDI in the past 6 months, or immunocompromised state, or severe CDI at presentation, or C. difficile ribotype 027.

ZINPLAVA™ injection will require manual review PA on a case-by-case basis. Prescriber must submit request in writing and provide documentation of medical necessity, and the patient's weight. At a minimum ALL of the following criteria will apply and prescriber must supply chart notes and documentation required:

- Patient has confirmed CDI; AND
- Patient currently receiving vancomycin HCl, metronidazole, or fidaxomicin for treatment of CDI; AND
- Patient is at high risk for CDI recurrence, defined as:
  - ≥ 65 years of age; OR
  - History of 1 or more episodes of CDI within 6 months prior to current episode under treatment; OR
  - Patient is immunocompromised; OR
  - Current episode is clinically severe CDI with a Zar score of ≥ 2; OR
  - Patient has a hypervirulent strain ribotypes 027 was isolated in a positive baseline culture;

AND

- A quantity edit of 1 vial for a single dose will be applied to the drug; if more than one vial is needed for the single dose for patient weight greater than 220 lb. (100 kg), the quantity edit can be overridden at time of PA request approval. The safety and efficacy of repeat administration of ZINPLAVA in patients with CDI have not been studied and will not be approved. A second dose of Zinplava cannot be administered sooner than 12 weeks after the previous dose and must be for a separate CDI occurrence

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

5) ORKAMBI® (lumacaftor 200 mg /ivacaftor 125 mg, or 100/125 mg) tablet:
EAC: either strength, 200/125 or 100/125 = $183.58 each tablet. Supplied as 112 count box = $20,560.95 for a 28-day supply.

ORKAMBI is a combination of lumacaftor and ivacaftor indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

LIMITATIONS OF USE
The efficacy and safety of ORKAMBI have not been established in patients with CF other than those homozygous for the F508del mutation.

The dose for patients, age 6 years through 11 years, is 2 lumacaftor 100 mg/ivacaftor 125 mg tablets every 12 hours. The dose for age 12 years and older has not changed and is still 2 lumacaftor 200 mg/ivacaftor 125 mg tablets every 12 hours.

The ORKAMBI® approval age has been changed and will allow patients age 6 years – 11 years approval for the strength tablet 100-125 mg tablet only. All previous manual review approval criteria and continuation criteria apply to the new approval age and to the lower strength tablet.

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. **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 (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.** This manual review is performed by the Medicaid Pharmacy Program board certified child

& adolescent psychiatrist. All documentation, chart notes, signed informed consent, and required lab work must be submitted and will be reviewed by the Medicaid Pharmacy Program child & adolescent psychiatrist.

2. **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. Each request will be reviewed on a case-by-case basis.

3. **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. Frequency of the emergency override is limited to once per year per drug class or drug category for non-LTC-eligible beneficiaries and once per 60 days per class for LTC-eligible beneficiaries. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, https://arkansas.magellanrx.com/provider/documents/.

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

5. **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. 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.

6. **REFILL TOO SOON ACCUMULATION LOGIC:** 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. 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.

7. **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.

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

9. **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.

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

11. **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.

12. **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. 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.

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

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.