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: **September 1, 2017**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board JULY 19, 2017 meeting and PDL changes approved by the PDL Drug Review Committee meeting August 9, 2017**

ADDITIONS TO THE AR MEDICAID PREFERRED DRUG LIST (PDL): Please see the PDL list below for specific Preferred-status and Non-preferred status agents in the following categories that are being added to the PDL for Long-acting injectable antipsychotic drugs and Anti-diabetes drugs in the following categories: TZDs, SGLT2 Inhibitors, DPP-4 Enzyme Inhibitors, GLP-1 Receptor Agonists, Meglitinides.

CHANGES TO EXISTING PA CRITERIA EDITS: ESBRIET® (pirfenidone) tablet/capsule; OFEV® (nintedanib) capsule; LYRICA® (pregabalin) capsule and oral solution; BUTALBITAL combination products that do not contain codeine; LINZESS™ (linaclotide) capsule; RELISTOR® (methylnaltrexone) SQ and oral tablet, MOVANTIK® (naloxegol) tablet, AMITIZA® (lubiprostone) capsule, TRULANCE™ (plecanatide) tablet;

CHANGES TO EXISTING CLAIM EDITS OR NEW CLAIM EDITS, INCLUDING AGE EDITS, DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS: CORTISPORIN® (neomycin and polymyxin b sulfates, bacitracin zinc, and hydrocortisone) ointment and cream; OPHTHALMIC ANTIBIOTIC drops; OPHTHALMIC ANTIBIOTIC-STEROID drops; OPHTHALMIC drops for treating GLAUCOMA; All OPIOID-CONTAINING ORAL LIQUIDS; CODEINE tablets, CODEINE-ACETAMINOPHEN TABLETS and oral solution, CODEINE-GUAIFENESIN COUGH/COLD PREPARATIONS, TRAMADOL IR tablets, TRAMADOL-ACETAMINOPHEN tablets, and TRAMADOL ER tablets and capsules;

NEW CLINICAL POS EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS: CYSTADANE® (betaine) powder for oral solution;

NEW MANUAL REVIEW EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS: RHOFADE™ (oxymetazoline) topical cream; ZEJULA™ (niraparib) capsule; 3) DUPIXENT® (dupilumab) SQ Injection; ZOLINZA® (vorinostat) capsule; 5) CAPRELSA® (vandetanib) tablet; ALUNBRIG™ (brigatinib) tablet; RYDAPT® (midostaurin) capsule; KISQALI® (ribociclib) tablet and KISQALI® FEMARA® (letrozole) CO-PACK;

REMINDERS: MME changes; Manual Review PA Requests;

CLARIFICATION: KALYDECO® (ivacaftor)

All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at https://arkansas.magellanrx.com/provider/documents . *Medicaid Pharmacy Program drug reimbursement rate methodology changed April 1, 2017; reimbursement rates stated in this memo are informational only and are only current as of the date the memo was drafted; the rates stated are approximate as they have been rounded.*

REMINDERS:

1) **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on MAY 9, 2017 to ≤ 250 MME/day, and *WILL DECREASE AGAIN* ON NOVEMBER 8, 2017, for non-cancer chronic pain beneficiaries.** Incoming opioid claims that will cause the total MME/day to exceed the existing limit of 250

MME/day (>250 MME/day) will reject at point of sale whether from same prescriber or different prescribers. **On NOVEMBER 8, 2017, the Maximum Daily Morphine Milligram Equivalent (MME) Dose will DECREASE to ≤ 200 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that will cause the total MME/day to exceed **200 MME/day** (>200 MME/day) on that date *will reject at point of sale* whether from same prescriber or different prescribers. *Please begin titrating the doses downward to prevent claims rejecting at point of sale.*

2) **On JULY 19, 2017 the new MME Limit of ≤ 90 MME/day for "New Starts" to opioids was implemented:** The maximum daily MME will not exceed 90 MME/day for Medicaid beneficiaries who do not have paid opioid drug claims in Medicaid history in the previous 60 days. Prescribers may submit chart notes and applicable documentation (including pharmacy printout if the patient is new to Medicaid and had previously filled with another insurance or paid cash) to request prior authorization for the medical necessity of a beneficiary to receive doses > 90 MME/day and the request will be reviewed.

3) **REGARDING MANUAL REVIEW PA REQUESTS:** Prior authorization (PA) requests for drugs that require a clinical manual review prior approval, prior authorization requests for a drug as an *exception* to established point of sale 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 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 Pharmacy Program approval of the PA request.***

CLARIFICATION:

1) **KALYDECO® (ivacaftor) tablet**: Clarification of approval criteria from the June 8, 2016 Provider Memo regarding the R117H mutation stated below.

R117H is a mutation that is known to be affected by intragenic modification. The R117H does not act as a CF-causing mutation if it is not in combination with another CF-causing mutation. Whether or not R117H causes disease is based on another region of the CFTR gene called the poly-T tract. The poly-T tract is present in every copy of the CFTR gene and occurs in one of three forms: 5T, 7T, or 9T. *Depending on which poly-T form is present in the same copy of the CFTR gene with R117H*, differing outcomes may occur. These possible combinations and their outcomes are listed in the table below. [1] [2] [3]

In order to correctly interpret the table, it is necessary to know the phase of the mutations. The phase refers to the specific combination of mutations that are present together in the same copy of the CFTR gene. For example, a patient may have the following mutation: R117H/G551D and 5T/7T. *Determining the phase* means *determining which poly-T variation* (for example, 5T or 7T in above illustration) *is in the same copy of the CFTR gene with the R117H* and which is in the same copy of the CFTR gene with G551D.

One mutation:	Second mutation: R117H + which poly-T variation?	Predicted outcome:
CF-causing mutation, such as F508del	R117H and 5T	R117H **will likely** act as a disease-causing mutation. Most patients with this combination of mutations and the 5T form of the poly-T tract will have elevated sweat chloride and clinical symptoms of CF. Symptoms for these patients may be variable. There is an increased risk for male infertility.
CF-causing mutation, such as F508del	R117H and 7T	R117H is **unlikely** to act as a disease-causing mutation (particularly for females), but may result in male infertility. However, a person with this combination of mutations and this form of the poly-T tract may have borderline or elevated sweat chloride and mild clinical symptoms of CF.

[1] FDA CDER Meeting of the Pulmonary-Allergy Drugs Advisory Committee. Guest Speaker Presentations. Overview of Cystic Fibrosis-Causing Mutations. Testimony by Patrick Sosnay, MD, pp. 50-54. Retrieved January 4, 2016, https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/pulmonaryallergydrugsadvisorycommittee/ucm433343.pdf

[2] Kalydeco® (Ivacaftor) Treatment for Cystic Fibrosis, Vertex Pharmaceuticals Incorporated, PowerPoint Presentation Pulmonary and Allergy Drugs Advisory Committee October 21, 2014. Presentation slide deck. Slide CM-10. Retrieved January 6, 2016.

[3] CFTR2 website. Clinical and Functional Translation of CFTR. Variant R117H Overview. US CF Foundation, Johns Hopkins University. Retrieved January 4, 2016. https://www.cftr2.org/r117h

CF-causing mutation, such as F508del	R117H and 9T	R117H is **highly unlikely** to act as a disease-causing mutation. The vast majority of individuals will not have CF. Male fertility is typically **not** affected by R117H and 9T.

Ivacaftor requires a manual review for all prior authorization (PA) requests on a case-by-case basis for all CF patients. The June 2016 Provider Memo stated: "For PA requests regarding the R117H mutation, requests will be reviewed on a case-by-case basis. Prescriber must submit documentation of the R117H mutation and the phase of the mutations explained above, and the standard documentation for clinical symptoms of CF." *For clarification purposes*, the memo should have been more clearly stated as: For PA requests regarding the R117H mutation, prescribers must submit documentation for the R117H mutation, documentation for the additional CFTR CF-causing mutation, documentation for the specific poly-T variation, documentation of which poly-T variation is in the same copy of the CFTR gene with the R117H as explained above, documentation of elevated sweat chloride, and documentation that the patient has clinical symptoms that require treatment using standard of care for treating CF.

PDL CHANGES, EFFECTIVE October 1, 2017:

Additions and changes below to the preferred drug list (PDL) are from the August 9, 2017 PDL Drug Review Committee (DRC) meeting
PDL PA Call Center 1-800-424-7895; t**he PDL FAX number is 1-800-424-5739.**

1) LONG-ACTING INJECTABLE (LAI) ANTIPSYCHOTIC AGENTS:
CATEGORY IS NEW TO PDL

****PREFERRED with criteria** Status,
***Existing MANUAL REVIEW PA for "new starts" on a preferred agent will continue; POS continuation "stable & compliant" criteria will continue;*

- fluphenazine decanoate
- haloperidol decanoate
- Abilify Maintena® (aripiprazole ER)
- Aristada® (aripiprazole lauroxil ER)
- Zyprexa Relprevv™ (olanzapine)
- Risperdal Consta® (risperidone microspheres)

NON-PREFERRED Status (*only *existing POS continuation "stable and compliant" on drug/same dose) criteria will remain)*

- *Invega Sustenna® (paliperidone palmitate)
- Invega Trinza® (paliperidone palmitate)

2) ANTI-DIABETES AGENTS:
CATAGORY RE-REVIEW

a) TZDs

PREFERRED with criteria Status, MANUAL REVIEW PA will continue

- pioglitazone

NON-PREFERRED Status

- Avandia® (rosiglitazone)
- Avandamet® (rosiglitazone/ metformin)
- pioglitazone/ metformin
- brand name Actos (pioglitazone)
- Actoplus Met (pioglitazone/ metformin)
- Actoplus Met XR (pioglitazone/ metformin extended-release)
- Duetact (pioglitazone/ glimepiride)

b) SGLT2 Inhibitors,

PREFERRED with criteria Status, with MANUAL REVIEW PA will continue

- Farxiga® (dapagliflozin)
- Xigduo® XR (dapagliflozin/ metformin ER)
- Jardiance® (empagliflozin)
- Synjardy® (empagliflozin/metformin)

NON-PREFERRED Status

- Invokana® (canagliflozin)

- Invokamet® (canagliflozin/ metformin)
- Invokamet® XR (canagliflozin/ metformin)
- Synjardy® XR (empagliflozin/ metformin ER)

c) DPP-4 Enzyme Inhibitors,

PREFERRED with criteria Status, with MANUAL REVIEW PA will continue

- Janumet® (sitagliptin/metformin)

NON-PREFERRED Status (DPP-4 Enzyme Inhibitors continued)

- Nesina (Alogliptin)
- Kazano (alogliptin/metformin)
- Oseni (alogliptin/pioglitazone)
- Glyxambi® (linagliptin/empagliflozin)
- Onglyza® (saxagliptin)
- Kombiglyze® XR (saxagliptin/metformin ER)
- Janumet® XR (sitagliptin/metformin extended release)
- Tradjenta® (linagliptin)
- Jentadueto® (linagliptin/metformin)
- Januvia® (sitagliptin)

d) GLP-1 Receptor Agonists,

PREFERRED with criteria Status, with MANUAL REVIEW PA will continue

- Byetta® (exenatide)
- Bydureon® (exenatide ER)
- Victoza® (liraglutide)

NON-PREFERRED Status

- Tanzeum® (albiglutide)
- Trulicity® (dulaglutide)
- Xultophy® (liraglutide/insulin degludec)
- Adlyxin™ (lixisenatide)
- Soliqua™ 100/33 (lixisenatide/insulin glargine)

e) Meglitinides.

PREFERRED with criteria Status with MANUAL REVIEW PA will continue

- nateglinide
- repaglinide

NON-PREFERRED Status

- repaglinide/ metformin

CHANGES TO EXISTING MANUAL REVIEW PA CRITERIA, OR CHANGES TO EXISTING CLAIM EDITS:

EFFECTIVE IMMEDIATELY:

1) **IPF DRUGS:** Manual review PA criteria have been revised.
   WAC: ESBRIET® 267 mg tablet or capsule, TID dosing = $31.54 each, #270 per month = $8,517.60; ESBRIET® 801 mg tablet = $94.64 each, #90 = $8,517.60 /30-day supply;
   WAC: OFEV 100 mg or 150 mg capsule, BID dosing = $144.00 each; #60 per month = $8,640 /30-day supply.

   OFEV® (nintedanib) capsule: OFEV® is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

   Revised approval criteria for OFEV® require all of the following:
   - Each request is reviewed on a case-by-case basis;
   - The request for OFEV® is because Beneficiary is unable to continue taking ESBRIET® due to allergy to ESBRIET® active ingredient or intolerance to ESBRIET®; AND
   - For allergy to ESBRIET®, Prescriber to provide all data and chart notes for treatment of allergy to ESBRIET®; AND

- For intolerance to ESBRIET®, Prescriber must include all data in chart notes documenting dose-related adverse effects, or intolerance, to ESBRIET® and documentation that dose was reduced and dates of reduction, in order to manage dose related adverse effects or intolerance; AND
- Prescribing provider to submit chart notes and all documents and test results, including updated tests as required in the ESBRIET® criteria, to substantiate the request to change to OFEV® that the beneficiary is allergic to or intolerant of ESBRIET®; AND
- Medicaid has the documentation that the Beneficiary previously met all initial approval criteria for ESBRIET®, and all documents and test results required for ESBRIET® approval were previously submitted to Medicaid by prescriber and the request for ESBRIET® was approved by Medicaid Pharmacy Program and the Medicaid drug profile contains ESBRIET® drug claim(s) and documentation data; AND

QUANTITY LIMIT for OFEV® shall remain as is. Child Pugh A may require a dose reduction; if dose reduction required, the reduced monthly quantity allowed shall be entered at the time of PA approval;

Revised Denial criteria for OFEV®
- OFEV® prescribed as the initial IPF drug therapy; or
- Switching to OFEV® because of failed treatment response to ESBRIET® therapy; or
- Beneficiary classified as Child Pugh B or Child Pugh C; or
- Absence of approval criteria;

ESBRIET® (pirfenidone) tablet and capsule:
Revised approval criteria for initial PA request for ESBRIET® shall require all of the following:
- Each manual review PA request is reviewed on a case-by-case basis;
- Beneficiary has diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung; AND
- Beneficiary must be a current non-smoker for approval and prescriber shall submit CO (carbon monoxide) test levels to substantiate non-smoker status; AND
- Prescriber must submit dose prescribed; AND
- Prescriber must submit PA request for ESBRIET® in writing and include documentation to substantiate medical necessity. At a minimum, all of the following are required:
- Chart notes;
- The IPF staging classification and data to support the staging;
- Submit liver function tests prior to initiating treatment and with each subsequent PA request; Note: Child Pugh A and Child Pugh B may need dose modification; if dose reduction is required, the reduced monthly quantity allowed shall be entered at the time of PA approval;
- Submit results of pregnancy test, if applicable; AND
- Submit pulmonary function tests (PFTs) at baseline prior to starting the drug and with each PA request, including %FVC and % predicted of the diffusing capacity of the lungs for carbon monoxide test (DLCO); AND
- Submit results of high resolution CT scan of lungs; AND
- Submit results of 6MWT distance test at baseline prior to starting the drug; AND
- Prescriber shall provide patient specific measurable goals for treatment outcomes with ESBRIET and include the treatment plan for possible ESBRIET® discontinuation if the treatment goals are not met;

Approval of initial PA request may be for up to 6 months.

QUANTITY LIMIT to remain as is unless otherwise specified on the prior authorization.

Denial criteria for ESBRIET®:
- Received lung transplant; or
- Recent MI or stroke; or
- Liver enzymes are >3 but ≤5 × ULN ALT and/or AST accompanied by symptoms or hyperbilirubinemia, or >5 × ULN ALT and/or AST; or
- Child Pugh C;

Revised approval CONTINUATION CRITERIA for ESBRIET®:
- Each manual review PA request is reviewed on a case-by-case basis. At a minimum, all of the following are required for an overall and ongoing assessment of the beneficiary:

- For continued approval, Beneficiary must be adherent to the prescribed drug therapy; Prescriber must provide the current prescribed dose with each PA request; if dose was reduced since last approved PA for any reason, prescriber must include all dates of dose modifications, or if dose interruptions occurred for any reason, prescriber must provide all dates for drug therapy interruptions. The Medicaid drug claims data will be reviewed and compared to prescribed dose, reduced dose, or interruptions to drug therapy and compared for adherence to therapy; AND
- For continued approval, Beneficiary must be current non-smoker; prescriber to submit CO (carbon monoxide) test levels to substantiate non-smoker status; AND
- Prescriber to submit current 6MWT distance results, which will be compared to baseline; AND
- Prescriber to submit current %FVC results and current %DLCO test results; which will be compared to baseline; AND
- Prescriber to submit liver function tests; AND
- Data submitted for continuation of drug will be compared to the prescribing provider's specific measurable goals for the beneficiary for treatment outcomes with ESBRIET® and the treatment plan that was submitted for possible ESBRIET® discontinuation if the treatment goals are not met;

Quantity edit for ESBRIET® will not be changed to a month-to-month quantity entry unless warranted. The adherence to the prescribed dose shall be monitored by the Medicaid clinical team reviewing the continuation requests, any dose changes to the drug, and drug claims data on the Medicaid drug profile. If it is determined the dose was reduced but the quantity dispensed by the pharmacy remained at a larger quantity, the start date of the continuation PA will be adjusted in order to accommodate the use of remaining medication on hand. At that time, if the dose reduction remains in place, the PA entered will be for the reduced quantity.

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 15, 2017

2) <u>LYRICA® (pregabalin) capsule and oral solution; AGE EDIT change</u>

NADAC Brand: 25 mg $6.04883; 50 mg $6.05; 75 mg $6.06; 100 mg $6.04; 150 mg $6.05; 200 mg $6.04; 225 mg $6.04; 300 mg $6.05; 20 mg/ 1 ml oral solution, billing unit per ml, available in 473 ml, WAC $1.67/ ml; 473 ml = $792.96

LYRICA® is indicated in adults for management of neuropathic pain associated with diabetic peripheral neuropathy; management of post-herpetic neuralgia in previous 60-days drug claim history t-herpetic neuralgia; adjunctive therapy for adult patients with partial onset seizures; management of fibromyalgia; management of neuropathic pain associated with spinal cord injury.

LYRICA is not FDA approved for children and there is no dose information for pediatrics in the package insert. Pediatric use is not supported in Micromedex DrugDex and there is no supported or suggested pediatric dosing information.

AGE EDIT: The Medicaid Pharmacy Program will implement a lower age limit for all strengths and formulations of LYRICA® that beneficiaries must be ≥18 years of age for POS approval. The existing Point of Sale (POS) approval criteria for LYRICA® oral solution shall be revised to include the revised age edit. All off-label requests for LYRICA® for pediatric use will be reviewed on a case-by-case basis and a search conducted in the CMS official compendia for supporting documentation for the off-label use in pediatrics and for supporting documentation for pediatric dosing information in order to approve the PA request.

QUANTITY LIMITS: Existing quantity edits remain in place.

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 15, 2017

3) <u>BUTALBITAL COMBINATION PRODUCTS THAT *DO NOT CONTAIN CODEINE* POS CRITERIA CHANGE</u> (e.g., BUTALBITAL/ACETAMINOPHEN; BUTALBITAL/ACETAMINOPHEN/CAFFEINE, ESGIC®, FIORICET®, MARGESIC, VANATOL™ LQ, ZEBUTAL®, butalbital-aspirin-caffeine, FIORINAL®):

Butalbital combination products that *do not contain codeine* are indicated for the relief of the symptom complex of tension (or muscle contraction) headache. Evidence supporting the efficacy and safety of this combination product in the treatment of multiple recurrent headaches is unavailable. Caution in this regard is required because butalbital is habit-forming and potentially abusable. Total daily dosage should not exceed 6 capsules or tablets. Extended and repeated use of these products is not recommended because of the potential for physical dependence. Safety and effectiveness in pediatric patients below the age of 12 have not been established.

The POS approval criteria have been revised because these drugs cannot be calculated for total MME per day and will not be included in the opioid criteria that calculates MME per day. However, the existing Therapeutic Duplication edit will remain in place and will not allow concurrent use of short-acting opioids with butalbital combination products that *do not contain codeine*.

QUANTITY LIMIT: The existing maximum daily quantity edit to not exceed 6 units per day or 93 per 31 days will remain in effect. The quantity allowed for the liquid butalbital-combination products without codeine will change to a maximum of 240 ml per 31 days' supply. And "swallow" criteria will be added to the liquid formulation for those who cannot swallow solid oral dosage forms that will look for diagnoses of NPO in adults and in children ≥ 12 years of age.

AGE EDIT: A lower age edit will be added to both the liquid formulation and to solid oral dosage forms that beneficiaries must be ≥ 12 years of age for approval. The butalbital products that do contain codeine will remain in short-acting opioid designation and will continue to be included in the MME calculated conversion.

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 15, 2017

4) <u>CHANGES TO DRUGS TREATING IDIOPATHIC CHRONIC CONSTIPATION (ICC) AND OPIOID-INDUCED CONSTIPATION (OIC),</u> including LINZESS™ (linaclotide) 72 mcg, 145 mcg, or 290 mcg capsule, RELISTOR® (methylnaltrexone) 12 mg or 8 mg SQ and 150 mg oral tablet, MOVANTIK® (naloxegol) 12.5 mg or 25 mg tablet, AMITIZA® (lubiprostone) 8 mcg or 24 mcg capsule, TRULANCE™ (plecanatide) 3 mg tablet:

NADAC Generic for bisacodyl 5 mg tablet = $0.02 each tablet
NADAC Generic for GLYCOLAX powder: $0.028 per gm, 119 gm = $3.43; 255 gm at WAC $0.02635/gm =$5.93; 527 gm @ WAC $0.02 per gm = $13.12
WAC: TRULANCE™ tablet = $11.78 each tablet; 30-day supply = $353.48
NADAC Brand: RELISTOR® tablet = $15.90 each tablet; 30-day supply @ 3 per day = $1,431.20
NADAC Brand: RELISTOR® SYRINGE 12 mg/0.6 ml $159.81939 per ml or $160.00278 per ml = $95.89 or $96 for the syringe after calculation per ml; 28-day supply = $2,688
NADAC Brand: RELISTOR® VIAL 12 MG/0.6 ML $159.43609 per ml or $95.66 after calculation per ml;
NADAC Brand: RELISTOR® SYRINGE 8 mg/0.4 ml $241.77036 per ml or $96.71 for the syringe after the calculation per ml; 28-day supply = $2,688
NADAC Brand AMITIZA 8 mcg = 5.61; 24 mcg = 5.61; #60/30-day = $336.71
NADAC Brand LINZESS = 145 mcg $11.33 ($340.16/30-day supply); 290 mcg = 11.32 ($339.69/30-day supply); 72 mcg WAC $11.78 ($353.48/30-day supply)
NADAC Brand MOVANTIK = 12.5 mg = $10.08 ($302.43/30-day supply); 25 mg =$10.04 ($301.24/30-day supply).

The Point of Sale (POS) criteria algorithm for all drugs treating Opioid Induced Constipation (OIC) or Idiopathic Chronic Constipation (ICC) have been revised for consistency.

The POS approval criteria for "new starts" for LINZESS™, RELISTOR® SQ, RELISTOR® tablet, MOVANTIK® tablet, TRULANCE™ tablet, or AMITIZA® capsule require include all of the following for POS approval:

- "New start" beneficiary defined as a Beneficiary who does not have a claim in history matching incoming ICC or OIC drug claim (e.g., LINZESS™, RELISTOR® SQ, RELISTOR® tablet, MOVANTIK® tablet, TRULANCE™ tablet, or AMITIZA® capsule) in the past 60 days; AND
- Beneficiary is age ≥18 years; AND
- "New start" Beneficiary must have all of the following in Medicaid drug claim history:

  - At least 1 Medicaid claim of Glycolax® (polyethylene glycol 3350) or lactulose solution in the past 14 to 60 days, AND
  - At least 1 Medicaid claim of bisacodyl 5 mg tablets in the past 14-60 days; AND
- For drugs with the indication of OIC, (e.g., RELISTOR® tablet, or RELISTOR® SQ injection, or MOVANTIK® tablet, or other new drugs to market), in addition to all of the above criteria, ALL beneficiaries must have at least 1 paid claim of an opioid in the past 15-30 days; AND
- Therapeutic Duplication (TD) edits will be added to all OIC and ICC drugs to not allow TD among the various agents, e.g., LINZESS™, RELISTOR® SQ, RELISTOR® tablet, MOVANTIK® tablet, TRULANCE™ tablet, or AMITIZA® capsule or the different strengths of any of these drugs, or new agents to market;

POS DENIAL CRITERIA for ALL ICC or OIC drugs:
- Absence of approval criteria; or
- History of mechanical gastrointestinal obstruction; or
- < 18 years of age;

ADDITIONAL POS DENIAL CRITERIA for LINZESS capsule or TRULANCE tablet,
- ≥ 1 Medicaid Paid claim for an opioid in the past 60 days;

CONTINUATION CRITERIA:
- There must be at least 1 claim in previous 60-days in Medicaid drug claim history matching the incoming OIC or ICC drug claim.

QUANTITY EDITS:
- Existing quantity edits remain for RELISTOR SQ inj., AMITIZA capsule, MOVANTIK tablet, and LINZESS tablet;
- A new QUANTITY EDIT of 3 tablets per day and 93/31-days' supply to RELISTOR tablet,
- A new QUANTITY EDIT of 1 tablet per day and 31/31-days' supply to TRULANCE 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.

NEW CLAIM EDITS, INCLUDING QUANTITY EDIT, AGE EDITS, DOSE-OP, DAILY DOSE/QUANTITY EDITS, CUMULATIVE QUANTITY EDIT, And ACCUMULATION EDITS:

EFFECTIVE OCTOBER 1, 2017:

1) CORTISPORIN® (neomycin and polymyxin b sulfates, bacitracin zinc, and hydrocortisone) ointment and cream:

NADAC brand for ointment is $8.48; 15 gm tube = $127.25. In 5 years the price has more than doubled. NADAC brand for cream is $12.62, 7.5 gm tube = $94.67. In 5 years the price has almost doubled.

QUANTITY LIMIT has been implemented to reduce waste. The quantity limit is equal to one package size per claim for the NDC for each product.

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 OCTOBER 1, 2017

2) **OPHTHALMIC ANTIBIOTIC drops; OPHTHALMIC ANTIBIOTIC-STEROID drops, and OPHTHALMIC drops for treating GLAUCOMA:**

QUANTITY LIMITS have been revised to reduce waste. The revised quantity limit on these ophthalmic agents is to equal one package size for the NDC for each product (e.g., one-2.5 ml container, one-5 ml container, one-7.5 ml container, etc.).

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

EFFECTIVE NOVEMBER 15, 2017

3) **QUANTITY EDIT for ALL OPIOID-CONTAINING ORAL SOLUTIONS/LIQUIDS/ELIXIRS,** for example, codeine-APAP liquid, hydrocodone/APAP solution, hydromorphone oral solution, oxycodone oral

concentrate or solution, oxycodone-APAP oral solution, meperidine oral solution, morphine oral solution, methadone oral solution, codeine-cough/cold solutions:

QUANTITY LIMITS applied to <u>all opioid</u>-containing liquid medications to prevent waste and ensure appropriate billing for package size for all opioid-containing liquids.

QUANTITY LIMIT FOR ORAL LIQUID OPIOID PAIN MEDICATIONS will equal the package size of the NDC per claim (e.g., one container of hydrocodone/APAP 7.5 mg-325mg/15 ml, 118 ml container, or one-30 ml size oxycodone oral concentrate 20 mg/ml container, etc.), up to a maximum of 240 ml for an opioid pain medication poured from a bulk container. All existing therapeutic duplication edits that prevent concurrent use of multiple short-acting opioid products will remain in place. Note that terminal cancer patients who meet the diagnosis criteria in the system are exempt from the quantity limit on oral liquid opioid pain medications.

QUANTITY LIMIT FOR COUGH/COLD PRODUCTS that contain an opioid is revised slightly to the quantity limit will equal the package size of the NDC per claim (118 ml or 120 ml), up to a maximum of 120 ml if poured from a bulk container, and the maximum quantity limit will remain as <u>1 claim</u> per month.

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) **<u>AGE EDITS for codeine tablets, codeine-acetaminophen tablets and oral solution, codeine-guaifenesin cough/cold preparations, tramadol IR tablets, tramadol-acetaminophen tablets, and tramadol ER tablets and capsules;</u>**

FDA issued a statement on April 20, 2017: "The Food and Drug Administration (FDA) is restricting the use of prescription codeine pain and cough medicines and tramadol pain medicines in children; These medicines carry serious risks including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. We are also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants."

The FDA also issued the following warning statements.

- "A new Contraindication to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids".
- "A new Warning to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems."
- "A strengthened Warning to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death."

Because the Medicaid POS system is not able to read a new diagnosis sooner than two weeks after the diagnosis is submitted to Medicaid, the Medicaid system would not be able to discern a surgery patient who is less than 18 years old from a non-surgery patient who may meet certain age requirements on a particular drug. Medicaid encourages all providers to heed the FDA warning statements regarding tramadol and codeine products if that differs from the Medicaid age edits.

EXISTING MEDICAID AGE EDITS FOR TRAMADOL from July 2015 **WILL REMAIN** in place. As a reminder, the **existing tramadol age edits are as follows**:

- **<u>Tramadol IR</u>**: Claims for children < 17 years of age will reject at point of sale. (POS approval for ≥ 17 years);

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

- **<u>Tramadol ER capsule, and Tramadol ER tablet</u>**: Claims for children < 18 years of age will reject at point of sale. (POS approval for ≥18 years)

- **Tramadol ODT is currently off the market.**

EFFECTIVE OCTOBER 1, 2107

AGE EDIT FOR CODEINE-CONTAINING PRODUCTS:

AGE EDITS for the POS system for codeine IR tablets and oral solution, codeine-acetaminophen tablets and oral solution, codeine-guaifenesin cough/cold preparations are as follows:

- **Codeine-acetaminophen medications, tablets and oral solution**: Claims for children < 12 years of age will reject at POS for pain medication codeine-acetaminophen combination, tablets and oral solution; (POS approval for ≥ 12 years)

- **Codeine-containing cough/cold preparations**: Claims for children < 12 years of age will reject at POS for codeine-containing cough/cold solutions; (POS approval for ≥ 12 years)
- **Codeine IR single-ingredient tablets and oral solution**: Claims for children < 18 years of age will reject at POS for codeine IR single-ingredient oral tablet and solution pain medication (POS approval ≥ 18 years)

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

NEW CLINICAL POS EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS:

EFFECTIVE NOVEMBER 15, 2017

1) **CYSTADANE® (betaine) powder for oral solution;**
WAC: billing unit is per gm, @ $7.92 per gm, 180 gm = $1,426.05

Cystadane® (betaine anhydrous for oral solution) is indicated for the treatment of homocystinuria to decrease elevated homocysteine blood levels. Included within the category of homocystinuria are:
• Cystathionine beta-synthase (CBS) deficiency
• 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
• Cobalamin cofactor metabolism (cbl) defect

The usual dosage in adult and pediatric patients is 6 grams per day administered orally in divided doses of 3 grams twice daily. Dosages of up to 20 grams per day have been necessary to control homocysteine levels in some patients. However, one pharmacokinetic and pharmacodynamic in vitro simulation study indicated minimal benefit from exceeding a twice-daily dosing schedule and a 150 mg/kg/day dosage for Cystadane®.

Point of Sale (POS) prior authorization approval criteria require ICD-10 code E72.11 (homocystinuria) in Medicaid diagnosis history in previous 2 years.

QUANTITY LIMIT: The quantity edit will allow up to 180 gm per 30 days. Quantities greater than 180 gm per 30 day will require manual review PA and prescriber must submit request in writing, explain the medical necessity of exceeding 6 gm per day, labs showing the plasma homocysteine levels, and documentation for compliance at 6 gm/day.

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.

NEW MANUAL REVIEW EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS:

EFFECTIVE IMMEDIATELY, FOR ALL NEW MANUAL REVIEW PA MEDICATIONS

1) **RHOFADE™ (oxymetazoline) topical cream;**
WAC: $15.83 per gm; $475 for 30-gm tube; 60-gm = $950

RHOFADE™ cream is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. The dose is a pea-sized amount of RHOFADE™ cream, once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips.

All requests for RHOFADE™ cream will require manual review PA on a case-by-case basis; all of the following are required for approval:

- All requests must be from a dermatologist enrolled provider, and must explain the medical necessity of receiving RHOFADE™ cream.
- Prescriber must submit an assessment using the Clinician Erythema Assessment (CEA) 5-point scale for the baseline pre-dose Day-1.
    - Beneficiary must have CEA score of moderate or severe for the pre-dose assessment.
- Prescribers to provide information as to whether or not prescriber has samples to provide for 1st month's use in order to determine how well the beneficiary will tolerate the cream with no adverse effects of worsening rosacea and erythema and provide chart notes to support the request.
    - If samples used prior to Medicaid request, prescriber must submit the beneficiary's CEA scale from baseline prior to use, and Beneficiary must have at least a 2-point improvement in CEA score compared to the baseline pre-dose on Day-1 to continue the drug through Medicaid approval.

DENIAL CRITERIA

- Absence of approval criteria; or
- Diagnosis history of acne vulgaris in previous 60-days; or
- Less than a 2-point improvement in CEA scale from baseline.

QUANTITY LIMIT for RHOFADE™ cream is 30 gm tube per 90 days using the peas-sized amount to cover the face once daily. Requests for the 60-gm tube will require additional manual review and prescriber must substantiate the medical necessity of beneficiary receiving the 60-gm size tube given the fact that the dose is "pea-size" amount to cover the face once daily.

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) <u>ZEJULA™ (niraparib) 100 mg capsule:</u>

WAC: $163.88 EACH CAPSULE; @ 300 mg/day (#90) = $14,750 per 30-day supply

ZEJULA™ is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. The recommended dose of ZEJULA as monotherapy is 300 mg (three 100 mg capsules) taken orally once daily. ZEJULA™ treatment should be continued until disease progression or unacceptable toxicity.

All requests for ZEJULA™ capsule will require manual review PA on a case-by-case basis; all of the following are required for approval:

- ZEJULA™ is being prescribed as maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (although rare, PPC can occur in males) to beneficiary who is in a complete or partial response to platinum-based chemotherapy;
- The prescriber must submit request in writing and explain the medical necessity of receiving the drug and include all of the following documentation to substantiate request:
    - Beneficiary has received at least 2 prior platinum-containing regimens and is in response (complete or partial) to most recent platinum-based regimen;
    - Treatment with ZEJULA™ to begin no later than 8 weeks after the most recent platinum-containing regiment completed
    - Documentation required to include chart notes, data regarding 2 previous platinum-based chemotherapy, date(s) of platinum-containing regimens started and completed, response to previous chemotherapy treatments, and labs for complete blood counts prior to starting ZEJULA™ therapy,
    - Prescriber to monitor complete blood counts weekly for the first month after starting ZEJULA™, then monitor blood counts monthly for the next 11 months of treatment and periodically after this time. All labs to be submitted with PA request.
- The clinical review will use data from the package insert, FDA approved dose, precautions and warnings section in package insert, and clinical trial information in the package insert.
- Beneficiary should have already recovered from hematological toxicity cause by the previous chemotherapy.
- PA approvals during the first year to be month to month due to possibility of dose-related adverse events that may require dose reduction or withholding ZEJULA™. Prescriber to provide current dose with each PA request, and submit blood counts with all subsequent PA requests. The manual review will include review of Medicaid drug profile for adherence to prescribed therapy.

DENIAL CRITERIA:

- Beneficiary currently experiencing hematological toxicity caused by previous chemotherapy; or
- Most recent platinum-containing chemo regiment ended longer ago than 8 weeks prior to initial request; or
- Absence of approval criteria; or
- Non-adherence to prescribed dose and therapy; or
- Disease progression

QUANTITY LIMIT not to exceed 3 capsules per day. ZEJULA™ is packaged as 90 capsules in each bottle. If dose reduction is necessary to manage adverse events, the monthly quantity limit will be entered as part of the PA.

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) <u>DUPIXENT® (dupilumab) 300 mg SQ Injection;</u>

WAC: $711.54 per ml. Billing unit is per ml. Each syringe is a 2 ml syringe = $1,423.08 per syringe. 2 syringes per month = $2,846.16

The FDA approved indication for DUPIXENT® is for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The recommended dose of DUPIXENT® for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

At this time, DUPIXENT® has not been reviewed against active comparators and is not included in current treatment guidelines for atopic dermatitis to determine its place in therapy.

The initial PA request for DUPIXENT® for treating atopic dermatitis will require a manual review prior authorization on a case-by-case basis; all of the following are required for approval:

- Prescriber must be board certified by American Board of Allergy and Immunology or by American Board of Dermatology; AND
- Prescriber must submit a letter explaining the medical necessity of beneficiary receiving DUPIXENT® SQ injection and include all written documentation, chart notes, etc. to substantiate the request that the patient is refractory to other treatments for atopic dermatitis; AND
- Beneficiary must be age 18 years or older; AND
- Beneficiary must have moderate to severe atopic dermatitis and prescriber must submit documentation as to his/her scoring of the patient's disease severity; AND
- Beneficiary must have an Eczema Area and Severity Index (EASI) total score of ≥16 on a scale of 0 to 72; AND
- Beneficiary must have a minimum body surface area involvement of ≥ 10%; AND
- Beneficiary must have a baseline weekly averaged peak pruritus Numeric Rating Scale (NRS) of at least 7 on a scale of 0-10;
- To substantiate the request, Prescriber must also submit documentation and chart notes of all other atopic dermatitis therapies tried that have failed, and data should include, at a minimum, the mean score measured of the surface area of involvement before and after each treatment, the EASI AD score at baseline and change in the score, and the specific length of time tried on each therapy. Prescriber must include drug claims data or retail pharmacy print out if the drug claims are not available in Medicaid drug claims history.
- The previous AD therapies tried must include both topical and systemic medications, and at a minimum must include:
    - Trials of topical drugs to treat atopic dermatitis, (topical corticosteroids and topical calcineurin inhibitors (TCIs)) that include:
        - Trials of at least two different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroid being "high" potency (Class-2) or superpotent (Class-1) depending on location of atopic dermatitis, AND
        - At least one trial of a TCI over a minimum of 30 days, AND
    - At least one trial of a systemic immunomodulatory therapy from the following:
        - a trial of cyclosporine for minimum of 6 weeks; or
        - a trial of azathioprine for a minimum of 12 weeks; or
        - a trial of methotrexate for a minimum of 12 weeks;

- The clinical reviewers may also review data from package insert, DUPIXENT® clinical trials, and AD treatment guidelines, to assist in the review and determination of the PA request.
- Prescriber must provide the planned start date for the injections.
- Approval of the initial PA shall not exceed 16 weeks.

CONTINUATION CRITERIA for DUPIXENT®:

- Prescriber is required to show positive treatment response at each PA request for DUPIXENT® for continued prior approval; and
- Positive treatment response shall be defined as:
    - Improvement by at least 75% in EASI score from baseline to week 16; AND
    - The atopic dermatitis severity score noted as clear or almost clear with at least a 2-point improvement at week 16; AND
    - Reduction in itch, as defined by at least a 4-point improvement in the peak pruritus numerical rating scale (NRS) from baseline to week 16. And
- Beneficiaries who received either systemic or topical "rescue treatment" to control unacceptable symptoms of atopic dermatitis while receiving DUPIXENT® are considered to be non-responders to DUPIXENT® and PA request to continue DUPIXENT® therapy will be denied. Systemic rescue meds will be defined as including but not limited to systemic glucocorticoids or nonsteroidal systemic immunosuppressive drugs (e.g., cyclosporine, methotrexate, mycophenolate mofetil, azathioprine, etc.).

DENIAL CRITERIA:

- Beneficiary did not meet positive treatment response requirements by week 16 as defined in approval criteria; or
- Quantity requested is greater than quantity and frequency allowed by the quantity edit; or
- Beneficiary received concurrent "rescue treatment", either topical or systemic rescue treatment; or
- Absence of approval criteria;

QUANTITY LIMIT: Depending on the start date of the injection, the quantity limit is sufficient to allow for up to 5 syringes in a 50-day period for administration every 2 weeks; however, allowing that quantity does not mean that Medicaid condones administering the SQ injection earlier than every 2 weeks. Depending on the start date during the first month of treatment, it may be necessary for the PA to include an override for the quantity.

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) <u>ZOLINZA® (vorinostat) 100 mg capsule;</u>
WAC: $113.81 each capsule; @ 400 mg daily, 30-day supply = $13,657.20

ZOLINZA® is indicated for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma who have progressive, persistent or recurrent disease on or following two systemic therapies. The recommended dose is 400 mg (100 mg x 4 capsules) orally once daily with food. Please see the manufacturer's drug package insert for dose reduction scheduled.

All requests for ZOLINZA® will require a manual review PA on a case-by-case basis; all of the following are required for approval:

- Beneficiary must have diagnosis of Stage IIB or higher CTCL (cutaneous manifestations with cutaneous T-cell lymphoma) and have progressive, persistent or recurrent disease; AND
- Prescriber must submit a letter explaining the medical necessity of receiving ZOLINZA® and include written documentation, chart notes, labs, etc.; AND
- Beneficiaries must have tried at least two systemic chemotherapies, and if the previously tried drugs are not on the Medicaid pharmacy program drug profile, prescriber to provide data on the two systemic therapies beneficiary previously received; AND
- Beneficiary should have received, been intolerant to, or not a candidate for oral bexarotene (Targretin®) capsules and prescriber to include chart documentation data of intolerance or chart documentation as to why beneficiary was not a candidate for oral bexarotene therapy; AND
- Beneficiary must be ≥ 18 years of age; AND
- Prescriber must submit the % of total body surface area (%TBSA) involved and area must be measured at time of PA request and converted to a Severity Weighted Assessment Tool (SWAT) to use as the baseline measurement. Prescriber to measure the % TBSA involvement separately for

patches, plaques, and tumors within 12 body regions using the patient's palm as a "ruler". The total %TBSA for each lesion type to be multiplied by a severity weighting factor (1=patch, 2=plaque, and 4=tumor) and summed to derive the SWAT score. AND

- Prescriber must submit blood counts, and chemistry labs, and liver function test results, serum glucose results monthly with every PA request. AND
- If the PA is approved, the PA approval will be month-to-month basis. Prescriber must provide current dose with each PA request, and state if dose reduction was necessary due to dose-related thrombocytopenia and anemia, clinical chemistry abnormalities, reduced liver function, or intolerance to dose, hyperglycemia.

CONTINUATION CRITERIA:

- Prescriber required to state dose requested with every PA request and note if this is a dose reduction; AND
- Adherence to prescribed drug therapy is required for continued approval; if subsequent PA request or drug claim is late, prescriber to provide chart notes and documentation of explanation; AND
- Chemistry labs (serum electrolytes, creatinine, magnesium, and calcium), blood counts, liver function labs, serum glucose, required to be checked every month for month-to-month PA in order to ensure appropriate quantity dispensed for any dose reductions; AND
- For continued prior authorization of the drug, Prescriber must provide documentation that beneficiary had positive treatment response to the drug, either Complete Clinical Response (CCR), or Partial Response (PR) defined as a ≥50% decrease in skin assessment compared to baseline, and maintained it for at least 4 weeks.

DENIAL CRITERIA:

- Evidence of progressive disease; or
- Not have positive treatment response to therapy; or
- Severe hepatic impairment (bilirubin > 3 × ULN). or
- Absence of approval criteria

QUANTITY LIMIT: The allowed quantity not to exceed 4 capsules per day or 120 capsules for 30-day supply. ZOLINZA® is packaged as 120 capsules in each bottle. If dose reduction is necessary to manage adverse events, the monthly quantity limit will be entered as part of the PA.

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) <u>CAPRELSA® (vandetanib) tablet, 100 mg and 300 mg;</u>
WAC: 100 mg $214.52 each; 300 mg $429.04 each; $12,871.19 for 300 mg/day for 30-day supply

CAPRELSA® is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. The recommended dose of CAPRELSA® is 300 mg taken orally once daily until disease progression or unacceptable toxicity occurs. The 300 mg daily dose can be reduced to 200 mg (two 100 mg tablets) and then to 100 mg for Common Terminology Criteria for Adverse Events (CTCAE) Grade 3 or greater toxicities. Please see manufacturer's drug package insert for information on dose reduction and dose interruptions.

All requests for CAPRELSA® require manual review PA on a case-by-case basis; all of the following are required for approval:

- Prescriber must submit a letter explaining the medical necessity of receiving CAPRELSA® and include all documentation, including chart notes, labs, etc., required for the review; and
- Provider to submit documentation that beneficiary has diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease; and
- Prescriber to submit baseline values for ECG and serum potassium, calcium, magnesium and TSH at baseline, 2–4 weeks and 8–12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter; and
- Prescriber to provide baseline data regarding renal function; reduction of the starting dose to 200 mg required in patients with moderate to severe renal impairment; and
- The clinical review will use information from the package insert, such as warnings and precautions section, and clinical trials in the package insert; and
- Approval of PA will be month-to-month due to the possibility of severe adverse reactions of the drug in order to make dose adjustments; Each PA request must include dose requested, and state if dose is a dose reduction;

QUANTITY LIMIT: The 100 mg and 300 mg tablets available in bottles of 30 tablets. The quantity limit for the 300 mg tablet is 1 per day with a cumulative quantity of 30 for 30 day supply; the maximum quantity limit of the 100 mg tablet is up to 2 tablets per day to allow for 200 mg dose. If dose reduction is necessary to manage adverse events, the monthly quantity limit will be entered as part of the PA.

CONTINUATION CRITERIA:

- Beneficiary does not have disease progression; and
- Beneficiary meets all renal function requirements, liver function requirements, all serum electrolyte level requirements; and
- Beneficiary does not have unacceptable toxicity; and
- Prescriber has provided current dose with each PA request or state if dose is reduced to manage adverse reactions; and
- Beneficiary is adherent to prescribed drug therapy;

DENIAL CRITERIA:

- Beneficiary has moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment; or
- Beneficiaries with congenital long QT syndrome or QTcF interval is greater than 450 ms, or beneficiaries with a history of Torsades de pointes, congenital long QT syndrome, bradyarrhythmias or uncompensated heart failure; or
- Beneficiary has ventricular arrhythmias or recent myocardial infarction; or
- Disease progression or unacceptable toxicity;

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

6) **ALUNBRIG™ (brigatinib) tablet, 30 mg and 90 mg;**

WAC: $79.16 each 30 mg tablet; 1st 7 day trial (90 mg daily (3x30mg) x 7 days) = 21 tablets = $1,662.50; If tolerate dose for 7 days, increase dose to 180 mg (6 x 30 mg) once daily, #180 tablets = $14,250 / 30-day supply. At this time, the 90 mg tablet strength is not available in the Medicaid system.

ALUNBRIG™ is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The recommended dosing regimen for ALUNBRIG™ is 90 mg orally once daily for the first 7 days; if 90 mg is tolerated during the first 7 days, the recommend dose is to increase to 180 mg orally once daily.

ALUNBRIG™ requires a manual review PA on a case-by-case basis; all of the following are required for approval:

- Prescriber is required to submit request in writing and explain medical necessity to receive ALUNBRIG™ and submit all documentation to substantiate the request; and
- Beneficiary must have diagnosis of locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC) who had progressed on crizotinib; and
- Beneficiary has an *ECOG Performance Status grad of 0-2 out of a scale of 0 to 5; and
- Beneficiary must have a documented ALK rearrangement based on an FDA-approved test with adequate archival tissue to confirm ALK arrangement. Requirement of the Vysis® ALK Break-Apart fluorescence in situ hybridization (FISH) Probe Kit test, or other qualifying test as part of the PA process for the drug is not to be construed as approval for the test or payment for the lab test. Provider is required to obtain authorization for the required test, if any is required, from the department or group responsible for authorization of the test; and
- Prescriber must provide the beneficiary's current dose information with every PA request; and
- Approval for PA of drug is be month-to-month due to possibility of dose reduction to manage adverse events.

QUANTITY LIMIT: The quantity allowed for the 30 mg tablet is up to 180 mg per day (6 tablets per day) or 180/30-day supply. If or when the 90 mg tablet is available, the allowed quantity of the 90 mg tablet will be up to 2 tablets per day (180 mg) or up to a quantity of 60 for a 30-day supply; the 30 mg quantity will be adjusted down. If dose reduction is necessary to manage adverse events, the monthly quantity limit for the strength prescribed will be entered as part of the monthly PA.

CONTINUATION CRITERIA:

- Beneficiary must show positive treatment response to continue the drug; and
- Beneficiary does not have unacceptable toxicity; and
- Prescriber has provided current dose with each PA request or state if dose is reduced to manage adverse reactions; and
- Prescriber must provide documentation of no disease progression at each PA request; and
- Beneficiary must be adherent to prescribed drug therapy;

DENIAL CRITERIA:

- Beneficiary has a history of interstitial lung disease (ILD); or
- Beneficiary has a history of drug-related pneumonitis, or
- Beneficiary received crizotinib within 3 days of the first dose of ALUNBRIG™ (brigatinib); or
- Beneficiary has new or worsening respiratory symptoms; or
- Beneficiary has grade 3 or 4 ILD/pneumonitis, or recurrence of Grade 1 or 2 ILD/pneumonitis; or
- Beneficiary has signs of disease progression while on ALUNBRIG™ (brigatinib);

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.

7) **RYDAPT® (midostaurin) 25 mg capsule;**
WAC: $133.84 each 25 mg capsule; package sizes 56 capsules in blister pack or 112 capsules in blister pack. #56 capsules = $7,495; #112 capsules = $14,990.00

AML dose 50 mg BID for 14 days (day 8-day 21) = 56 capsules = $7,495; for AML as single agent after induction and consolidation chemo completed is 50 mg once daily or 112 capsules = $14,990 for 28 day supply;
ASM, SM-AHN, AND MCL 100 mg BID; 112 capsules = $14,990.00 for a 14 day supply or $29,980.00 for a 28-day supply for ASM, SM-AHN, AND MCL. Please see the manufacturer drug package insert for complete dosing information and information on dose reductions.

RYDAPT® is FDA approved for the following indications:

- Indicated, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by a FDA approved test. RYDAPT is not indicated as a single-agent induction therapy for the treatment of patients with AML. Patient selection is based on the presence of FLT3 mutation positivity with FDA-approved tests for detection of FLT3 mutation in AML.
- Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). Monitor patients for toxicity at least weekly for the first 4 weeks, every other week for the next 8 weeks, and monthly thereafter while on treatment.

RYDAPT® will require manual review PA on a case-by-case basis using all of the following in the section for Acute Myeloid Leukemia (AML) with FLT3+, or using all of the following in the section for the treatment of adults with aggressive systemic mastocytosis (SM), SM with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL):

RYDAPT® will require manual review PA on a case by case basis; all of the following are required for approval for the different diagnoses sections.

AML with FLT3+ mutation diagnosis; all of the following required for approval**:**

- Prescriber to submit request in writing and explain medical necessity and provide all documentation required for the clinical review; and
- Patient selection for AML for treatment with RYDAPT® is requires to have the presence of FLT3 mutation positivity with FDA-approved tests for detection of FLT3 mutation in AML. Lab results of the test used must be submitted. One such FDA approved companion diagnostic is the LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies Inc.), for use with midostaurin to test patients with AML for the FLT3 mutation. Approval of the PA for this drug does not include approval of any lab test to determine FLT3 mutation positivity or payment for such lab tests. And

- Requests for RYDAPT must be in combination treatment with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy; and
- Prescriber to provide monthly documentation regarding chemotherapy induction and consolidation schedules; and
- After induction and consolidation chemotherapy completed, prescriber to provide documentation that RYDAPT will be prescribed as a single agent and starting date; and
- The recommended dose of midostaurin in AML is 50 mg twice daily with food on days 8 to 21 of each cycle of induction and consolidation chemotherapy, followed by continuous daily midostaurin for up to 12 cycles; and
- PA approval to be month to month. Once on continuous daily dosing, approval is allow for up to 12 cycles; and
- RYDAPT® is packaged as unit dose packages of 56 capsules and 112 capsules. If a dose reduction is made and the beneficiary does not require the package of the 112 capsules, the quantity limit will be entered at time of PA using appropriate package size.

CONTINUATION CRITERIA for AML with FLT3+ mutation diagnosis:

- Prescriber must provide all lab data with each PA request, and beneficiary must have acceptable lab values with each PA request; and
- Prescriber must follow all dose modifications provided in package insert and provide reduced dose information with each PA request; and
- Beneficiary must be adherent to prescribed drug therapy;

QUANTITY LIMIT FOR AML with FLT3+ mutation diagnosis: the quantity allowed for PA is to be entered at each PA approval. Prescriber to submit documentation of dose and if beneficiary has received dose reduction due to adverse events. During the induction and consolidation chemotherapy phase the RYDAPT® dose is only for days 8 to 21 (14 days of therapy, or 56 capsules each month) and PA will be entered for appropriate NDC of 56 capsules; the continuous daily dose phase will require a quantity of 112 capsules per 28 days and PA will be entered for appropriate NDC. If dose reduction is necessary to manage adverse events, the monthly quantity limit for the strength prescribed will be entered as part of the monthly PA.

DENIAL CRITERIA for AML with FLT3+ mutation diagnosis

- Deny beneficiary with serum creatinine > 2.0 mg/dL, hepatic transaminases > 2.5 x upper limit of normal (ULN) or > 5 x ULN if disease-related, total bilirubin > 1.5 x ULN or > 3 x ULN if disease-related, QTc > 450 msec, cardiovascular disease including left-ventricular ejection fraction < 50%, or any pulmonary infiltrates; or
- Deny beneficiary with signs or symptoms of pulmonary toxicity, i.e., interstitial lung disease or pneumonitis without an infectious etiology;

ASM, SM-AHN, AND MCL diagnosis; all of the following required for approval:

- Prescriber to submit request in writing and explain medical necessity and provide all documentation required for the clinical review; and
- Beneficiary to have diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL); and
- If beneficiary is on medications that can prolong the QT interval, interval assessments of QT by EKG required, prescriber to provide information of the dose modification; and
- Initial baseline lab results (ANC, hemoglobin, liver enzymes, bilirubin, platelets) must be submitted with initial request. All subsequent lab results to be provided with each monthly PA request. And
- Maximum dose is 100 mg twice daily, and prescriber to provide prescribed dose with monthly PA request; and
- Prior Authorization approvals to be month-to-month.

CONTINUATION CRITERIA for ASM, SM-AHN, AND MCL diagnosis:

- Prescriber to provide all lab data with each PA request, and beneficiary must have acceptable lab values with each PA request; and
- Prescriber to follow dose modifications provided in package insert and provide dose with each PA request; and
- Beneficiary is adherent to prescribed drug therapy; and
- Beneficiary does not have disease progression or unacceptable toxicity;

QUANTITY LIMIT FOR ASM, SM-AHN, AND MCL diagnosis: the quantity limit allowed for these cancers will be entered at each PA approval due to possibility of dose modifications caused by drug toxicity adverse effects. Maximum dose allowed is 100 mg twice daily or 8 capsules per day, total 224 capsules per 28 days. Prescriber to submit documentation of dose and that there has not been dose reduction due to adverse events. If dose reduction is necessary to manage adverse events, the monthly quantity limit for the strength prescribed will be entered as part of the monthly PA.

DENIAL CRITERIA for ASM, SM-AHN, AND MCL:

- Deny beneficiary with serum creatinine > 2.0 mg/dL, hepatic transaminases > 2.5 x upper limit of normal (ULN) or > 5 x ULN if disease-related, total bilirubin > 1.5 x ULN or > 3 x ULN if disease-related, QTc > 450 msec, cardiovascular disease including left-ventricular ejection fraction < 50%, or any pulmonary infiltrates; or
- Deny beneficiary with signs or symptoms of pulmonary toxicity, i.e., interstitial lung disease or pneumonitis without an infectious etiology; or
- Beneficiary has disease progression or unacceptable toxicity;

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.

8) KISQALI® (ribociclib) 200 mg tablet and KISQALI® FEMARA® (letrozole) CO-PACK;

KISQALI® is only available as a 200 mg tablet and is packaged as a 21-day supply for each daily dose (200 mg, 400 mg, and 600 mg):
WAC: KISQALI® 200 mg daily dose, packaged as blister pack containing 21 tablets @ $208.57 each tablet =$4,380; KISQALI for 400 mg daily dose, packaged as 3 blister packs, each containing 14 tablets x 200 mg tablets @ $208.57 each tablet; = $8,760; KISQALI 600 mg daily dose, packaged as 3 blister packs, each containing 21 tablets x 200 mg @ $208.57 each tablet; = $13,140;

KISQALI®-FEMARA® CO-PAK, is packaged as 21-day supply of Kisqali® 200 mg tablet with the quantity of Kisqali to make the daily dose of 200 mg, 400 mg, or 600 mg + 28-day supply of Femara® tablets. 200-2.5 mg = $89.38, packaged as total of 49 tablets = $4,380; 400-2.5 mg = $125.14, packaged as total of 70 tablets = $8,760; 600-2.5 mg = $120.33, packaged as total of 91 tablets = $10,950

NADAC Generic for FEMARA® (letrozole) 2.5 mg = $0.14 each tablet

KISQALI® FEMARA® CO-PACK will require Manual review prior authorization on a case-by-case basis; all of the following are required for approval:

- Beneficiary must be postmenopausal, and HR-positive, and HER2-negative, and advanced or metastatic breast cancer; and
- Prescriber must submit request in writing and explain the medical necessity of receiving KISQALI® FEMARA® CO-PACK and provide all documentation of H+ and HE2 negative to substantiate the request; and
- Beneficiary has an *ECOG Performance Status of 0-1; and
- Baseline ECG required prior to initiation of treatment. Initiate treatment with KISQALI FEMARA CO-PACK only in patients with QTcF values less than 450 msec; and
- Baseline serum electrolytes required (including potassium, calcium, phosphorous and magnesium) prior to the initiation of treatment, and at the beginning of the first 6 cycles; and
- Baseline liver function tests required prior to initiating therapy, and performed every 2 weeks for first 2 cycles, and at the beginning of each subsequent 4 cycles, and results submitted with every PA request; and
- Prescriber to submit the repeat ECG from approximately Day 14 of the first cycle for 2nd month PA the beginning of the second cycle of therapy; and
- KISQALI® packaged without the FEMARA as the co-packaged product will not be approved unless the KISQALI® FEMARA® COPACK is unavailable in the market place because there is no indication for treatment with KISQALI® alone; and
- Length of PA to be month-to-month due to long list of adverse reactions and possible dose reductions;

QUANTITY LIMITS: Dose information required at the time of the PA request due to the packaging of the KISQALI®. Each NDC has a different number of 200 mg tablets to make the daily dose. If dose

reduction is necessary to manage adverse events, the monthly quantity limit for the appropriate quantity/NDC will be entered as part of the monthly PA.

CONTINUATION CRITERIA:

- Beneficiary must not have electrolyte abnormalities; and
- QTcF values must be less than 450 msec; and
- All laboratory values are in normal ranges.

DENIAL CRITERIA:

- QTcF values greater than 450 msec; or
- Diagnosis of Long QT Syndrome; or
- Uncontrolled or significant cardiac disease including recent myocardial infarction, congestive heart failure, unstable angina and bradyarrhythmias; or
- Electrolyte abnormalities; or
- Concurrent elevations in ALT or AST greater than three times the ULN and total bilirubin greater than two times the ULN, with normal alkaline phosphatase, in the absence of cholestasis; or
- Disease progression
-

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 and the dose. 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 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.

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. 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.

13. **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

14. **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.