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: **NOVEMBER 22, 2017**

SUBJ: **AR Medicaid PA edits approved at the AR Medicaid DUR Board OCTOBER 18, 2017 meeting and PDL changes approved by the PDL Drug Review Committee meeting NOVEMBER 8, 2017**

UPDATE OF THE AR MEDICAID PREFERRED DRUG LIST (PDL) DRUG CATEGORIES:
ACEI Inhibitors, Renin Inhibitors, and Combination Products; Angiotensin II Receptor Blockers (ARB) and ARB Combination Products; ADD/ADHD Medications; INSULINS; Targeted Immune Modulators (TIMS); Self-Injected Epinephrine;

CHANGES TO *EXISTING CRITERIA*, INCLUDING POINT OF SALE (POS) CRITERIA, MANUAL REVIEW PA CRITERIA, OR CLAIM EDITS,: MME daily limits; KALYDECO® (ivacaftor); PULMICORT (budesonide) RESPULES®; MONTELUKAST; ENBREL® (etanercept); HUMIRA® (adalimumab); REVISED POS Criteria for Medicaid Beneficiaries Who Are "*New Starts* To Opioid Therapy"; Preferred and Non-Preferred Pulmonary Arterial Hypertension (PAH) Drugs; Refill Too Soon Early Refill Accumulation Limit;

NEW CLINICAL POS EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS: Edits to Improve the Safe Prescribing of Opioids and Benzodiazepines after Non-Fatal Poisoning or Overdose; CAROSPIR® (Spironolactone 25mg/5mL) Suspension; ACYCLOVIR Oral Suspension 200 mg/ 5 mL;

NEW MANUAL REVIEW EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS:
ZYKADIA® (ceritinib) Capsule 150 mg; INGREZZA™ (valbenazine) Capsule 40 mg; AUSTEDO® (deutetrabenazine) Tablet 6 mg, 9 mg, 12 mg; XERMELO™ (telotristat ethyl) 250 mg Tablet; 4) MYDAYIS™ (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate capsule, extended release) 12.5 mg, 25 mg, 37.5 mg, 50 mg; IDHIFA® (enasidenib mesylate) tablet, film coated 50 mg, 100 mg;

REMINDERS: MME Changes; Manual Review PA Requests;

ANNOUNCEMENTS: SEROQUEL XR® (quetiapine); Non-cosmetic BOTOX® (onabotulinumtoxina) injection

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.*

ANNOUNCEMENTS:
EFFECTIVE IMMEDIATELY: **SEROQUEL XR® will no longer be State Supported Brand required status**. *The AR Medicaid Pharmacy Program will continue to pay for the brand version of Seroquel XR® at the Brand NADAC rate through 12/31/2017*. Generic version Quetiapine Fumarate ER is payable, as of 10/20/18 going forward, and will reimburse off the Generic NADAC rate on file. A pharmacy will be able to submit a claim for the brand OR generic version and will be paid off the corresponding NADAC rate of the brand or generic version being dispensed. ***BEGINNING 01/01/2018, BRAND SEROQUEL XR DISPENSED WILL PAY AT THE GENERIC NADAC RATE*** *WHICH IS THE PLAN DEFAULT.*

EFFECTIVE JANUARY 1, 2018: Non-cosmetic BOTOX® (onabotulinumtoxina) injection **will no longer be a covered benefit through the Medicaid Pharmacy Program.** Non-cosmetic BOTOX® is already a covered benefit through the Medicaid Physician's Program ("medical side") and Medicaid providers should contact Medicaid Utilization Review regarding requirements for approval prior to use.

REMINDERS:

1) **SUBOXONE SL FILM:** The **FDA approved dose** for treating opioid addiction, as stated in the drug's package insert, is prescribing the dose as a ***single daily dose***. The Suboxone film can be placed under the tongue for sublingual administration or inside the right or left cheek for buccal administration. One film is placed under the tongue or inside of the right or left cheek. If the dose requires more than one film, the additional film is placed on the opposite side from the first film. The film(s) must remain in place until completely dissolved. If a third film is necessary to achieve the prescribed dose, the 3rd film is then placed after the first 2 films have dissolved.

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

   The 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. The ultimate Medicaid goal is to reduce the TOTAL MME PER DAY for chronic non-cancer pain patients to meet the CDC recommendations.

   BENEFICIARIES WHO PAY CASH FOR OPIOIDS, IN ADDITION TO THE OPIOIDS PAID FOR BY MEDICAID, RESULT IN A MUCH HIGHER DAILY MME THAN WHAT IS CALCULATED IN THE MEDICAID SYSTEM EDITS, ARE ABOVE THE CDC RECOMMENDATIONS, AND COULD PUT THE PATIENT AT RISK FOR OVERDOSE.

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

4) **SAMHSA TIP 40**: The SAMHSA "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction" state "Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. *They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids in the course of their medical treatment*." http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf

EFFECTIVE JANUARY 1, 2018

I. PDL CHANGES

Additions and changes below to the preferred drug list (PDL) are from the NOVEMBER 8, 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) **ANGIOTENSIN RECEPTOR MODULATORS (Re-Review):**

   i) **ACEI Inhibitors, Renin Inhibitors, and Combination Products**

PREFERRED Status

BENAZEPRIL
BENAZEPRIL/HCTZ
ENALAPRIL
ENALAPRIL/HCTZ
LISINOPRIL
LISINOPRIL/HCTZ
QUINAPRIL
QUINAPRIL/HCTZ
RAMIPRIL

NON-PREFERRED STATUS

BENAZEPRIL/AMLODIPINE
CAPTOPRIL/HCTZ
FOSINOPRIL
FOSINOPRIL/HCTZ
MOEXIPRIL
MOEXIPRIL/HCTZ
PERINDOPRIL
PRESTALIA
TRANDOLAPRIL
TRANDOLAPRIL/VERAPAMIL
ZESTORETIC
TEKTURNA
TEKTURNA HCT
ENALAPRIL SOLUTION (EPANED)
LISINOPRIL SOLUTION (QBRELIS)

NON-PREFERRED WITH CRITERIA STATUS

**CAPTOPRIL

ii) Angiotensin II Receptor Blockers (ARB) and ARB Combination Products

***PREFERRED Status-POS criteria to be removed 1/1/18**

IRBESARTAN
IRBESARTAN/HCTZ
LOSARTAN
LOSARTAN/HCTZ
VALSARTAN
VALSARTAN/HCTZ
VALSARTAN/AMLODIPINE
EXFORGE HCT® (BRAND ONLY)

PREFERRED Neprilysin Inhibitor/Angiotensin II Receptor Blocker, Existing Manual Review PA Criteria Will Remain

ENTRESTO™ (sacubitril and valsartan tablet)

NON-PREFERRED ARB and ARB Combination Products

AZILSARTAN (EDARBI)
AZILSARTAN/CHLORTHALIDONE (EDARBYCLOR)
AMLODIPINE/OLMESARTAN
AMLODIPINE/OLMESARTAN/HCTZ
BYVALSON
CANDESARTAN
CANDESARTAN/HCTZ
EPROSARTAN
EPROSARTAN/HCTZ
OLMESARTAN
OLMESARTAN/AMLODIPINE
OLMESARTAN/HCTZ
OLMESARTAN/AMLODIPINE/HCTZ
TELMISARTAN

TELMISARTAN/AMLODIPINE
TELMISARTAN/HCTZ
VALSARTAN/AMLODIPINE/HCTZ

2) ADD/ADHD MEDICATIONS (Re-Review)

PREFERRED with Point of Sale criteria

ADDERALL XR (Brand only)
AMPHETAMINE SALTS TABLET (generic only)
ATOMOXETINE (generic only)
DEXTROAMPHETAMINE 5MG, 10MG TABLET
FOCALIN (Brand only)
FOCALIN XR (Brand only)
VYVANSE CAPSULES
METHYLPHENIDATE SWALLOW TABLET
Guanfacine ER (generic only)
Guanfacine IR
Clonidine IR

NON-PREFERRED status

AMPHETAMINE SALTS ER CAPSULE (ADDERALL XR) - Generic only
DEXMETHYLPHENIDATE ER CAPSULE (FOCALIN XR) - Generic only
DEXMETHYLPHENIDATE TABLET (FOCALIN) - Generic only)
CLONIDINE ER SUSPENSION (NEXICLON XR)
CLONIDINE ER TABLET (KAPVAY ER, NEXICLON XR)
DEXTROAMPHETAMINE CAPSULE (DEXEDRINE SPANSULE)
DEXTROAMPHETAMINE SOLUTION (PROCENTRA)
DEXTROAMPHETAMINE 2.5MG, 7.5MG, 15MG, 20MG, 30MG TABLET (ZENZEDI)
INTUNIV ER (brand only)
METHAMPHETAMINE TABLET (DESOXYN)
METHYLPHENIDATE CHEWABLE TABLET (METHYLIN)
METHYLPHENIDATE ER CAPSULE (METADATE CD, RITALIN LA, APTENSIO XR)
METHLYPHENIDATE ER PATCH (DAYTRANA)
METHYLPHENIDATE ER SUSPENSION (QUILLIVANT XR)
METHYLPHENIDATE ER TABLET (CONCERTA)
METHYLPHENIDATE ER TABLET (METADATE ER, RITALIN SR)
METHYLPHENIDATE SOLUTION (METHYLIN)
METHYLPHENIDATE (COTEMPLA XR-ODT)
DEXTROAMPHETAMINE /AMPHETAMINE SALTS CAPSULE, EXTENDED RELEASE (MYDAYIS)
STRATTERA Brand (ATOMOXETINE)
VYVANSE CHEWABLE TABS (LISDEXAMFETAMINE CHEWABLE)

3) INSULINS (Category Is New To PDL)

PREFERRED REGULAR/INTERMEDIATE ACTING INSULIN

HUMULIN R U-500 VIAL
HUMULIN R U-100 VIAL OTC
NOVOLIN N U-100 VIAL

PREFERRED LONG ACTING INSULIN

LEVEMIR PENS & VIALS
‡LANTUS SOLOSTAR PEN
LANTUS VIAL

PREFERRED RAPID ACTING INSULIN

HUMALOG VIAL
‡APIDRA SOLOSTAR PEN
APIDRA VIAL
‡NOVOLOG PEN
NOVOLOG VIAL
‡NOVOLOG CARTRIDGE
‡HUMALOG PEN

PREFERRED COMBINATION INSULINS

HUMALOG MIX VIAL
ŦHUMALOG MIX PEN
ŦNOVOLOG MIX PEN
NOVOLOG MIX VIAL
HUMULIN 70/30 VIAL OTC

NON-PREFERRED INSULINS WITH CONTINUATION CRITERIA

▲NOVOLIN 70/30 VIAL OTC
ŦŦHUMULIN 70/30 PEN OTC
ŦŦHUMULIN N U-100 PEN OTC
ŦŦHUMULIN R U-500 PEN

NON-PREFERRED INSULINS

HUMALOG CARTRIDGE
HUMALOG JR QUICKPEN
HUMALOG 200 PEN
AFREZZA
TRESIBA PEN
BASAGLAR KWIKPEN
TOUJEO SOLOSTAR PEN
TRESIBA FLEXTOUCH PEN
FIASP

4) TARGETED IMMUNE MODULATORS (TIMS) (Re-Review)

PREFERRED with Point of Sale criteria (No Changes in Preferred Status)

HUMIRA (ADALIMUMAB)
ENBREL (ETANERCEPT)

NON-PREFERRED TIMS status

ABATACEPT (ORENCIA)
ANAKINRA (KINERET)
APREMILAST (OTEZLA)
CERTOLIZUMAB (CIMZIA)
GOLIMUMAB (SIMPONI)
INFLIXIMAB (REMICADE, INFLECTRA, RENFLEXIS)
IXEKIZUMAB (TALTZ)
SECUKINUMAB (COSENTYX)
TOCILIZUMAB (ACTEMRA)
TOFACITINIB (XELJANZ)
USTEKINUMAB (STELARA)
GUSELKUMAB (TREMFYA)
SARILUMAB (KEVZARA)
BRODALUMAB (SILIQ)
VEDOLIZUMAB (ENTYVIO)
CANAKINUMAB (ILARIS)
RILONACEPT (ARCALYST)

5) SELF-INJECTED EPINEPHRINE (Re-Review)

PREFERRED Status

Epinephrine Authorized Generic of Epipen & Epipen Jr.

NON-PREFERRED status

Epipen & Epipen Jr. (Brand)
Adrenaclick authorized generic

UPDATED INFORMATION ON PDL DRUGS WITH PA CRITERIA:

ARBS:

- ***EFFECTIVE JANUARY 1, 2018,** the Point of Sale Criteria requiring an ACEI in history that is currently applied to the preferred ARBS will be removed.

ACEIs:

- ****** **EFFECTIVE JANUARY 1, 2018, CAPTOPRIL** is moving to NON-PREFERRED STATUS; however, an age edit for point of sale Approval is implemented for children ≤ 12 years of age;

PREFERRED INSULIN PENS:

- ŦŦ**EFFECTIVE JANUARY 1, 2018,** PA Criteria will be removed from *PREFERRED INSULIN PENS*, although quantity edits will remain**;**

NON-PREFERRED AGENTS WITH CONTINUATION CRITERIA

- ▲**NOVOLIN 70/30 VIAL OTC** – Continuation of this non-preferred insulin is implemented **for 6 months** as long as beneficiary is "stable and compliant" during this time and has 90 days of this insulin therapy in Medicaid drug profile in previous 120 days. The continuation criteria is allowed for 6 months to **allow prescribers time to switch beneficiary to preferred status HUMULIN 70/30 VIAL** OTC. As a courtesy, prescribers will receive a letter with a list of his/her patients currently receiving NOVOLIN 70/30 insulin. Effective **Tuesday, JULY 10, 2018**, the continuation criteria will end and claims will deny.

- ŦŦThe following **Non-Preferred Insulin Pens** currently have continuation criteria that will remain in effect for those beneficiaries who remain stable and compliant with 90 days of the insulin drug therapy in the Medicaid drug profile in the previous 120 days:
  - HUMULIN 70/30 PEN OTC
  - HUMULIN N U-100 PEN OTC
  - HUMULIN R U-500 PEN

TIMS

- **SEE HUMIRA AND ENBREL CRITERIA UPDATES LISTED FUTHER IN THE MEMO**

II. *CHANGES TO EXISTING* CRITERIA, INCLUDING CHANGES TO POINT OF SALE (POS) CRITERIA, MANUAL REVIEW PA CRITERIA, OR CLAIM EDITS

EFFECTIVE IMMEDIATELY:

1) KALYDECO® (ivacaftor) tablet:

WAC: $426.71 each tablet or packaged granule, tablets packaged as 60-count bottle; granules packaged as 56-count carton; 30-day supply tablets = $25,602.60; 28-day supply granules = $23,895.75;

KALYDECO® will continue to require Manual Review Prior Authorization (PA) on a case-by-case basis.

INITIAL APPROVAL CRITERIA require all of the following:

- Beneficiary must have diagnosis of Cystic Fibrosis (CF) with the presence of mutations in both copies of the gene for the CFTR protein; AND
- Prescriber must submit the baseline sweat chloride value prior to starting ivacaftor and the sweat chloride value must be indicative of CF; AND
- Beneficiary must have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data, and prescriber must submit documentation that identifies both copies of CF causing mutations. The list of mutations responsive to ivacaftor are listed in the following table:

CFTR Mutations Responsive to KALYDECO						
10 APPROVED PRIOR TO 2017		**23 ADDDED MAY 2017**				**5 ADDED JULY 2017**
G1244E	*S1251N*	*A1067T*	*D579G*	*K1060T*	*R347H*	*2789+5G→A*
G1349D	*S1255P*	*A455E*	*E193K*	*L206W*	*R352Q*	*3272-26A→G*
G178R	*S549N*	D110E	E56K	P67L	R74W	*3849+10kbC→T*
G551D	*S549R*	D110H	*F1052V*	*R1070Q*	*S945L*	*711+3A→G*
G551S		*D1152H*	*F1074L*	*R1070W*	*S977F*	*E831X*
R117H		*D1270N*	*G1069R*	R117C		
10 CFTR mutations indicated based on clinical data		**23 CFTR mutations indicated based on in vitro data**				**5 CFTR mutations indicated based on clinical data**
F508del and 26 other mutations are considered not responsive to ivacaftor						

AND

- Prescriber must submit documentation that beneficiary is not homozygous for the F508del Mutation in the CFTR Gene; AND
- Beneficiary must be age 2 years or older; AND
- Beneficiary must be a non-smoker; AND
- If the PA request is for the R117H mutation, the following documentation is required:
    - Documentation of identification of the second CFTR CF-causing mutation, AND
    - Documentation of the specific poly-T variation for the R117H mutation and for the 2nd CFTR CF-causing mutation, AND
    - Documentation stating which poly-T variation is in the same copy of the CFTR gene with the R117H mutation and which poly-T variation is with the 2nd CFTR CF causing mutation; AND
- Documentation must be submitted to substantiate clinical manifestations of CF that require standard of care treatment; AND
- Prescriber is required to submit current lab results for the transaminases, alanine transaminase (ALT) and aspartate transaminase (AST); current ALT and AST lab results are required at baseline prior to receiving ivacaftor, and must be submitted every 3 months during the 1st year of treatment, and then annually thereafter. If beneficiary has a history of elevated liver transaminases, the ALT and AST lab results are required to be submitted to Medicaid Pharmacy Program with every PA request every 3 months after the 1st year; AND
- ALT or AST lab values must be less than 5 times the upper limit of normal (ULN) as part of approval criteria; AND
- Child-Pugh or Child-Turcotte-Pugh score are required at baseline for dose evaluation review; ivacaftor has not been studied in Child-Pugh Class C; AND
- Prescriber shall provide patient specific measurable goals for treatment outcomes with ivacaftor and include the treatment plan for possible ivacaftor discontinuation if the treatment goals are not met;

KALYDECO® CONTINUATION CRITERIA require all of the following:

- When requesting the first PA for continuation at 3 months after starting ivacaftor, prescriber must submit current sweat chloride value. The sweat chloride value at 3 months after starting ivacaftor must reflect a net change (decrease) over baseline of at least 10%; AND
- Beneficiary must be adherent to daily prescribed therapy, and the Medicaid drug profile will be reviewed for compliance. If fill dates do not correspond to prescribed dose, prescriber must submit documentation of explanation. If dose was reduced, prescriber must submit data and chart notes to substantiate dose reduction date; AND
- ALT and AST lab values must be submitted every 3 months for the 1st year and annually thereafter. If beneficiary has a history of elevated ALT or AST lab values then the ALT and AST lab values must be submitted every 3 months thereafter. ALT or AST lab values must be less than 5 times the upper limit of normal (ULN) as part of the PA approval criteria; AND
- Prescriber shall provide results of the patient specific measurable goals for treatment outcomes with ivacaftor and include the treatment plan for possible ivacaftor discontinuation if the treatment goals are not met; AND
- Beneficiary must remain non-smoker; AND
- Prescriber to submit documentation to substantiate the following:
    - Stabilization or improvement in lung function (FEV1);
    - Stabilization or improvement in weight gain;
    - Reduction in exacerbations/hospitalizations.

KALYDECO® DENIAL Criteria for Any One of the Following:

- Deny PA requests for any of the following mutations that are non-responsive to ivacaftor:
  - #A46D, G85E, E92K, P205S, R334W,R347P, T338I, S492F, I507del, V520F, A559T, R560S, R560T, A561E, L927P, H1054D, G1061R, L1065P, R1066C, R1066H, R1066M, L1077P, H1085R, M1101K, W1282X, N1303K; OR
- Deny request for PA if beneficiary is homozygous for the F508del Mutation in the CFTR Gene Mutations; OR
- Deny request for PA if beneficiary is a smoker; OR
- Deny request if beneficiary is non-adherent to prescribed dose; OR
- Deny request if beneficiary does not meet approval criteria or continuation criteria; OR
- Deny PA request if ALT or AST greater than 5 times the upper limit of normal (ULN); OR
- Deny PA request if beneficiary is Child-Pugh C; OR
- Deny PA request if beneficiary does not have positive response to ivacaftor; OR
- Deny PA request if sweat chloride value after 3 months of treatment with ivacaftor did not reflect a net change (decrease) over baseline of at least 10%.

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 8, 2017:

2) UPCOMING CHANGE IN MAXIMUM DAILY MME:

On MAY 8, 2017, the Maximum Daily Morphine Milligram Equivalent (MME) Dose will DECREASE to ≤ 150 MME/day for non-cancer chronic pain beneficiaries. Incoming opioid claims that will cause the total MME/day to exceed **150 MME/day** (>150 MME/day) on that date *will deny at point of sale* whether from same prescriber or different prescribers. *Please begin titrating the doses downward to prevent claims from denying at point of sale. Medicaid will continue lowering the MME*
In 2016, per the CDC official figures, **Arkansas ranked No. 2 in the nation for highest opioid prescribing rates by dispensing 114.6 opioid prescriptions per 100 persons.** The national average in 2016 was 66.5 opioid prescriptions per 100 persons.

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. The ultimate Medicaid goal is to reduce the TOTAL MME PER DAY for chronic non-cancer pain patients to meet the CDC recommendations.

BENEFICIARIES WHO PAY CASH FOR OPIOIDS, IN ADDITION TO THE OPIOIDS PAID FOR BY MEDICAID, RESULT IN A MUCH HIGHER DAILY MME THAN WHAT IS CALCULATED IN THE MEDICAID SYSTEM EDITS, ARE ABOVE THE CDC RECOMMENDATIONS, AND COULD PUT THE PATIENT AT RISK FOR OVERDOSE.

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 JANUARY 24, 2018

3) PULMICORT (budesonide) RESPULES® FOR NEBULIZER BEING USED OFF-LABEL FOR Eosinophilic Esophagitis (EOE)

NADAC BRAND, price per mL, 30 ampules per carton; each ampule is 2 mL, billing unit is per 1 mL for all strengths;
0.25 mg/2mL = $4.17328 per mL = $8.35 per ampule = $250.40 per carton of 30 ampules.

0.5 mg/2 mL = $4.93345 per mL = $9.87 per ampule = $296.01 per carton of 30 ampules; off-label use of EOE was found to be 1 mg dose daily (4 mL, or 2 ampules) used for *children < 10 years of age*, **2 cartons for 30-day supply = $592.01**;

1 mg/2 mL = $9.85587 per mL = $19.71 per 2 mL ampule, $591.35 per carton of 30 ampules; off-label use of EOE was found to be 2 mg dose daily (4 mL or 2 ampules) in *older children and adults*, **2 cartons for 30-day supply = $1,182.70**.

Fluticasone (FLOVENT® HFA) aerosol metered inhaler is PREFERRED STATUS ON PDL; each Fluticasone canister contains 120 metered doses. The off-label dose for EOE was found to be the same as the asthma dose.

NADAC Generic
44 mcg inhaler = **$164.60** per inhaler
110 mcg inhaler = **$220.69** per inhaler
220 mcg inhaler = **$341.95** per inhaler

The off-label use of PULMICORT RESPULES® to treat EOE is not listed in the official compendia and therefore is not supported in the official compendia. The existing point of sale approval criteria for PULMICORT RESPULES® was designed to approve the drug claim for children < 4 years of age for inferred asthma diagnosis.

Point of Sale (POS) DENIAL CRITERIA is added to PULMICORT Respules® if the diagnosis of EOE is in the Medicaid medical history in the previous 2 years. Currently, brand name Pulmicort Respules® is included as preferred status for asthma in children < 4 years of age, and the generic budesonide inhalation suspension is non-preferred. If there is an EOE diagnosis in Medicaid medical history in previous 2 years, the claim for PULMICORT Respules® will deny at POS.

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 FEBRUARY 7, 2018

4) MONTELUKAST (aka brand name Singulair®) POS ALGORITHM FOR TREATING ALLERGIC RHINITIS

NADAC GENERIC: 10 mg tablet-- $.090947 each;
5 mg chew tablet $0.145 each;
4 mg chew tablet $0.175 each;
4 mg granule pkt $3.25 each;

Montelukast is FDA approved for asthma, exercise-induced bronchoconstriction, and allergic rhinitis. The FDA approved dosing for all approved ages is once daily. For adults and adolescents 15 years of age and older the dose is one 10 mg tablet daily. For pediatric patients 6 to 14 years of age the dose is one 5 mg chewable tablet daily. For pediatric patients 2 to 5 years of age the dose is one 4-mg chewable tablet daily. The 4-mg oral granule formulation once daily should be used for pediatric patients 12 to 23 months of age for the treatment of asthma, or for pediatric patients 6 to 23 months of age for the treatment of perennial allergic rhinitis. Safety and effectiveness in pediatric patients younger than 6 months of age with perennial allergic rhinitis and less than 12 months of age with asthma have not been established. See package insert for further dose information.

Serious neuropsychiatric events have been reported in adult, adolescent, and pediatric patients taking montelukast sodium and the information can be found under the Warnings and Precautions section of the package insert. Post-marketing neuropsychiatric events reported with montelukast sodium use include agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal thinking and behavior (including suicide), tic, and tremor.

The montelukast POS approval criteria for treating *Allergic Rhinitis* is revised to the following:

- If there is no paid drug claim(s) in history for an inhaled corticosteroid, long-acting beta2 agonist/inhaled corticosteroid, or short-acting beta$_2$ agonist in the last 365 days [inferred treatment for asthma], then
    - Search for ≥ one paid claim for an intranasal steroid in the ***30-days back*** to 124 days back in Medicaid history for inferred diagnosis of treating allergic rhinitis. If at least one claim for an intranasal steroid is found in that timeframe, allow montelukast claim as inferred change in treatment or inferred add-on treatment for allergic rhinitis.

In addition, age edits are implemented as follows:

- An age edit is implemented for the montelukast 10 mg tablet of beneficiary is ≥15 years;

- The *maximum* age edit of 16 years on the 4 mg & 5 mg chew tablets will remain; claims for infants ≤ 23 months of age will reject at point of sale for the 4 mg and 5 mg chewable tablets;
- The age edit is implemented for the montelukast 4 mg granule for beneficiary is ≥ 6 months old < 24 months old;
- Claims for pediatric patients < 6 months of age will deny 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 FEBRUARY 14, 2018

5) REVISED CRITERIA FOR TARGETED IMMUNE MODULATORS (TIMs) CRITERIA: ENBREL® (etanercept) AND HUMIRA® (adalimumab):

HUMIRA: NADAC brand pricing and WAC pricing for NDCs for 40mg/0.8 mL and 10 mg/0.2mL, and 20 mg/0.4 mL have a range of pricing for the different NDCs from $2,147.09 ea to $2,220.62 each;

ENBREL: NADAC Brand pricing 25 mg vial each or 25 mg/0.51 mL syringe are approximately $537 to $540; the 50 mg/mL syringes and pens vary slightly in price from $1,075 to $1,110.

ENBREL® (etanercept) AND HUMIRA® (adalimumab) are the two preferred drugs on the PDL for the Targeted Immune Modulator (TIMs) drug category. The Point of Sale approval criteria for rheumatoid arthritis/psoriatic arthropathy for both ENBREL® (etanercept) and HUMIRA® (adalimumab) have been updated to remove gold compounds, penicillamine, and azathioprine from the list of drugs required to have been used in the past 365 days for treating RA or psoriatic arthropathy prior to starting therapy with a TIMs.

The HUMIRA® (adalimumab) POS approval criteria for Crohn's disease in *pediatric beneficiaries age* ≥ 6 years < 18 years have been revised to the following:

Criteria to infer corticosteroid refractory pediatric patients when inducing remission:
- For children ≥6 years of age but <18 years of age, AND beneficiary has diagnosis of Crohn's Disease in Medicaid medical history in previous 2 years; AND
- Beneficiary has a minimum of 14-days' supply in previous 30-days of oral prednisone or prednisolone, or budesonide EC 3 mg capsule.

OR
Criteria to infer failure of maintenance medications when treating Crohn's disease in pediatric patients:
- For children ≥6 years of age but < 18 years of age, AND beneficiary has diagnosis of Crohn's Disease in Medicaid medical history in previous 2 years; AND
- ≥30 days of drug therapy in previous 45 days of one of the following: azathioprine or 6-mercaptopurine or methotrexate.

OR
Criteria for fistulising Crohn's disease with fistula in pediatric beneficiaries:
- For children ≥6 years of age but <18 years of age, AND submitted diagnosis code for Crohn's disease or regional enteritis in the past two years, AND submitted diagnosis code for fistula in the past two years;

OR
Criteria for Crohn's disease continuation criteria after starting HUMIRA®, aka "stable and compliant" criteria:
- For children ≥6 years of age but <18 years of age, AND Crohn's disease or regional enteritis in the past two years, AND
- Drug claim for adalimumab (HUMIRA®) in the past 45 days (signifying one of above criteria previously met);

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 FEBRUARY 21, 2018:

6) REVISED CRITERIA ALGORITHMS FOR POS CRITERIA FOR PREFERRED PULMONARY ARTERIAL HYPERTENSION (PAH) DRUGS on the PDL, AND FOR MANUAL REVIEW CRITERIA FOR NON-PREFERRED PAH DRUGS:

PREFERRED DRUGS:
LETAIRIS® (ambrisentan) 5 mg or 10 mg tablet = WAC: $308.487 each tablet; #30 = $9,254.61 for 30-day supply;
TRACLEER® (bosentan) 62.5 mg or 125 mg tablet = $166.50 each tablet; #60 = $9,990 for 30-day supply; TRACLEER's new 32 mg tablet for pediatric use - pricing not available at this time;
ADCIRCA® (tadalafil) 20 mg tablet: NADAC Brand = $58.57472 each tablet; #60 = $3,514.48 30-day supply;
Generic sildenafil (aka REVATIO®) 20 mg tab: NADAC Generic = $0.327 ea tablet; #90 =$29.43/ 30-day supply

NON-PREFERRED DRUGS:
OPSUMIT® 10 mg: WAC: = $276.40 each tablet; #30 = $8,292 for 30-day supply
REVATIO® ORAL SUSPENSION, 112 mL bottle: NADAC Brand: = $64.28826 per mL or $7,200 per bottle
ADEMPAS® 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg: WAC: = $102.22888 ea tablet, #90 = $9,200.60 30-day supply;
UPTRAVI® 200 mcg: WAC: = $161.90 each tablet or $9,714 for 30-day supply; the 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg tablets =$251.68 each tablet, #60 = $15,101 for 30-day supply;
ORENITRAM® ER 0.125 mg: WAC = $4.875; .25 mg = $9.75 ea, 1 mg $39 ea; 2.5 mg = $97.50 ea; 5 mg = $195 ea; "maximum dose is determined by tolerability" so max dose not stated in pkg insert; Dose BID for 0.25, and TID for 0.125 mg; did find 2 mg TID (using 1 mg tablet). 0.125 mg TID #90 = $438.75; 0.25 mg BID #60 = $585; 1 mg # 60 = $2,340, 1 mg #180 = $7,020. 2.5 mg #60 = $5,850; 5 mg #60 = $11,700.
TYVASO®, max dose requires use of 1 ampule per day for QID dosing; Tyvaso® starter kit: WAC = $16,750 for 28-day supply; **refill box of 28 ampules $15,015 for 28-day supply;**
VENTAVIS® 10 mcg/mL, and 20mcg/mL, cartons of 30; both strengths: $123.70 per mL; dose is 6-9 times per day; at max dose of 9 times per day using 1 ampule per dose: WAC = $33,399 for 30-day supply; price per carton is $3,711 (3.3 day supply at max dose);

Revised Point of Sale criteria for the PREFERRED PAH Drugs, LETAIRIS® (ambrisentan) Tablet, TRACLEER® (bosentan) Tablet, REVATIO® (sildenafil) Tablet, ADCIRCA® (tadalafil) Tablet, are as follows:

- **A THERAPEUTIC DUPLICATION (TD) edit is added to the preferred drugs to not allow therapeutic duplication within same drug class type (ERA, PDE5, and Prostacyclin) or same pathway (endothelin, NO/cGMP, and prostacyclin). See chart below.**

PDL STATUS	DRUG	DRUG CLASS	PATHWAY
PREFERRED	LETAIRIS (ambrisentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	TRACLEER (bosentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	REVATIO (sildenafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway
PREFERRED	ADCIRCA (tadalafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway

- **POS APPROVAL will be added to TRACLEER® 32 mg tablet, when it becomes available in the system, if a diagnosis code from chart below is found in the beneficiary's Medicaid medical history in the previous 2 years. TRACLEER® 32 mg tablet is indicated for idiopathic or congenital PAH in pediatric beneficiaries who are ≥3 years of age. (At the time of this writing, the new strength, TRACLEER® 32 mg, was not available in the system.)**

Source Code Title	ICD-10-Diagnosis Code	Target Code Title
Persistent fetal circulation	P29.3	Persistent fetal circulation
Chronic respiratory disease arising in the perinatal period	P27.0	Wilson-Mikity syndrome
Chronic respiratory disease arising in the perinatal period	P27.1	Bronchopulmonary dysplasia originating in the perinatal period
Chronic respiratory disease arising in the perinatal period	P27.8	Other chronic respiratory diseases originating in the perinatal period
Chronic respiratory disease arising in the perinatal period	P27.9	Unspecified chronic respiratory disease originating in the perinatal period

- **NEW POS DENIAL CRITERIA: the following contraindications have been added to point of sale denial criteria for the Preferred PAH drugs (LETAIRIS® (ambrisentan), TRACLEER® (bosentan), ADCIRCA® (tadalafil), generic sildenafil (aka REVATIO®)) as follows:**
  - LETAIRIS® (ambrisentan), TRACLEER® (bosentan), ADCIRCA® (tadalafil), OR generic sildenafil (aka REVATIO®): Deny claim for diagnosis of current pregnancy in Medicaid medical history.
  - LETAIRIS®: Deny incoming LETAIRIS claim if diagnosis of idiopathic pulmonary fibrosis (ICD-10 code J84.112) is in Medicaid medical history in previous 2 years.
  - TRACLEER®: Deny incoming TRACLEER® claim if beneficiary has a drug claim for glyburide in Medicaid drug history in previous 45 days, and vice-versa (deny incoming claim for glyburide if beneficiary has drug claim for TRACLEER® in Medicaid drug history in previous 45 days.)
  - ADCIRCA®: Deny incoming ADCIRCA® claim if beneficiary has a drug claim for ADEMPAS® (riociguat) in Medicaid drug history in previous 45 days.

NON-PREFERRED DRUGS INCLUDE OPSUMIT® (macitentan) Tablet, REVATIO® (sildenafil) Oral Suspension, ADEMPAS® (riociguat) Tablet, UPTRAVI®(selexipag) Tablet, ORENITRAM® ER (treprostinil) Tablet, VENTAVIS® (iloprost) Inhalant solution, TYVASO® (treprostinil) Inhalant solution.

- **INITIAL APPROVAL CRITERIA for NON-PREFERRED PAH drugs will require a manual review Prior Authorization on a case-by-case basis and *at a minimum* will require all of the following for a thorough clinical review:**
  - Prescriber must submit letter explaining medical necessity of beneficiary receiving a non-preferred PAH drug *over a preferred PAH drug that does not require additional manual review*, including a request to add a non-preferred PAH drug in combination with a preferred PAH drug. Prescriber must submit all chart notes, lab documentation, etc., to substantiate the medical necessity of receiving the non-preferred PAH drug;
  - Beneficiary must be a non-smoker; if beneficiary recently quit smoking, additional documentation of CO (carbon monoxide) test levels to substantiate non-smoker status may be required to substantiate non-smoking status;
  - Prescriber must submit the WHO Group or Category number (1 – 5) that best describes the patient's classification for Pulmonary Hypertension (e.g., WHO Group-1 through WHO Group-5), *AND* must include the patient's Functional Class (FC) of the WHO Group category, if applicable. (e.g., beneficiary is WHO Group-1, Functional Class (FC)-II; or WHO Group-1, FC-IV; or WHO Group-3, etc.);
  - Request for non-preferred drug must be for FDA approved indication for the drug; in addition, clinical reviewers will refer to FDA approved indications and other data in the package insert as well as the appropriate WHO Group treatment guidelines. Currently no PAH drugs are FDA approved for treating WHO Group-3;
  - Prescriber must provide patient specific measurable goals for treatment outcomes with the requested PAH drug and include the treatment plan for possible PAH drug discontinuation if the treatment goals are not met;
  - If non-preferred PAH drug is approved, the initial approved PA request will not exceed 3 months.

- **CONTINUATION CRITERIA for Non-preferred PAH drug require all of the following:**
  - Beneficiary adherent to prescribed dose; AND
  - Beneficiary must remain non-smoker; AND
  - Prescriber must submit documentation, chart notes, lab tests, etc., that document the beneficiary has a positive response to the drug, e.g. documentation to substantiate improved hemodynamics from the drug in question; AND
  - Prescriber shall provide results of patient specific measurable goals for treatment outcomes with the requested PAH drug and include the treatment plan for possible PAH drug discontinuation if the treatment goals are not met; AND
  - If approved for continuation, PA approval shall not exceed 6 months.

- **DENIAL CRITERIA for Non-preferred PAH drug for Any One of the Following::**
  - Deny if beneficiary is a current smoker; OR
  - Deny if beneficiary does not meet approval criteria; OR
  - Deny if beneficiary is non-adherent to prescribed dose; OR
  - Deny if no documentation of a positive response to the requested drug; OR

- Deny if requested drug is in same class or same pathway as another PAH drug beneficiary is currently receiving.

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 FEBRUARY 14, 2018:

7) REVISION TO THE REFILL TOO SOON (RTS) *EARLY REFILL ACCUMULATION LIMIT* FOR CONTROLLED DRUGS

In February 2016, the *Refill Too Soon (RTS) logic with an Early Refill Accumulation Limit* edit was implemented for both non-controlled drugs and controlled drugs, which *limited the accumulation of extra days' supply* for those beneficiaries who routinely filled prescriptions early. At that time, the RTS logic with the Early Refill *Accumulation* Limit allowed beneficiaries to *accumulate an extra 15-days' supply* in the previous 180 day period. The ***RTS logic with Early Refill Accumulation Limit*** **edit** is **revised for the *controlled drugs only*. The revised edit for controlled drugs will allow *an extra 7-days' supply* accumulation through early fills in previous 180 day period rather than an accumulation of an extra 15-days' supply.** The RTS logic with Early Refill Accumulation Limit edit for non-controlled drugs will remain as is at the accumulation through early fills of an extra 15-days' supply in previous 180 days.

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

EFFECTIVE FEBRUARY 14, 2018:

8) REVISED POS CRITERIA FOR MEDICAID BENEFICIARIES WHO ARE "*NEW STARTS* TO OPIOID THERAPY":

The following criteria exclude terminal cancer patients who have a cancer diagnosis in the Medicaid medical history in the previous 365 days.

For purposes of this criteria, **"New Start to opioid therapy" for a Medicaid Beneficiary is defined as *no claims for any opioid drugs for pain in the beneficiary's Medicaid drug profile in the previous 60 days***.

- **For a "*New Start to opioid therapy*" beneficiary,** the maximum MME/DAY is *decreased* to a **maximum of 50 MME/da**y; AND
- The initial prescription for the **"**New Start to opioid therapy**"** beneficiary for the **short-acting opioid is limited to a 7-day supply** with the corresponding **quantity limit of up to 6 tablets or capsules per day**; AND
- **Long-Acting (LA) opioid claim will reject at Point of Sale if there is no claim for a LA opioid in the beneficiary's Medicaid drug profile in the previous 60-days.** If the beneficiary has been paying CASH or using an insurance prescription drug plan for previous claims of a LA opioid, the prescriber must submit documentation (copy of PDMP or pharmacy printout) that the beneficiary is opioid tolerant and has been receiving a LA opioid; the prescriber may request a PA for a LA opioid approval through a manual review PA request for an opioid tolerant beneficiary. This will include a beneficiary being switched from chronic use of a short-acting opioid to a long-acting opioid; AND
- If the Medicaid beneficiary has been *paying CASH for opioid prescriptions* OR has been *filling opioid prescriptions through an insurance prescription drug plan (TPL)* rather than filling opioid prescriptions through the Medicaid Pharmacy Program in the previous 60 days, then there will be no Medicaid history to indicate that the beneficiary has been receiving opioid claims and is an opioid tolerant beneficiary. The prescribing provider may request an override (PA) to this criterion and must provide the prescription opioid drug claim documentation (copy of PDMP or pharmacy printout) to the Medicaid Pharmacy Program to substantiate that his/her patient is opioid tolerant and may receive up to the current MME limit as part of the exception to the established criteria.

BENEFICIARIES WHO PAY CASH FOR OPIOIDS, IN ADDITION TO THE OPIOIDS PAID FOR BY MEDICAID, RESULT IN A MUCH HIGHER DAILY MME THAN WHAT IS CALCULATED IN THE MEDICAID SYSTEM EDITS, ARE ABOVE THE CDC RECOMMENDATIONS, AND COULD PUT THE PATIENT AT RISK FOR OVERDOSE.

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 FEBRUARY 14, 2018:

III. *NEW* CLINICAL POS EDITS WITH OR WITHOUT ADDITIONAL CLAIM EDITS

1) EDITS TO ASSIST IN SAFE PRESCRIBING OF OPIOIDS AND BENZODIAZEPINES AFTER NON-FATAL POISONING OR OVERDOSE:

The following criteria exclude terminal cancer patients who have a cancer diagnosis in the Medicaid medical history in the previous 365 days.

A POS edit is implemented as follows to ensure prescribing providers are aware when his/her patient incurs a poisoning (overdose) diagnosis through the emergency room and opioid and/or benzodiazepines are continued.

- An incoming claim for any opioid pain medication or an incoming claim for a benzodiazepine medication will trigger a search of the beneficiary's Medicaid medical diagnoses history for diagnosis of poisoning or overdose the previous 3 months.
- If a *diagnosis* for poisoning (overdose) for opioids, narcotics, barbiturates, benzodiazepines, or "unspecified drug or substance" is found in the Medicaid medical history in the previous 3 months, an incoming claim for an opioid pain medication or an incoming claim for a benzodiazepine medication will deny at point of sale.
- The prescriber may request a Prior Authorization for the beneficiary to continue the opioid, benzodiazepine, or both, using all of the following:
    - Submit a letter to the Medicaid Pharmacy Program explaining the medical necessity of the beneficiary to continue receiving the opioid, the benzodiazepine, or both medications, despite the recent non-fatal poisoning (overdose) diagnosis in Medicaid history; AND
    - Provide an opioid taper schedule to decrease the opioid(s) dose and reduce the maximum daily MME; AND
    - The prescriber must agree to *not* provide prescriptions for cash for opioids or for benzodiazepines that avoid the Medicaid dose edits, quantity edits, or MME edits; AND
    - If the poisoning diagnosis was due to an opioid, an unspecified narcotic, or unspecified drug or substance", the prescriber must provide proof that the beneficiary filled a naloxone vial or naloxone pre-filled syringe (naloxone vials and naloxone pre-filled syringes do not require a Prior Authorization with Medicaid Pharmacy Program); AND
    - If the poisoning was due to a benzodiazepine, or the beneficiary is receiving both a benzodiazepine and an opioid medication, provide a benzodiazepine taper schedule and information as to why the beneficiary cannot be switched to a different, non-benzodiazepine medication, for treatment of the anxiety disorders, panic disorder, agitation, insomnia, etc.; AND
    - Any approved PAs will include the reduced dose if it is less than the current limits or current MME/day; AND
    - Prior Authorizations will be on a month-to-month basis for an undetermined amount of time.

BENEFICIARIES WHO PAY CASH FOR OPIOIDS, IN ADDITION TO THE OPIOIDS PAID FOR BY MEDICAID, RESULT IN A MUCH HIGHER DAILY MME THAN WHAT IS CALCULATED IN THE MEDICAID SYSTEM EDITS, ARE ABOVE THE CDC RECOMMENDATIONS, AND COULD PUT THE PATIENT AT RISK FOR OVERDOSE.

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 JANUARY 17, 2018:

2) CAROSPIR® (Spironolactone 25mg/5mL) suspension:
WAC: $2.05496 per mL; **$1,232.98** at maximum dose (100 mg daily), or 600 mL for 30-day supply.

Point of Sale APPROVAL CRITERIA is implemented as follows:
- Beneficiary is an adult age ≥ 18 years of age; AND
- Beneficiary has "NPO" diagnosis in Medicaid medical history in previous 365 days.

Point of Sale Denial Criteria:
- Hyperkalemia diagnosis in history in previous 60 days; OR
- Beneficiary has concomitant administration with potassium supplementation drug claim in previous 60 days; OR
- Addison's disease diagnosis in history in previous 2 years; OR
- Concomitant use of eplerenone (aka INSPRA® brand name) claim in previous 60 days; OR
- Beneficiary has lithium drug claim in history in previous 60 days; OR
- Beneficiary is pregnant.

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 JANUARY 17, 2018:

3) ACYCLOVIR ORAL SUSPENSION 200 mg/ 5 mL:
Acyclovir 200 mg/5 mL suspension: ACA FUL = $0.55988 per each mL; or $2.71 for 200 mg suspension dose;
Acyclovir capsule: $0.11812 each capsule;
200 mg suspension every 4 hours, 5 times daily for 10 days = 25 mL/day = 250 mL =$139.97
200 mg capsule = $0.11812 each capsule; #50 capsules for 10-day supply = $5.91

Point of Sale APPROVAL CRITERIA is implemented as follows:
- Child must be < 7 years of age; OR
- Child ≥ 7 years and adults must have NPO diagnosis in Medicaid medical history in previous 365 days.

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

EFFECTIVE IMMEDIATELY

IV. ***NEW MANUAL REVIEW CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS***

1) **ZYKADIA® (ceritinib) capsule 150 mg**
WAC: $105.35628 each capsule, package size 70 capsules; recommended dose = 750 mg (5 capsules) daily = $526.78 per day, or #140 capsules = **$14,749.84** for a **28-day supply**

ZYKADIA® (ceritinib) capsule will require Manual Review PA on a case-by-case basis.

ZYKADIA® (ceritinib) INITIAL APPROVAL CRITERIA require all of the following:
- Prescriber must submit letter explaining the medical necessity of receiving ZYKADIA®; AND
- Beneficiary has diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test; AND
- Beneficiary is an adult; AND
- Prescriber to submit monthly liver lab tests with each PA request (ALT, AST, alkaline phosphatase, bilirubin); AND
- Electrolyte values (calcium chloride, potassium, magnesium, sodium) at baseline; AND
- ECG at baseline; AND
- Prescriber to submit fasting serum glucose at baseline; AND
- Prescriber to submit lipase and amylase values at baseline; AND
- PA approval to be month-to-month due to high possibility of dose reductions or dose interruptions due to high adverse event (AE) profile; AND
- Blood creatinine at baseline; AND
- Pregnancy test if applicable; AND
- WHO performance status 0-2; AND

QUANTITY LIMIT: Not to exceed #140 for a 28 day supply; quantity to be entered at time of PA approval due to high AE profile;

CONTINUATION CRITERIA, PA required monthly:
- Beneficiary adherent to prescribed dose; AND

- Chart notes with documentation of review for signs and symptoms of AEs; AND
- The following lab values or tests required for monthly PA requests; dose reduction or permanent discontinuation based on data in package insert for the AEs:
    - Submit monthly liver lab values (bilirubin, ALT, AST, alkaline phosphatase); AND
    - Chart notes regarding severe GI AEs (diarrhea, nausea, vomiting, abdominal pain); AND
    - Submit lipase and amylase labs monthly; AND
    - Submit fasting serum glucose monthly; AND
    - Submit heart rate monthly; AND
    - In the presence of pulmonary symptoms indicative of ILD/pneumonitis, submit appropriate documentation to determine if ILD/pneumonitis is treatment-related or from other potential causes; AND
    - In patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities or those who are taking medications know to prolong the QTc interval, submit ECG results with PA request. AND
- Prescriber to submit daily dose documentation with monthly PA request due to high potential for dose interruption and/or dose reductions (in clinical trial, dose interruptions due to adverse reactions occurred in 77%, dose reductions were required in 66%). The quantity limit for the PA will be entered at the time the PA is approved.

DENIAL CRITERIA using any of the following:

- Beneficiary non-adherent to prescribed dose; OR
- Pregnancy; OR
- Disease progression; OR
- Beneficiaries with uncontrolled diabetes mellitus; OR
- Beneficiaries with history of interstitial lung disease or interstitial pneumonitis; OR
- Beneficiaries with a history of pancreatitis or increase amylase or lipase that was due to pancreatic disease; OR
- Beneficiaries with severe renal impairment (CrCl less than 30 mL/min) at baseline; OR
- See package insert list for list of adverse reactions with specific instructions to withhold drug and monitor conditions, and resume at reduced dose regarding any of the following:
    - Severe or intolerable nausea and vomiting; OR
    - Lipase or amylase elevations; OR
    - Hyperglycemia; OR
    - Cardiac arrhythmias;
    - QTc intervals >500 on at least 2 separate ECGs; OR
    - Symptomatic bradycardia or clinically significant bradycardia requiring intervention; OR
    - Hepatotoxicity (if ALT or AST elevation> 5 times ULN with total bilirubin ≤2 times ULN to ALT or AST elevation is ≤ 3 times ULN); OR Disease progression; OR
- Permanently discontinue for any of the following AEs:
    - Moderate to severe hepatic impairment, ALT or AST elevation greater than 3 times ULN with total bilirubin elevation greater than 2 times ULN in the absence of cholestasis or hemolysis;
    - Any Grade treatment-related ILD/pneumonitis;
    - QTc interval prolongation in combination with Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia;
    - Life-threatening bradycardia in patients who are not taking a concomitant medication also known to cause bradycardia or known to cause hypotension;
    - If, despite optimal antihyperglycemic therapy, hyperglycemia is > 250 mg/dL and control cannot be achieved with optimal medical management; OR
- Beneficiary unable to tolerate reduced dose of 300 mg per day (i.e., deny if dose is <300 mg 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) DRUGS FOR TREATING TARDIVE DYSKINESIA (TD): INGREZZA™ (valbenazine) capsule 40 mg; AUSTEDO® tablet 6 mg, 9 mg, 12 mg:

INGREZZA™ available as a 40 mg and 80 mg: WAC pricing; ONCE DAILY DOSING
40 mg = $175.83 each capsule; **#30** / **30-day supply = $5,274.90**;

80 mg = $207.50 each capsule; **#30 /30-day supply = $6,225. 00**
AUSTEDO®, 3 strengths, WAC pricing; TWICE DAILY DOSING
6 mg = $54.80 each tablet
9 mg = $61.65 each tablet; @ 36 mg/day (#120 of 9 mg) = **$7,398** for **30-day supply;**
12 mg = $82.20 each tablet; @ 24 mg/day (#60 of 12 mg) = **$4,932** for **30-day supply;**
@48 mg/day (#120 of 12 mg, maximum dose**) = $9,864** for **30-day supply;**
Titration with AUSTEDO® to achieve maximum dose using 6 mg tablet requires **98 tablets in Month-1 ($5,370.40**), and **203 tablets in Month-2 ($11,124.40**).

Price Comparison for Benztropine tablet used in other movement disorders:
0.5 mg = NADAC Generic $0.09479 each tablet;
1 mg = NADAC Generic $0.08631 each tablet;
2 mg = NADAC Generic $0.11559 each tablet;

INGREZZA™ approval criteria will require Manual Review PA on a case-by-case basis.

INGREZZA™ INITIAL APPROVAL CRITERIA:

- Beneficiary must have diagnosis of moderate to severe tardive dyskinesia caused by long-term use of dopamine receptor antagonist (e.g., antipsychotics or metoclopramide), AND beneficiary is currently receiving antipsychotic agent, AND beneficiary has concurrent diagnosis of schizophrenia/schizoaffective disorder or mood disorder, AND beneficiary must also have stable psychiatric symptoms without suicidal or violent behavior; AND
- Prescriber must submit the completed Medicaid "INGREZZA™ / AUSTEDO® Statement of Medical Necessity" form with the initial request as part of the manual review PA; AND
- Prescriber must submit *all* previous and current AIMS assessment rating (Abnormal Involuntary Movement Scale) forms as part of the manual review PA; AND
- Beneficiary is an adult ≥ 18 years of age; AND
- Female beneficiary of child bearing age is not pregnant and is on effective birth control; AND
- Prescriber must submit chart notes; AND
- Prescriber must provide data if benztropine, or any other agent, was tried for other EPS symptoms or TD symptoms and show data for improvement of symptoms, or lack of improvement, to the agent; AND
- Prescriber must submit Child-Pugh score; dose will be limited to 40 mg/day for Child-Pugh score 7 to 15; AND
- Prescriber must submit baseline alkaline phosphatase and bilirubin levels, and current levels with every PA request;
- Prescriber must submit baseline creatinine clearance results; AND
- Beneficiary must not have severe renal impairment (creatinine clearance <30 mL/min); AND
- Prescriber must provide data that substantiates beneficiary does not have congenital long QT syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval; AND
- Beneficiary is not a CYP2D6 poor metabolizer, AND beneficiary is not on current medications that are strong CYP3A4 inducers or strong CYP3A4 or CYP2D6 inhibitors; AND
- Initial approval for INGREZZA™ 40 mg not to exceed # 55 and 1 month for titration; AND
- Prescriber to submit final titrated dose with 2nd PA request; approval to be for 1 month.

CONTINUATION CRITERIA for requests for INGREZZO™:

- Beneficiary must be adherent to prescribed daily dose of requested drug; AND
- Total daily dose of drug is contingent upon dosage warnings in package inserts; AND
- For the Month-3 PA request, and for every PA request thereafter, prescriber must submit a current AIMS assessment rating evaluation form for the beneficiary; AND
- Beneficiary must show a positive response to INGREZZA™, defined as a mean change from baseline of at least a 50% reduction in the items numbered 1-7 of the AIMS assessment score at the end of Week 8, and must maintain the improvement with every subsequent PA request; AND
- If beneficiary has moderate or severe hepatic impairment (Child-Pugh score 7 to15), dose will be limited to 40 mg/day and quantity limit of 1 per day must be entered at time of PA approval; AND
- Prescriber must submit current alkaline phosphatase and bilirubin levels to rule out dose-related increase in alkaline phosphatase and bilirubin levels and the potential risk for cholestasis;
- For INGREZZA™, creatinine clearance must show beneficiary does not have severe renal impairment;
- Approval not to exceed 6 months at a time after maintenance dose achieved.

QUANTITY LIMITS

INGREZZO™ is available as 40 mg & 80 mg capsule:

- The maximum dose is 80 mg daily. Dose limit set as 1 capsule per day, #31/31 days' supply. First month will require an override of quantity for the 40 mg capsule as part of the initial prior authorization. Final titrated dose must be provided when requesting month-2 prior authorization.

DENIAL CRITERIA for INGREZZA™

- Beneficiary <18 years of age; OR
- Beneficiary is not adherent to prescribed dose; OR
- Requested dose > 80 mg/day for INGREZZA™; OR
- Beneficiary does not show a positive response to requested drug;
- Beneficiary is pregnant; OR
- Female beneficiary is breastfeeding; OR
- Beneficiary has unstable psychiatric symptoms; OR
- Beneficiary has significant risk for suicidal or violent behavior; OR
- Beneficiary has Congenital long QT syndrome; OR
- Beneficiary has severe renal impairment (creatinine clearance <30 mL/min); OR
- Beneficiary has dose related increase in alkaline phosphatase and bilirubin and a potential risk for cholestasis; OR
- Beneficiary has cholestasis; OR
- Beneficiary has concomitant use of strong CYP3A4 inducers; OR
- The INGREZZA™ 80 mg dose is denied for Child-Pugh score 7-15, beneficiary is known CYP2D6 Poor Metabolizer, co-administration with strong CYP3A4 Inhibitors, or co-administration with Strong CYP2D6 Inhibitors; OR
- Failure to meet approval criteria;

AUSTEDO® approval criteria will require Manual Review PA on a case-by-case basis.

AUSTEDO® INITIAL APPROVAL CRITERIA

- Beneficiary must have diagnosis of moderate to severe tardive dyskinesia caused by long-term use of dopamine receptor antagonist (e.g., antipsychotics or metoclopramide) AND is currently receiving long-term antipsychotic drugs, AND has concurrent diagnosis of schizophrenia/schizoaffective disorder or mood disorder, AND must also have stable psychiatric symptoms without suicidal or violent behavior; OR
- Beneficiary has a diagnosis of chorea associated with Huntington's disease with no history of depression or suicidal ideation or attempts; AND
- For treating diagnosis of chorea associated with Huntington's disease, prescriber must submit letter explaining medical necessity of receiving AUSTEDO®; AND
- If the request is for treating a diagnosis of moderate to severe tardive dyskinesia caused by long-term use antipsychotic agent, provider must explain the medical necessity of receiving AUSTEDO® over INGREZZA™ due to the more complex dosing titration schedule for AUSTEDO®; AND
    - Prescriber must substantiate that the beneficiary is competent to achieve compliance with the prescribed titration schedule to attain the maintenance dose or that the beneficiary has a caregiver who is capable of managing the titration schedule to achieve the maintenance dose; prescriber must provide titration schedule with PA request; AND
- Prescriber must submit the completed Medicaid "*INGREZZA™ / AUSTEDO® Statement of Medical Necessity*" form with the initial request as part of the manual PA review; AND
- For treating Tardive Dyskinesia, Prescriber must submit *all* previous and current AIMS assessment rating (Abnormal Involuntary Movement Scale) forms as part of the manual PA review; AND
- Beneficiary is an adult ≥ 18 years of age; AND
- Female beneficiary of child bearing age is not pregnant and is on effective birth control; AND
- Prescriber must submit chart notes; AND
- Prescriber must provide data if benztropine, or any other agent, was tried for other EPS symptoms or TD symptoms and show data for improvement of symptoms, or lack of improvement, to the agent; AND
- Prescriber must submit baseline hepatic panel test results indicate beneficiary does not have any hepatic impairment; AND
- Prescriber must submit baseline creatinine clearance results; beneficiary must not have renal impairment; AND

- Prescriber must provide data that substantiates beneficiary does not have congenital long QT syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval; AND
- Prescriber to submit the hepatic function panel tests results and all results must be in normal range for approval; AND
- Beneficiary is not on current medications that are strong CYP3A4 inducers or strong CYP3A4 or CYP2D6 inhibitors; AND
- For AUSTEDO®, if beneficiary is a CYP2D6 poor metabolizer, the dose cannot exceed 36 mg per day (18 mg BID); AND
- AUSTEDO® will be approved on a month-to-month basis during the titration time-period of the first 2 months until the maintenance dose is achieved, and prescriber must submit the current titration schedule with each PA request; AND
- The QUANTITY limit for AUSTEDO® must be entered at time of the first 2 PA requests based on the titration schedule provided by prescriber (e.g., Month-1, 6 mg tablet #98; Month-2, 6 mg tablet #203).

CONTINUATION CRITERIA for requests for AUSTEDO®:

- Beneficiary must be adherent to prescribed daily dose of requested drug; AND
- Total daily dose of either drug is contingent upon dosage warnings in package inserts; AND
- For the Month-3 PA request, and for every PA request thereafter, prescriber must submit a current AIMS assessment rating evaluation form for the beneficiary; AND
- Beneficiary must show a positive response to AUSTEDO®, defined as a mean change from baseline of at least a 50% reduction in the items numbered 1-7 of the AIMS assessment score at the end of Week 8, and must maintain the improvement with every subsequent PA request; AND
- Hepatic panel test results indicate beneficiary does not have any hepatic impairment; AND
- Creatinine clearance results must indicate beneficiary does not have renal impairment; AND
- In patients who are CYP2D6 poor metabolizers, the daily dose of AUSTEDO should not exceed 36 mg; AND
- Approval not to exceed 6 months at a time after maintenance dose achieved.

QUANTITY LIMITS:

AUSTEDO® tablet is available as 6 mg, 9 mg, and 12 mg tablets.

- The dose is twice daily dosing for all strengths and the daily dose cannot exceed maximum of 48 mg per day.
- The 6 mg will be set as the default quantity of 2 tablets/day and cumulative quantity of #60 for 30-day supply; 9 mg tablets set for 4/day for 36 mg/day;
- The 12 mg tablet will be set as maximum dose of 4 tablets per day, cumulative quantity of 120 tablets for 30-day supply in order to make the 48 mg dose;
- During the titration phase, the quantity for the 6 mg tablet will have to be overridden during the prior authorization approval based on the titration schedule the prescriber provides; maximum quantities would be #98 of 6 mg tablets for month-1, and #203 tablets of 6 mg for month-2, to reach maximum daily dose per package insert instructions. Final titrated dose must be provided when requesting month-2 or month-3 prior authorization.

DENIAL CRITERIA for AUSTEDO®:

- Beneficiary <18 years of age; OR
- Beneficiary is not adherent to prescribed dose; OR
- Requested dose >48 mg/day for AUSTEDO®; OR
- Beneficiary does not show a positive response to requested drug;
- Beneficiary is pregnant; OR
- Female beneficiary is breastfeeding; OR
- Beneficiary has unstable psychiatric symptoms; OR
- Beneficiary has significant risk for suicidal or violent behavior; OR
- Beneficiary has Congenital long QT syndrome; OR
- Beneficiary has any hepatic impairment; OR
- Beneficiary taking reserpine, MAOIs; OR
- If beneficiary is CYP2D6 poor metabolizer, dose > 36 mg of AUSTEDO denied; OR
- If beneficiary has diagnosis of chorea associated with Huntington's disease and is suicidal, or is untreated/inadequately treated for depression; OR
- Failure to meet approval criteria;

The "*INGREZZA™ / AUSTEDO® Statement of Medical Necessity*" form is available on the Medicaid Pharmacy Program website at the following link:
https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Ingrezza_Austedo.pdf

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) XERMELO™ (telotristat ethyl) 250 mg tablet

WAC: $61.47619; supplied as a monthly case of 84 tablets, which is a 28 day supply; each monthly case contains four weekly boxes, each weekly box contains seven daily dose packs of three 250 mg tablets in a child resistant daily dose pack; 28 day supply = $5,164.00.

APPROVAL CRITERIA for XERMELO™ will require Manual Review PA on a case-by-case basis using ALL of the following:
- Prescriber must submit letter explaining the medical necessity of receiving XERMELO™; AND
- Beneficiary is an adult ≥18 years of age; AND
- Beneficiary has diagnosis of metastatic neuroendocrine tumors and carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy; AND
- Beneficiary must currently be receiving and adherent to prescribed dose of SSA therapy, e.g., Sandostatin® (octreotide), Sandostatin® LAR depot, or Lanreotide, at a stable dose for at least 3 months; AND
- Beneficiary Medicaid drug profile shows beneficiary has received other medications for treating diarrhea in recent 30-days (e.g. Loperamide, and/or pancreatic enzyme replacement medications), or chart notes submitted to explain why beneficiary unable to do so; AND
- Prescriber shall provide patient specific measurable goals for treatment outcomes with XERMELO™ and include the treatment plan for possible XERMELO™ discontinuation if the clinical treatment goals are not met.

CONTINUATION CRITERIA for XERMELO™
- Beneficiary adherent to prescribed dose; AND
- Beneficiary adherent to SSA therapy (Sandostatin® (octreotide), Sandostatin® LAR depot, or Lanreotide); AND
- Prescriber must submit chart notes to substantiate positive clinical response to drug; AND
- Prescriber shall provide results of the patient specific measurable goals for treatment outcomes with XERMELO™ and include the treatment plan for possible XERMELO™ discontinuation if the treatment goals are not met (e.g., XERMELO™ reduces number of daily bowel movements on average by 1.4 per day)

DENIAL CRITERIA for XERMELO™:
- Severe constipation noted as diagnosis in system or in chart notes after starting XERMELO™; OR
- Severe persistent or worsening abdominal pain noted as diagnosis in system or in chart notes after starting XERMELO™; OR
- Non-adherent to SSA therapy, or SSA therapy discontinued;

QUANTITY LIMIT (QL) for XERMELO™: packaged as 84 tablets; QL = 3 tablets per day for dose of 250 mg TID, cumulative quantity of 84 tablets for 28-day supply;

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

4) MYDAYIS™ (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate capsule, extended release) 12.5 mg, 25 mg, 37.5 mg, 50 mg

WAC: all strengths = $9.02 each capsule; $279.62 = 31-day supply

MYDAYIS™ is a long-acting C-II stimulant and is indicated for the treatment of ADD/ADHD in patients 13 years of age and older. Requests will not be approved for children less than 13 years of age. Mydayis should be administered upon awakening because the effects may last up to 16 hours and there is the potential for insomnia. In the event of a missed dose, do not administer later in the day.

MYDAYIS™ is a **non-preferred ADD/ADHD drug on the PDL**. As with other non-preferred drugs, it will require manual review PA on a case-by-case basis and physician must submit letter explaining medical necessity of receiving this *non-preferred* long-acting C-II stimulant drug over the *preferred* status C-II stimulant drugs that do not require additional manual review.
Based on the FDA approved dose, there are additional Age Edits applied to the non-preferred drug MYDAYIS™ that are different from the other C-II stimulants:

- Beneficiary must be ≥13 years of age for the 12.5 mg and the 25 mg strengths;
- Beneficiaries who are 13 -17 years of age cannot exceed a daily dose of 25 mg/day (using one 25 mg capsule);
- Beneficiary must be ≥18 years of age, and must meet all other criteria for this age group, for the 37.5 mg and 50 mg strengths;
- Quantity limit for all strengths is 1 capsule per day; cumulative quantity 31 per 31-day supply;

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

5) IDHIFA® (enasidenib mesylate) tablet, film coated 50 mg, 100 mg
WAC: 50 mg or 100 mg tablet = **$829.07 each tablet**; 30-count bottle;
Recommended dose is 100 mg daily = **$24,872.10** for 30-day supply

APPROVAL CRITERIA for IDHIFA® will require Manual Review PA on a case-by-case basis using ALL of the following:

- Beneficiary is an adult ≥18 years of age; AND
- Beneficiary has diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test, such as Abbott RealTi*me*™ IDH2 assay. Prescriber must submit results of the FDA-approved test with PA request; AND
- Beneficiary must have received at least one prior chemotherapy treatment and prescriber must submit results data from previous drug therapy; the clinical review will include reviewing the cancer guidelines to ensure place in therapy for this drug; AND
- Prescriber must submit letter explaining the medical necessity of beneficiary receiving IDHIFA® and include chart notes, all lab data, and other data to substantiate the beneficiary has relapsed AML or refractor AML and that, after taking into account the cancer guidelines for treating the beneficiary, this specific drug is the next best choice for continued pharmacotherapy for this beneficiary; AND
- Female beneficiaries of child bearing age and intact uterus must have current negative pregnancy test and be receiving effective birth control measures; AND
- Prescriber must submit baseline blood counts and blood chemistries for leukocytosis and tumor lysis syndrome prior to the initiation of IDHIFA and must monitor at a minimum of every 2 weeks for at least the first 3 months during treatment and provide the results of the blood counts for leukocytosis and tumor lysis syndrome with every PA request; AND
- Prescriber to submit baseline hepatic function panel test results and every 2 weeks for 3 months; AND
- PA approval is month-to-month for at least the first 3 months;

CONTINUATION CRITERIA

- No disease progression; AND
- Beneficiary must be compliant with prescribed dose; AND
- Prescriber to submit hepatic function panel test results with each PA request; dose will be adjusted or discontinued based on degree of hepatic impairment; AND
- Prescriber to submit results of the blood counts and blood chemistries used to detect leukocytosis and tumor lysis syndrome with every PA request; AND
- Prescriber must provide any changes to the prescribed dose with every PA request; AND

DENIAL CRITERIA

- Disease progression; OR
- Non-compliance to prescribed dose; OR
- Unacceptable toxicities; OR
- Evidence of leukocytosis and tumor lysis syndrome

QUANTITY LIMIT: 1 tablet per day for both strengths (50 mg and 100 mg tablets); cumulative quantity limit is 30 tablets for 30-day supply.

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

FRIENDLY REMINDERS:

1. **"CLAIM EDITS"** referred to in this memo include quantity edits, cumulative quantity edits, monthly quantity edits, age edits, gender edits, accumulation quantity edits, and daily dose edits.

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

3. **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.

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

   To submit a claim using this emergency provision, the pharmacy provider must submit "03" in the Level of Service (418-DI) field. For any Schedule-II controlled substance filled using the Medicaid Emergency Override process, please refer to the Arkansas State Board of Pharmacy regulations regarding partial fill of a Schedule-II controlled substance. See information posted on the Medicaid Pharmacy Program website, https://arkansas.magellanrx.com/provider/documents/.

5. **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.

6. **HARD EDIT ON EARLY REFILL FOR CONTROLLED AND NON-CONTROLLED DRUGS:** The hard edit disallowing early refills (ER) for non-controlled drugs sooner than 75% of days' supply expended was implemented on February 16, 2016. Pharmacies will no longer be able to override the ProDUR early refill edit to refill non-controlled drugs sooner than 75% of the days' supply has elapsed. Refills for non-controlled drugs sooner than 75% of the days' supply elapsed will require a manual review PA and the pharmacy or prescriber must provide documentation to Medicaid that the dose was increased during the month which caused the prescription to run out sooner than expected/calculated. The increased dose must be within the allowed Medicaid dose edits or an approved PA must be in the system for the beneficiary for the higher dose or an early refill PA will *not* be approved.

7. **REFILL TOO SOON ACCUMULATION LOGIC for NON-CONTROLLED DRUGS:** Beginning February 16, 2016, when a pharmacy refills a prescription claim early (e.g., for a non-controlled drug or a controlled drug 1 day early to 7 days early without a PA or sooner with a PA), the Medicaid system began adding together the accumulated "early days" filled. Each prescription is tracked by the Generic Sequence Number (GSN), which means the drug claim is the same generic name, same strength, and same dosage form, rather than tracking by prescription number or NDC. Once the beneficiary has accumulated an "extra" 15 days' supply for that GSN, any incoming claim that is early will reject at point of sale. For example, if the prescription drug claim was for a 30-day supply and was filled 7 days early on February 16, 2016, and filled 7 days early again on March 10, 2016, the beneficiary can only refill the prescription 1 day early on the next refill date, which would be April 8, 2016 (1 day early). The accumulation edit is set so that the beneficiary cannot accumulate *more than* an *extra* 15 days' supply early during a 180-day period. In this example, the drug claim cannot be filled early again until *after* August 14, 2016, which is 180 days from the February 16, 2016 date. The limits for the "Refill Too Soon Accumulation Logic" are currently the same for non-controlled drugs and controlled drugs, including opioids.

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

8. **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.

9. **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.

10. **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.

11. **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.

12. **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.

13. **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.

14. **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

15. **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.