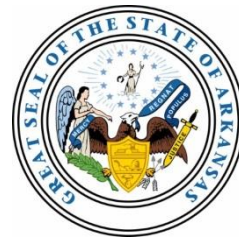




**Division of Medical Services
Pharmacy Program**



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

MEMORANDUM

TO: Arkansas Medicaid Enrolled Prescribing Providers and Pharmacy Providers

FROM: Cynthia Neuhofer, Pharm.D. Division of Medical Services Pharmacy Program *Cynthia Neuhofer*

DATE: **May 17, 2019**

SUBJ: **AR Medicaid Prior Authorization Edits Approved at the AR Medicaid DUR Board April 17, 2019 meeting for the following:** Manual review criteria for DUPIXENT® (dupilumab); DAURISMO™ (glasdegib); XOSPATA® (gilteritinib); VITRAKVI® (larotrectinib); SYMPAZANTM (clobazam); TALZENNA™ (talazoparib); TEGSEDI™ (inotersen); INBRIJA™ (levodopa inhalation); ARIKAYCE® (amikacin liposome); Heredity Angioedema Therapy. POS criteria for Oral typical and atypical antipsychotic agents for adult age 18 years and older; PRIMAQUINE tablets; KRINTAFEL (tafenoquine).
Preferred Drug List (PDL) Drugs from the May 8, 2019 Drug Review Committee Meeting for the following: Oral antipsychotics and proton pump inhibitors

Table of Contents

ANNOUNCEMENTS:

- 1) [REMINDER: Morphine Milligram Equivalents \(MME\) Final Reduction November 14, 2018](#)
- 2) [ELECTRONIC PROVIDER MEMO](#)

PREFERRED DRUG LIST (PDL) UPDATE:

Oral antipsychotic agents and proton pump inhibitors

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

- 1) [Hereditary Angioedema Therapy](#)
- 2) [Oral typical and atypical antipsychotic agents for adult age 18 years and older](#)
- 3) [DUPIXENT® \(dupilumab\) injection—Asthma Criteria](#)
- 4) [DAURISMO™ \(glasdegib\) 25mg & 100mg tablets](#)
- 5) [XOSPATA® \(gilteritinib\) tablets 40mg](#)
- 6) [VITRAKVI® \(larotrectinib\) 25mg & 100mg capsules and 20mg/ml oral solution](#)
- 7) [SYMPAZAN™ \(clobazam\) oral film 5MG, 10MG, 20MG](#)
- 8) [TALZENNA™ \(talazoparib\) capsules 0.25mg & 1mg](#)
- 9) [TEGSEDI™ \(inotersen\) injection 284mg Subcutaneous injection](#)
- 10) [INBRIJA™ \(levodopa inhalation\) powder](#)
- 11) [ARIKAYCE® \(amikacin liposome\) inhalation suspension unit-dose glass vial](#)
- 12) [PRIMAQUINE tablets and KRINTAFEL \(tafenoquine\) tablets](#)

FRIENDLY REMINDERS:

All criteria for the point of sale (POS) clinical edits and claim edits can be viewed on the Medicaid website at <https://arkansas.magellanrx.com/provider/documents/> Select "Resources" tab at the top right, then select "Documents" from the drop-down box. All Provider Memos are under the "Pharmacy" tab at the top.

Medicaid Pharmacy Program drug reimbursement rate methodology changed April 1, 2017; reimbursement rates stated in this memo are informational only and are only current as of the date the memo was drafted; the rates stated are approximate as they may have been rounded.

ANNOUNCEMENTS

1) REMINDER: Morphine Milligram Equivalents (MME) Final Reduction November 14, 2018:

The final MME was reduced to **≤90 MME/day** on **November 14, 2018**. This is an additive edit for all opioid drug claims with overlapping days' supply. The beneficiaries with certain cancer diagnoses in Medicaid medical diagnosis history are exempted from the MME edit.

2) ELECTRONIC PROVIDER MEMO:

To reduce paper waste beginning April 2019, Arkansas Medicaid will no longer mail Pharmacy Program Provider Memos. An electronic message will be sent to all Medicaid enrolled prescribing providers and pharmacy providers as an alert message when the complete Provider Memo is posted on the Arkansas Medicaid Pharmacy Program website.

The Arkansas Medicaid Pharmacy Program Provider Memos can be found at <https://medicaid.mmis.arkansas.gov/Provider/Provider.aspx>. To access the memos, select the OTHER LINKS drop-down menu in the upper-left corner of the screen, click MAGELLAN MEDICAID ADMINISTRATION, select the Administrator box, select the RESOURCES drop-down menu in the upper-right corner, click Documents, select the PHARMACY tab in the top row of tabs, and then click MEMORANDUMS. The Memo can also be found at: <https://arkansas.magellanrx.com/provider/documents/>. To access the memos, select the Pharmacy tab and then click Memorandums.

An added benefit of viewing the Medicaid Pharmacy Program Provider Memo online is the Search feature, which will allow a more accessible and efficient user experience. To use this feature, use the shortcut by pressing the Ctrl + F keys, enabling a keyword search. Starting with the January 2018 memo, the online versions of the Provider Memos will also contain active hyperlinks in the Table of Contents. To activate these hyperlinks, open the Provider Memo, hover the mouse over the Table of Contents, press the Ctrl key until the mouse cursor ("hand") appears, then place the cursor on the item desired and click the mouse. The hyperlink in the Table of Content will then redirect to the corresponding chapter of the Provider Memo.

EFFECTIVE JULY 1, 2019:

PREFERRED DRUGS LIST (PDL):

Oral antipsychotic agents and proton pump inhibitors were reviewed at the May 8, 2019 PDL meeting. The Preferred status and Non-preferred status drugs were selected based on a review of comparative effectiveness as well as cost-effectiveness for the state Medicaid program and are listed below. *Prior Authorization criteria* and quantity limits will remain in place for Preferred-status drugs unless otherwise noted below. Agents in **bold** font indicate a change in designation on the PDL.

ANTIPSYCHOTICS

PREFERRED

Risperidone Tablets, Solution, and ODT

Quetiapine Tablets

Olanzapine Tablets and ODT

Aripiprazole Tablets

Ziprasidone Capsules

Clozapine Tablets
Haloperidol Lactate Conc
Perphenazine Tablets
Haloperidol Tablets
Trifluoperazine Tablets
Loxapine Tablets
Thioridazine Tablets
Thiothixene Capsules
Pimozide Tablets
Amitriptyline/Perphenazine tablets
Fluphenazine Tablets

NON-PREFERRED

Fazacllo ODT/Clozapine ODT/Versacloz
Latuda Tablets
Saphris Sublingual
Paliperidone Tablets (Brand and Generic)
Fanapt Tablets
Aripiprazole Solution and ODT
Zyprexa Zydis
Vraylar Tablets
Rexulti Tablets
Olanzapine/Fluoxetine Capsules
Fluphenazine Elixir/Solution
Molindone Tablets
Chlorpromazine Tablets

PROTON PUMP INHIBITORS

PREFERRED

Omeprazole capsules (20 mg and 40 mg)
Pantoprazole tablets

NON-PREFERRED

Dexilant (dexlansoprazole)
Esomeprazole capsules (Nexium)/ Esomeprazole Strontium
Pantoprazole (Protonix) Suspension
Rabeprazole (Aciphex) tablets
Aciphex (rabeprazole) sprinkle
Omeprazole/Sodium Bicarbonate (Zegerid)
Lansoprazole Solutab (Prevacid Solutab)
Lansoprazole capsules (Prevacid)

NON-PREFERRED WITH CRITERIA

Nexium Suspension- Approvable at POS for Under 7 or NPO

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

1) [HEREDITARY ANGIOEDEMA THERAPY](#)

QUANTITY EDITS EFFECTIVE 5/1/19

Previously, medications for the treatment of Hereditary Angioedema were either payable in the pharmacy program or payable in the medical program for Arkansas Medicaid beneficiaries. The DUR board reviewed which program the medications would be available, maximum doses per month once meet criteria, and continuation policy.

ON-DEMAND TREATMENT IN ADULTS PER MICROMEDEX®

Generic name (tradenname)	Dosage
C1-esterase inhibitor, human - plasma derived (Berinert)	20 international units/kg IV
C1-esterase inhibitor, human plasma derived (Cinryze)	1000 units IV
C1-esterase inhibitor, recombinant (Ruconest)	Less than 84 kg: 50 units/kg 84 kg or greater: 4200 units
Ecallantide (Kalbitor)	30 mg subQ
Icatibant (Firazyr)	30 mg subQ
Fresh frozen plasma	2 units

PROPHYLACTIC TREATMENT IN ADULTS PER MICROMEDEX®

Generic name (tradenname)	Dosage
C1-esterase inhibitor, human plasma derived (Cinryze)	1000 units IV every 3 or 4 days; doses up to 2500 units (not exceeding 100 units/kg) every 3 or 4 days may be considered based on individual patient response
C1-esterase inhibitor, human - plasma derived (Haegarda)	60 international units/kg subQ twice weekly (every 3 or 4 days).
Plasma kallikrein inhibitor (Takhzyro)	Starting dose is 300 mg every 2 weeks. A dosing interval of 300 mg every 4 weeks may be considered

Danazol (Danacrine)	Initial: 200 mg 2 or 3 times a day; Maintenance: Decrease the dosage by 50% or less at intervals of 1 to 3 months or longer if frequency of attacks prior to treatment dictates. If an attack occurs, the daily dosage may be increased by up to 200 mg.
Oxandralone (Oxandrine)	10 mg/day or less
Methyltestosterone (Android)	10 mg/day or less
Epsilon aminocaproic acid (Amicar)	1 to 2 g 3 times daily
Tranexamic acid (Lysteda)	1 g twice daily

PROPHYLAXIS AND TREATMENT IN PEDIATRIC PATIENTS PER MICROMEDEX®

Generic name (tradename)	Use	Dosage
C1-esterase inhibitor, human plasma derived (Cinryze)	Prophylaxis	1000 units IV in adults
C1-esterase inhibitor, human - plasma derived (Berinert)	On demand	20 international units/kg IV
C1-esterase inhibitor, human - plasma derived (Haegarda)	Prophylaxis	60 international units/kg subQ twice weekly (every 3 or 4 days).
C1-esterase inhibitor, recombinant (Ruconest)	On demand	Less than 84 kg: 50 units/kg 84 kg or greater: 4200 units
Icatibant (Firazyr)	On demand	30 mg subQ
Ecallantide (Kalbitor)	On demand	30 mg subQ
Tranexamic acid (Lysteda)	Prophylaxis	20 to 40 mg/kg up to 3 g/day orally
Fresh frozen plasma	On demand	1 to 2 units

PROPOSAL with changes from Board discussion

a) General information needed for acute and prophylaxis treatment

- Provide **confirmation of HAE diagnosis** by providing the following from allergist/immunologist/hematologist:
 - Date/age of symptom onset
 - Does patient respond to antihistamines, glucocorticoids or epinephrine?
 - Description of typical angioedema attack (abdominal, extremity, airway, etc.)
 - Prodromal symptoms
 - Documentation of angioedema in the absence of urticaria
 - Provide the following labs:
 - Complement C1 esterase inhibitor level

- Complement C4 level
- Functional C1 inhibitor activity
- Provide written, comprehensive management plan for acute attacks and prophylaxis treatment
- Provide patient's diary of events requiring acute treatment and include symptoms, medication/therapy needed and time to relief
- ER discharge summaries for the last 12 months for initial request
- Provide current chart notes with each request and notes for the last 12 months for the initial request
- Provide verification if taking estrogens or ACE inhibitors (should not be taking)

b) Proposal of requested information for acute and prophylaxis treatment

PROPOSAL (acute treatment)

APPROVAL CRITERIA:

- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack or had 2-3 moderate attacks causing extremity, facial or abdominal swelling in the last year
- Provider must submit a proposed treatment plan for **both acute and prophylaxis** treatment (if meets prophylaxis criteria)
- Depending on the medication, provider must verify that the patient or caregiver is appropriately trained on IV administration
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Initial PA maximum of 3-month trial if approved
- Quantity limit of 2 doses per prescription fill

DENIAL CRITERIA:

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- Does not meet acute attack requirements for approval
- Beneficiary is not diagnosed with Type I or Type II HAE
- Failure to provide adequate records

CONTINUATION CRITERIA:

- Continues to meet above criteria
- Provide updated diary of events
- If patient needs to use acute medications, then on renewal we should reassess on a case-by-case basis.

PROPOSAL (prophylaxis treatment):

APPROVAL CRITERIA:

- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks
- Provider must submit a proposed treatment plan for **both acute attacks and prophylaxis** treatment
- Depending on the medication--Provider must verify that the caregiver is appropriately trained on IV administration
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Documentation of attack frequency, comorbidities, and access to emergency care
- IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation.
 - 17 α -alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
 - Antifibrinolytic agents (e.g. ϵ -aminocaproic acid, tranexamic acid)
- Initial PA maximum 3-month trial if approved

DENIAL CRITERIA:

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- < 1 severe or life-threatening laryngeal attack per month or < 4 moderate attacks per month causing extremity, facial or abdominal swelling
- Beneficiary is not diagnosed with Type I or Type II HAE (Type III would be considered separately)
- Failure to provide adequate records
- No therapeutic duplication of 2 or more agents

CONTINUATION CRITERIA:

- Continues to meet above criteria
- Provide updated diary of events
- Compliance on maintenance medication
- If there is no response from prophylaxis in severity and frequency, considering changing the medication and/or question diagnosis of Type I or Type II. It may be Type III. Question triggers or accuracy of diagnosis.

c) Proposal for placement of HAE medications with quantity limits:

- BERINERT® 500IU vial
 - Suggest adding to the pharmacy program for at home use
 - Suggest remaining as medical billing for provider administration
 - Max of 2 doses per prescription fill
 - Manual Review on case-by-case basis
- KALBITOR® 10mg/mL vial
 - Suggest remaining as medical billing for provider administration
- RUCONEST® 2100units/25mL vial
 - Suggest adding to the pharmacy program for at home use
 - Suggest remaining as medical billing for provider administration
 - Max quantity of 2 doses per prescription fill
 - Manual Review on case-by-case basis
- FIRAZYR® 30mg/3mL syringe
 - Suggest remaining in pharmacy program
 - Max quantity of 2 doses per prescription fill
 - Manual review on case-by-case basis
- DANAZOL 50mg, 100mg, 200mg capsules
 - Suggest remaining in pharmacy program
 - No change in quantity edits
- OXANDROLONE 2.5mg, 10mg tablets
 - Suggest remaining in pharmacy program
 - No change in quantity edits
- TRANEXAMIC ACID 650mg tablets
 - Suggest remaining in pharmacy program
 - Manual review on case-by-case basis
 - No change in quantity edits
- AMINOCAPROIC ACID 500mg, 1000mg tablets
 - Suggest remaining in pharmacy program
 - No change in quantity edits
- Cinryze 500 units/vial
 - Suggest remaining in pharmacy program
 - Max quantity of 20 vials per month (1000 units every 3-4 days)
 - Manual review on a case-by-case basis
- Haegarda 2000 units per vial or 3000 units per vial
 - Suggest remaining in pharmacy program
 - Manual review on a case-by-case basis
- Takhzyro 300mg per syringe
 - Suggest remaining in pharmacy program
 - Max quantity of 2 syringes per month
 - Manual review on a case-by-case basis

2) ORAL TYPICAL AND ATYPICAL ANTIPSYCHOTIC AGENTS FOR ADULT AGE 18 YEARS AND OLDER

CRITERIA EFFECTIVE 7/1/2019; DOSE EDITS EFFECTIVE 10/1/2019

PROPOSAL:

Implement POINT OF SALE edits that will include **AGE EDIT of 18 years and older**, **DRUG THERAPEUTIC DUPLICATION (TD)** edits and Maximum Therapeutic **DOSE EDITS**.

- ❖ ORAL ANTIPSYCHOTIC agents, both typical and atypical, were reviewed at the PDL meeting on **May 8, 2019** and selections made for preferred status with criteria and non-preferred status. The PDL selections for ORAL ANTIPSYCHOTICS will be implemented **July 1, 2019**.
- **POS PA criteria, dose, and quantity edits for ADULTS for ORAL ANTIPSYCHOTIC agents:**
 - Maximum therapeutic dose tables (*SEE PROPOSED DOSING CHARTS BELOW*)
 - Doses above the maximum therapeutic dose (see chart) will require manual review PA;
 - POS Therapeutic Duplication rules for *oral* antipsychotic agents for adults:
 - Before *switching* to a different preferred agent or *adding* a second oral antipsychotic preferred agent to therapy, maximize the dose on current medication unless contraindicated; ****RECOMMENDATION BY DUR BOARD BUT NOT A REQUIREMENT****
 - IF Beneficiary *is* receiving a long-acting injectable antipsychotic agent, 1 preferred oral antipsychotic agent may be added to therapy without a PA;
 - Requests to add a 3rd oral antipsychotic agent, OR requests for 2 oral antipsychotic agents + 1 long-acting injectable antipsychotic agent will require manual review PA;
 - Long-acting injectable antipsychotic agents are on the preferred drug list and require manual review.
- **CONTINUATION CRITERIA:**
 - Upon implementation of criteria for ORAL ANTIPSYCHOTIC Agents for Adults, a beneficiary may continue a drug or dose that is outside of the established criteria (e.g., continue a non-preferred status drug, continue dose higher than the maximum therapeutic dose), or continue therapy with > 2 antipsychotic agents as long as the beneficiary is “stable and compliant” on all antipsychotic drug therapy(-ies).
 - For the purposes of these criteria “Stable and compliant” is defined as the patient has received at least 90 days of medication therapy (same dose/same drug) out of the previous 120 days based on claims in the patient’s Medicaid drug profile history.

**• ATYPICAL ANTIPSYCHOTIC MAXIMUM THERAPEUTIC DOSING
AND QUANTITIES FOR ADULTS (≥ 18 YEARS OLD)**

Aripiprazole (e.g. Abilify®) Tablet Medicaid Max Daily Dose = 30mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Aripiprazole (e.g. Abilify®) 2 mg Tablet	8 mg	4	124
Aripiprazole (e.g. Abilify®) 5 mg Tablet	5 mg	1	31
Aripiprazole (e.g. Abilify®) 10 mg Tablet & Discmelt	10 mg	1	31
Aripiprazole (e.g. Abilify®) 15 mg Tablet & Discmelt	15 mg	1	31
Aripiprazole (e.g. Abilify®) 20 mg Tablet	20 mg	1	31
Aripiprazole (e.g. Abilify®) 30 mg Tablet	30 mg	1	31

Asenapine (e.g. Saphris®) SL Tablet Medicaid Max Daily Dose = 20mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Asenapine (e.g. Saphris®) 2.5mg SL Tablet	5 mg	2	62
Asenapine (e.g. Saphris®) 5mg SL Tablet	10 mg	2	62
Asenapine (e.g. Saphris®) 10mg SL Tablet	20 mg	2	62

Brexpiprazole (e.g. Rexulti ®) Tablet Medicaid Max Daily dose = 4mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Brexpiprazole (e.g. Rexulti ®) 0.25mg Tablet	0.25 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 0.5mg Tablet	0.5 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 1mg Tablet	1 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 2mg Tablet	2 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 3mg Tablet	3 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 4mg Tablet	4 mg	1	31

AR MEDICAID DUR BOARD MEETING APRIL 17, 2019

Cariprazine (e.g. Vraylar ®) Capsule Medicaid Max Daily Dose = 6mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Cariprazine (e.g. Vraylar ®) 1.5mg Capsule	1.5 mg	1	31
Cariprazine (e.g. Vraylar ®) 3mg Capsule	3 mg	1	31
Cariprazine (e.g. Vraylar ®) 4.5mg Capsule	4.5 mg	1	31
Cariprazine (e.g. Vraylar ®) 6mg Capsule	6 mg	1	31

Clozapine (e.g. Clozaril ®) Tablet Medicaid Max Daily Dose = 900mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Clozapine (e.g. Clozaril ®) 25mg Tablet	75 mg	3	93
Clozapine (e.g. Clozaril ®) 50mg Tablet	50 mg	1	31
Clozapine (e.g. Clozaril ®) 100mg Tablet	900 mg	9	279

Iloperidone (e.g. Fanapt ®) Tablet Medicaid Max Daily Dose = 24mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Iloperidone (e.g. Fanapt ®) 1mg Tablet	2 mg	2	62
Iloperidone (e.g. Fanapt ®) 2mg Tablet	4 mg	2	62
Iloperidone (e.g. Fanapt ®) 4mg Tablet	8 mg	2	62
Iloperidone (e.g. Fanapt ®) 6mg Tablet	12 mg	2	62
Iloperidone (e.g. Fanapt ®) 8mg Tablet	16 mg	2	62
Iloperidone (e.g. Fanapt ®) 10mg Tablet	20 mg	2	62
Iloperidone (e.g. Fanapt ®) 12mg Tablet	24 mg	2	62

Lurasidone (e.g. Latuda ®) Tablet Medicaid Max Daily Dose = 160mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Lurasidone (e.g. Latuda ®) 20mg Tablet	20 mg	1	31
Lurasidone (e.g. Latuda ®) 40mg Tablet	40 mg	1	31
Lurasidone (e.g. Latuda ®) 60mg Tablet	60 mg	1	31
Lurasidone (e.g. Latuda ®) 80mg Tablet	160 mg	2	62

Olanzapine (e.g. Zyprexa ®) Tablet Medicaid Max Daily Dose = 20mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Olanzapine (e.g. Zyprexa ®) 2.5mg Tablet	2.5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 5mg Tablet & ODT	5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 7.5mg Tablet	7.5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 10mg Tablet & ODT	10 mg	1	31
Olanzapine (e.g. Zyprexa ®) 15mg Tablet & ODT	15 mg	1	31
Olanzapine (e.g. Zyprexa ®) 20mg Tablet & ODT	20 mg	1	31

AR MEDICAID DUR BOARD MEETING APRIL 17, 2019

Olanzapine/Fluoxetine combination (e.g. Symbyax ®) Capsule Medicaid Max Daily Dose = 18mg/75mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Olanzap/Fluoxetine combo (e.g. Symbyax ®) 3mg/25mg Caps	9mg/75mg	3	93
Olanzap/Fluoxetine combo (e.g. Symbyax ®) 6mg/25mg Caps	18mg/75mg	3	93
Olanzap/Fluoxetine combo (e.g. Symbyax ®) 6mg/50mg Caps	6mg/50mg	1	31
Olanzap/Fluoxetine combo (e.g. Symbyax ®) 12mg/25mg Caps	12mg/25mg	1	31
Olanzap/Fluoxetine combo (e.g. Symbyax ®) 12mg/50mg Caps	12mg/50mg	1	31

Paliperidone ER (e.g. Invega ®) Tablet Medicaid Max Daily dose = 12mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Paliperidone ER (e.g. Invega ®) 1.5mg Tablet	1.5 mg	1	31
Paliperidone ER (e.g. Invega ®) 3mg Tablet	3 mg	1	31
Paliperidone ER (e.g. Invega ®) 6mg Tablet	12 mg	2	62
Paliperidone ER (e.g. Invega ®) 9mg Tablet	9 mg	1	31

Quetiapine (e.g. Seroquel®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Quetiapine (e.g. Seroquel®) 25mg Tablet	75 mg	3	93
Quetiapine (e.g. Seroquel®) 50mg Tablet	150 mg	3	93
Quetiapine (e.g. Seroquel®) 100mg Tablet	200 mg	2	62
Quetiapine (e.g. Seroquel®) 200mg Tablet	400 mg	2	62
Quetiapine (e.g. Seroquel®) 300mg Tablet	600 mg	2	62
Quetiapine (e.g. Seroquel®) 400mg Tablet	800 mg	2	62

Quetiapine ER (e.g. Seroquel XR®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Quetiapine ER (e.g. Seroquel XR®) 50mg Tablet	100 mg	2	62
Quetiapine ER (e.g. Seroquel XR®) 150mg Tablet	150 mg	1	31
Quetiapine ER (e.g. Seroquel XR®) 200mg Tablet	200 mg	1	31
Quetiapine ER (e.g. Seroquel XR®) 300mg Tablet	600 mg	2	62
Quetiapine ER (e.g. Seroquel XR®) 400mg Tablet	800 mg	2	62

Risperidone (e.g. Risperdal®) Tablet Medicaid Max Daily Dose = 16mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Risperidone (e.g. Risperdal®) 0.25mg Tablet	0.5 mg	2	62
Risperidone (e.g. Risperdal®) 0.5mg Tablet & ODT	1 mg	2	62
Risperidone (e.g. Risperdal®) 1mg Tablet & ODT	2 mg	2	62
Risperidone (e.g. Risperdal®) 2mg Tablet & ODT	4 mg	2	62
Risperidone (e.g. Risperdal®) 3mg Tablet & ODT	9 mg	3	93
Risperidone (e.g. Risperdal®) 4mg Tablet & ODT	16 mg	4	124
Risperidone (e.g. Risperdal®) 1mg/ml Oral Solution (30ml)	4 mg	4 ml	120

Ziprasidone (e.g. Geodon®) Capsule Medicaid Max Daily Dose = 160mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Ziprasidone (e.g. Geodon®) 20mg Capsule	40 mg	2	62
Ziprasidone (e.g. Geodon®) 40mg Capsule	80 mg	2	62
Ziprasidone (e.g. Geodon®) 60mg Capsule	120 mg	2	62
Ziprasidone (e.g. Geodon®) 80mg Capsule	160 mg	2	62

**TYPICAL ANTIPSYCHOTIC MAXIMUM THERAPEUTIC DOSING AND QUANTITIES
FOR ADULTS**

Chlorpromazine (e.g. Thorazine®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Chlorpromazine (e.g. Thorazine®) 10mg Tablet	40 mg	4	124
Chlorpromazine (e.g. Thorazine®) 25mg Tablet	75 mg	3	93
Chlorpromazine (e.g. Thorazine®) 50mg Tablet	200 mg	4	124
Chlorpromazine (e.g. Thorazine®) 100mg Tablet	700 mg	7	217
Chlorpromazine (e.g. Thorazine®) 200mg Tablet	800 mg	4	124

Fluphenazine (e.g. Prolixin®) Tablet Medicaid Max Daily Dose = 40mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Fluphenazine (e.g. Prolixin®) 1mg Tablet	4 mg	4	124
Fluphenazine (e.g. Prolixin®) 2.5mg Tablet	10 mg	4	124
Fluphenazine (e.g. Prolixin®) 5mg Tablet	20 mg	4	124
Fluphenazine (e.g. Prolixin®) 10mg Tablet	40 mg	4	124

Haloperidol (e.g. Haldol®) Tablet Medicaid Max Daily Dose = 40mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Haloperidol (e.g. Haldol®) 0.5mg Tablet	1.5mg	3	93
Haloperidol (e.g. Haldol®) 1mg Tablet	3 mg	3	93
Haloperidol (e.g. Haldol®) 2mg Tablet	6 mg	3	93
Haloperidol (e.g. Haldol®) 5mg Tablet	15 mg	3	93
Haloperidol (e.g. Haldol®) 10mg Tablet	30 mg	3	93
Haloperidol (e.g. Haldol®) 20mg Tablet	40 mg	2	62

Loxapine (e.g. Loxitane®) Capsule Medicaid Max Daily Dose = 250mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAXIMUM CUMULATIVE QTY
Loxapine (e.g. Loxitane®) 5mg Capsule	20 mg	4	124
Loxapine (e.g. Loxitane®) 10mg Capsule	60 mg	6	186
Loxapine (e.g. Loxitane®) 25mg Capsule	100 mg	4	124

AR MEDICAID DUR BOARD MEETING APRIL 17, 2019

Loxapine (e.g. Loxitane®) 50mg Capsule	250 mg	5	155
--	--------	---	-----

Perphenazine (e.g. Trilafon®) Tablet Medicaid Max Daily Dose = 64mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Perphenazine (e.g. Trilafon®) 2mg Tablet	8 mg	4	124
Perphenazine (e.g. Trilafon®) 4mg Tablet	16 mg	4	124
Perphenazine (e.g. Trilafon®) 8mg Tablet	32 mg	4	124
Perphenazine (e.g. Trilafon®) 16mg Tablet	64 mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) Tablet Medicaid Max Daily Dose = 16MG/100MG			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Perphenazine-Amitriptyline (e.g. Etrafon®) 2mg/10mg Tablet	8mg/40mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 2mg/25mg Tablet	8mg/100mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/10mg Tablet	16mg/40mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/25mg Tablet	16mg/100mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/50mg Tablet	8mg/100mg	2	62

Pimozide (e.g. Orap) Tablet Medicaid Max Daily Dose = 10mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Pimozide (e.g. Orap) 1mg Tablet	3 mg	3	93
Pimozide (e.g. Orap) 2mg Tablet	10 mg	5	155

Thioridazine (e.g. Mellaril®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Thioridazine (e.g. Mellaril®) 10mg Tablet	40 mg	4	124
Thioridazine (e.g. Mellaril®) 25mg Tablet	100 mg	4	124
Thioridazine (e.g. Mellaril®) 50mg Tablet	200 mg	4	124
Thioridazine (e.g. Mellaril®) 100mg Tablet	800 mg	8	248

Thiothixene (e.g. Navane®) Capsule Medicaid Max Daily Dose = 60mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Thiothixene (e.g. Navane®) 1mg Capsule	3mg	3	93
Thiothixene (e.g. Navane®) 2mg Capsule	8mg	4	124
Thiothixene (e.g. Navane®) 5mg Capsule	15mg	3	93
Thiothixene (e.g. Navane®) 10mg Capsule	60mg	6	186

Trifluoperazine (e.g. Stelazine®) Tablet Medicaid Max Daily Dose = 40mg			
DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Trifluoperazine (e.g. Stelazine®) 1mg Tablet	3 mg	3	93
Trifluoperazine (e.g. Stelazine®) 2mg Tablet	8 mg	4	124
Trifluoperazine (e.g. Stelazine®) 5mg Tablet	15 mg	3	93
Trifluoperazine (e.g. Stelazine®) 10mg Tablet	40 mg	4	124

3) [DUPIXENT® \(dupilumab\) injection](#)

QUANTITY EDITS EFFECTIVE 5/1/19

Sanofi-Aventis U.S. LLC

MEDICAID estimated reimbursement rate:

300mg/2ml syringe--\$754.875 per ml (\$1509.75 per syringe); \$3019.50 per month

200mg/1.14ml syringe--\$1324.342 per syringe; \$2648.68 per month

DUPIXENT® INDICATIONS:

- for the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT® can be used with or without topical corticosteroids.
- as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

APPROVAL CRITERIA FOR DUPIXENT® FOR ASTHMA DIAGNOSIS:

- Manual review on a case-by-case basis
- Prescriber must be board certified by American Board of Allergy and Immunology
- Age ≥ 12 years old; AND
- Diagnosis of moderate-to-severe asthma with eosinophilic phenotype or with oral corticosteroid dependence (provide documentation); AND
- Must be compliant on at least two asthma maintenance medications for at least six months (one must be an inhaled corticosteroid); AND
- History of 1 or more severe asthma exacerbations in the previous year despite compliance on maintenance medications that required treatment with systemic corticosteroids or emergency department visit or hospitalization for the treatment of asthma; AND
- No therapeutic duplication with any Interleukins (daclizumab, mepolizumab, or others new to the market) or omalizumab; AND
- Medical necessity over omalizumab (Xolair®); AND
- Provide the following documentation for review:
 - Current chart notes
 - Documentation of previous therapies tried for asthma with response
 - Baseline blood eosinophilic count
 - Baseline Asthma Control Questionnaire (ACQ-5) OR Asthma Quality of Life Questionnaire (AQLQ) scores (adults only)
 - Current Pulmonary Function Test (PFT) results

DENIAL CRITERIA FOR DUPIXENT® FOR ASTHMA DIAGNOSIS:

- Noncompliance with two asthma maintenance medications for at least 6 months including inhaled corticosteroid
- Baseline blood eosinophil level > 1500 cells/μL (exclusion criteria in clinical trials)
- Baseline blood eosinophil level < 150 cells/μL (response similar to placebo)

CONTINUATION CRITERIA FOR DUPIXENT® FOR ASTHMA DIAGNOSIS:

- Compliance on injections and maintenance asthma medications
- Improvement in FEV₁ over baseline
- Improvement in ACQ-5 and AQLQ scores
- Decrease in blood eosinophil count
- Decrease in oral steroid usage

QUANTITY EDITS:

- Max of 5 syringes in a 50-day period to account for months that may have 3 doses due to the number of weeks.

4) DAURISMO™ (glasdegib) 25mg & 100mg tablets

Pfizer Laboratories

MEDICAID estimated reimbursement rate:

\$282.083 per 25mg tablet; Max of 2 tabs per day; #60 = \$16,924.98 for 30-day supply
#56 = \$15,796.65 for 28-day supply

\$584.167 per 100mg tablet; Max of 1 tab per day; #30 = \$17,525.01 for 30-day supply
#28 = \$16,356.68 for 28-day supply

**25mg is packaged as #60 and 100mg is packaged as #30 but dosing is based on a 28-day cycle.

DAURISMO™ is a hedgehog pathway inhibitor indicated, in combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

The recommended dose of DAURISMO™ is 100 mg orally once daily on days 1 to 28 in combination with cytarabine 20 mg subcutaneously twice daily on days 1 to 10 of each 28-day cycle in the absence of unacceptable toxicity or loss of disease control. For patients without unacceptable toxicity, treat for a minimum of 6 cycles to allow time for clinical response.

PROPOSAL:

DAURISMO™ will require manual review PA on a case-by-case basis using the following criteria:

APPROVAL CRITERIA:

- will require manual review PA on a case-by-case basis
- Age ≥ 75 years old (PI study for ≥ 55 years)
- Must be newly diagnosed with acute myeloid leukemia (AML)
- Must use in combination with low-dose cytarabine
- Must have comorbidities that preclude the use of intensive induction chemo such as severe cardiac disease (LVEF <45%), ECOG ≤ 3 or baseline serum creatinine >1.3mg/dL. *
- Must also receive low-dose cytarabine on days 1 to 10 of each 28-day cycle
- Provide the following labs
 - Complete blood counts—initially and then weekly for first month
 - Electrolytes—initially, weekly for first month, then monthly

- Renal function—initially, weekly for first month, then monthly
- Hepatic function—initially and then weekly for first month
- Serum creatine kinase prior to starting DAURISMO™ as baseline
- Initial ECG report—must be repeated one week later after starting DAURISMO™ and then monthly for next two months
- Bone marrow blast count $\geq 20\%$ *
- Approve PA for one month at a time due to extensive adverse effects

DENIAL CRITERIA:

- If does not meet approval criteria above
- QTc interval prolongation with life-threatening arrhythmia
- Platelets less than 10 Gi/L for more than 42 days in the absence of disease
- Neutrophil count less than 0.5 Gi/L for more than 42 days in the absence of disease
- Grade 4 nonhematologic toxicity
- Drug interaction with Strong CYP3A Inducers—avoid use due to decreased effect of Daurismo™ (i.e. Rifampin)
- Drug interaction with other QTc prolonging drugs –avoid use as increased probability for QTc prolongation
- Drug interaction with Strong CYP3A4 Inhibitors—caution use due to increase Daurismo™ level (i.e. Ketoconazole)
- AML M3 Acute Promyelocytic Leukemia (APL) or patients with a t(9:22) cytogenetic translocation.*
- Patients with known active uncontrolled central nervous system (CNS) leukemia. *

CONTINUATION CRITERIA:

- Labs and ECG results with in manufacturer’s requirements.
- Provider should verify current dose
- Remains on low-dose Cytarabine

QUANTITY EDITS:

- DAURISMO™25MG TABLETS # 60/30 DAYS

5) [XOSPATA® \(gilteritinib\) 40mg tablets](#)

Astellas Pharma US, Inc

MEDICAID estimated reimbursement rate:

\$250.00 per tablet; #90 = \$22,500 for 30-day supply

XOSPATA® is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test (i.e. LeukoStrat CDx FLT3 Mutation Assay).

The recommended starting dose of XOSPATA® is 120 mg orally once daily with or without food. Response may be delayed. In the absence of disease progression or unacceptable toxicity, treatment for a minimum of 6 months is recommended to allow time for a clinical response.

APPROVAL CRITERIA:

- Age ≥ 18 years old
- Will require manual review PA on a case-by-case basis
- Patient has a relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test.
- ECOG score 0-2*
- AST/ALT ≤ 2.5 ULN*
- SCr ≤1.5 ULN*
- eGFR > 50ml/min *
- Refractory to ≥1 cycle of induction chemo or relapsed after achieving remission w/ prior therapy*
- Provide complete blood count (CBC), basic metabolic panel (BMP) and liver function tests (LFT); hypokalemia and/or hypomagnesemia has been corrected
- Provide initial creatinine phosphokinase (NOTE—should be drawn weekly for the first month, every other week for 2nd month and once monthly thereafter).
- Baseline ECG results (NOTE—repeat on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles.)
- Approval one month at a time due to significant adverse reactions

DENIAL CRITERIA:

- Age < 18 years old
- Currently pregnant
- Heart failure class 3 or 4 unless LVEF ≥45%*
- Consistent prolonged QTc interval >500 msec (dose adjustment may be needed) *
- Had hematopoietic stem cell transplant (HSCT) within 2 months OR significant GVHD occurring due to transplant OR any grade 2 or higher non-hematological toxicity related to transplant within the past 30 days*
- Has active CNS leukemia*
- Drug interaction with combined P-gp and Strong CYP3A Inducers—Avoid concomitant use due to decrease in Xospata® efficacy
- Drug interaction with Strong CYP3A Inhibitors—caution concomitant use due to increased Xospata® exposure
- Diagnosis of Posterior Reversible Encephalopathy Syndrome

CONTINUATION CRITERIA:

- Absence of disease progression
- Absence of unacceptable toxicity
- Able to tolerate a minimum of 80mg once daily
- Provide CBC, BMP, LFT and creatinine phosphokinase
- Labs and ECG results within manufacturer's requirements
- Provider should verify current dose

DOSE ADJUSTMENT:

- QTc interval > 500 msec
- QTc interval increased by > 30 msec on ECG on day 8 of cycle 1
- Diagnosis of pancreatitis

- Grade 3 or higher toxicity

QUANTITY EDITS: #90/30 DAYS

6) VITRAKVI® (larotrectinib) 25mg & 100mg capsules and 20mg/ml oral solution

Loxo Oncology, Inc.

MEDICAID estimated reimbursement rate: Dosing based on body surface area (BSA)

\$182.222 each 25mg capsule; #180 = \$32,799.96 for 30-day supply (75mg twice daily)

#120 = \$21,866.64 for 30-day supply (50mg twice daily)

#60 = \$10,933.32 for 30-day supply (25mg twice daily)

\$546.667 each 100mg capsule; #60 = \$32,800.02 for 30-day supply (If BSA >1m²)

\$145.778 per ml oral solution; 100ml bottle = \$14577.80 (bottle must be discarded after opened for 90 days)

VITRAKVI® is indicated for the treatment of adult and pediatric patients with solid tumors that:

- have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have no satisfactory alternative treatments or that have progressed following treatment.

This indication is approved under accelerated approval based on overall response rate and duration of response [see Clinical Studies (14)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Must have diagnosis of unresectable or metastatic solid tumors (i.e. salivary gland tumors, soft tissue sarcoma, infantile fibrosarcoma, and thyroid cancer among others) with neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired mutation.
- Must have progressed following systemic therapy or there are no satisfactory alternatives
- Patient must have documented and laboratory-confirmed NTRK1, NRK2, or NRK3 gene fusion. Identification of positive NTRK gene fusion status was prospectively determined in local laboratories using next generation sequencing (NGS) or fluorescence in situ hybridization (FISH).*
- Provide documentation of gene mutation with resistance test
- Current Body Surface Area (BSA) must be provided. Dosing based on BSA—If BSA < 1m² should be dosed at 100mg/m² twice daily; If BSA is ≥ 1m² should be dosed at 100mg twice daily

- Provide baseline LFTs and CBCs (LFTs should be repeated every 2 weeks for the first month then monthly thereafter)
- Reduced dose by 50% with moderate to severe hepatic impairment
- Negative pregnancy test
- ECOG 0-2*

DENIAL CRITERIA:

- Does not meet above approval criteria
- Currently pregnant
- Drug interaction with Strong CYP3A4 Inhibitors causing increased Vitrakvi® plasma concentrations—Avoid co-administration if possible
- Drug interaction with Strong CYP3A4 Inducers due to decrease efficacy—monitor
- Discontinue if does not tolerate 3rd dose modification

CONTINUATION CRITERIA:

- Submit current CBCs and LFTs (Dose reduction needed for Child-Pugh B or C)
- Absence of disease progression
- Absence of intolerable toxicity

QUANTITY EDITS:

- Vitrakvi® 25mg #180/30 days
- Vitrakvi® 100mg #60/30 days
- Vitrakvi® 20mg/ml oral solution 100ml bottle/30 days

7) [SYMPAZAN™ \(clobazam\) 5mg, 10mg & 20mg oral film](#)

Aquestive Therapeutics

MEDICAID estimated reimbursement rate:

5mg film--\$13.00 each; #60 = \$780 for 30-day supply

10mg film--\$26.00 each; #60 = \$1560 for 30-day supply

20mg film--\$52.00 each; #60 = \$3120 for 30-day supply

In comparison:

Clobazam 10mg tablets are \$0.709 each = \$42.54 for 30-day supply

Clobazam 20mg tablets are \$1.244 each = \$74.64 for 30-day supply

Clobazam 2.5mg/ml susp is \$1.449 per ml = \$173.88 per 120ml bottle (5mg twice daily)

SYMPAZAN™ is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older. A daily dose of SYMPAZAN™ greater than 5 mg should be administered in divided doses twice daily; a 5 mg daily dose can be administered as a single dose. Dose patients according to body weight.

	30 kg or Less Body Weight	Greater than 30 kg Body Weight
Starting Dose	5 mg	10 mg
Starting Day 7	10 mg	20 mg
Starting Day 14	20 mg	40 mg

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Patient must have a diagnosis of Lennox-Gastaut syndrome or refractory epilepsy
- Patient must have uncontrolled drop seizures
- Patient must currently be on ≥ 1 seizure medication
- Must have tried and failed ≥ 2 non-benzodiazepine seizure medications
- Provide the medical necessity of Sympazan™ over generic Clobazam tablets or suspension as well as Clonazepam tablets
- Provide number of seizures for baseline
- Provide current weight for dose calculation
- Provide requested dose (manufacturer does not dose higher than 40mg per day)
- Child-Pugh classification

DENIAL CRITERIA:

- Does not meet approval criteria
- No medical necessity of Sympazan™ over Clobazam and Clonazepam
- Severe hepatic impairment (Child-Pugh C)
- Dose outside of manufacturer's recommendations
- Requested in conjunction with Clobazam tablets or suspension

CONTINUATION CRITERIA:

- Decrease in seizures from baseline
- Current chart notes

QUANTITY EDITS:

- 60 films/30 days
- Also, therapeutic duplication edit to prevent more than one Sympazan™ strength at a time.

8) TALZENNA™ (talazoparib) 0.25mg & 1mg capsules

Pfizer Laboratories Div Pfizer Inc

MEDICAID estimated reimbursement rate:

0.25mg \$162.00 each capsule; #90 = \$14,580 for 30-day supply (0.75mg daily)

#60 = \$9,720 for 30-day supply (0.50mg daily)

#30 = \$4,860 for 30-day supply (0.25mg daily)

1mg \$486.00 each capsule; #30 = \$14,580 for 30-day supply (1mg daily)

TALZENNA™ is indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA™.

Select patients for the treatment of advanced breast cancer with TALZENNA™ based on the presence of germline BRCA mutations. Information on the FDA-approved test for the detection of BRCA mutations is available at <http://www.fda.gov/companiondiagnostics>.

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Age ≥ 18 years
- Provide documentation that the beneficiary has a diagnosis of deleterious or suspected deleterious germline breast cancer that is locally advanced or metastatic with a BRCA1 or BRCA2 mutation and is HER2 negative based on laboratory findings.
- ECOG 0-2*
- Provide current chart notes
- Provide current labs including CBC, basic metabolic panel and LFTs
- Pregnancy test
- Dosing for patient taking amiodarone, carvedilol, clarithromycin, itraconazole, and verapamil must be 0.75mg once daily
- Dosing for CrCl 30-59 mL/min: 0.75mg once daily
- ≤3 prior cytotoxic chemotherapy regimens for metastatic or locally advanced disease*
- Treatment with an anthracycline and/or a taxane unless contraindicated*

DENIAL CRITERIA:

- Does not meet above approval criteria
- Pregnant
- Moderate to severe hepatic impairment (total bilirubin >1.5 and any AST)
- Severe renal impairment (CrCl <30mL/min)
- Prior treatment of PARP inhibitor (Olaparib)*
- Discontinue if requires >3 dose reductions (minimum dose of 0.25mg per day)
- Confirmed Myelodysplastic Syndrome or AML

CONTINUATION CRITERIA:

- Absence of disease progression and unacceptable toxicity
- Current chart notes
- Current labs including CBC, BMP and LFTs
- Dose reduction for the following until resolved:
 - Hemoglobin < 8g/dL
 - Platelets <50,000 /μL
 - Neutrophils <1,000 /μL
 - Non-hematologic Grade 3 or Grade

QUANTITY EDITS:

- 1mg #30/30 days
- 0.25mg #90/30 days

9) [TEGSEDI™ \(inotersen\) 284mg subcutaneous injection](#)

Akcea Therapeutics, Inc.

MEDICAID estimated reimbursement rate:

284mg/1.5ml syringe \$5766.667 each; #4 = \$23,066.67 per month

TEGSEDI™ is a transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults (also referred to as Familial Amyloid Polyneuropathy).

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Age ≥ 18 years
- Diagnosed with polyneuropathy due to hereditary transthyretin-mediated amyloidosis
- Provide chart notes
- Provide current labs including complete blood count (CBC) including platelets, basic metabolic panel (BMP) including SCr and eGFR, urine protein to creatinine ratio(UPCR), and LFTs
- Current urinalysis prior to beginning treatment with TEGREDI and directly following treatment initiation
- **Baseline** modified Neuropathy Impairment Scale+7 (mNIS+7) composite score and the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
 - NIS objectively measures deficits in cranial nerve function, muscle strength, reflexes, and sensations, and the Modified +7 assesses heart rate response to deep breathing, postural blood pressure, quantitative sensory testing (touch-pressure and heat-pain), and peripheral nerve electrophysiology.
 - Norfolk QoL-DN scale is a patient-reported assessment that evaluates the subjective experience of neuropathy in the following domains: physical functioning/large fiber neuropathy, activities of daily living, symptoms, small fiber neuropathy, and autonomic neuropathy.
- Provide the medical necessity over preferred neuropathic pain agents UNLESS there is a definitive diagnosis for FAP
- Documented transthyretin variant by genotyping*
- Documented amyloid deposit by biopsy*
- Provide staging—must be Stage 1 or Stage 2*

Signs and symptoms	Stage 1	Stage 2	Stage 3
Motor	Mild	Mild/moderate	Severe
Limb involvement	Lower	Lower/upper	Lower/upper
Autonomic	Mild	Moderate	Severe
Activities of daily living	None/minimal	Significant	Profound
Ambulation	No assistance required	Assistance required	Wheelchair/ bed-bound

DENIAL CRITERIA:

- Platelets < 100 x 10⁹/L on initiation of treatment and stop treatment if platelets are < 100 x 10⁹/L during therapy; only resume if platelets rise above 100 x 10⁹/L
- History of acute glomerulonephritis caused by TEGSEDI™
- Urine protein to creatinine ratio (UPCR) of 1000 mg/g or higher
- Estimated glomerular filtration rate (eGFR) below 45 mL/minute/1.73 m²
 - Once UPCR and eGFR are within required range, dosing may be restarted
- Heart failure NYHA class ≥ 3*
- Pregnancy
- Prior liver transplant or anticipated liver transplant within 1 year*

- Primary or leptomenigeal amyloidosis*
- Not able to adhere to recommended laboratory monitoring

CONTINUATION CRITERIA:

- Provide current labs
- Platelets must be $\geq 100 \times 10^9/L$
- eGFR must be $\geq 45 \text{ mL/minute}/1.73\text{m}^2$
- UPCR $< 1000\text{mg/g}$
- Updated mNIS+7 composite score and QoL-DN total score
- Current chart notes

QUANTITY EDITS:

- 4 syringes/ 28 days

10) [INBRIJA™ \(levodopa\) inhalation powder](#)

Acorda Therapeutics, Inc.

MEDICAID estimated reimbursement rate:

42mg capsule \$15.833; #60 = \$949.98 per month if using 2 capsules once daily

#300 = \$4749.90 per month if using 10 capsules per day

INBRIJA™ is an aromatic amino acid indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

INBRIJA™ capsules are for oral inhalation only and should be used only with the INBRIJA™ inhaler. INBRIJA™ should be taken when symptoms of an OFF period start to return. The recommended dosage of INBRIJA™ is oral inhalation of the contents of two 42 mg capsules (84 mg) as needed, up to 5 times a day. The maximum dose per OFF period is 84 mg, and the maximum daily dosage is 420 mg. INBRIJA™ has been shown to be effective only in combination with carbidopa/levodopa.

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Age ≥ 30 years old and ≤ 85 years old*
- Baseline labs including CBC, BMP and LFTs
- At baseline, beneficiary has at least 2 hours per day of "OFF" time per day excluding wakening each morning with motor fluctuations
- Carbidopa/levodopa medication did not exceed 1600 mg levodopa per day.
- Hoehn and Yahr Stage 1-3 in an "ON" state (see stages below)*
- Must be compliant on current carbidopa/levodopa therapy
- Baseline Unified Parkinson's Disease Rating Scale (UPDRS) Part III motor score from pre-dose "OFF" state. The UPDRS part III is designed to assess the severity of the cardinal motor findings (e.g., tremor, rigidity, bradykinesia, postural instability) in patients with Parkinson's disease.
- Provide the medical necessity of adding this medication over increasing current Carbidopa/Levodopa dose

DENIAL CRITERIA:

- Taking a nonselective monoamine oxidase (MAO) inhibitor
- Diagnosed with a major psychotic disorder or suicide ideation/attempt in last year

- Not recommended in patients with asthma, COPD or another chronic lung disease
- Pregnant
- ≤ 2 hours per day of “OFF” time
- Hoehn and Yahr Stage >3 in an “ON” state

CONTINUATION CRITERIA:

- Discontinue if reports significant daytime sleepiness or episodes of falling asleep during activities that require active participation
- If concomitant use with Dopamine D2 receptor antagonist, monitor for worsening Parkinson’s symptoms
- 12-week UPDRS Part III motor score from pre-dose “OFF” state to 30 minutes post-dose
- Chart notes
- Current labs

QUANTITY EDITS:

#300/30-day supply

11) [ARIKAYCE® \(amikacin liposome\) inhalation suspension](#)

Insmed Incorporated

MEDICAID estimated reimbursement rate:

\$43.214 per ml; \$362.998 for 8.4ml vial; #28 vials = \$10,163.944 for a 28-day supply

ARIKAYCE® is an aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy

APPROVAL CRITERIA:

- Will require manual review PA on a case-by-case basis
- Age ≥ 18 years old
- Patient must be diagnosed with refractory *Mycobacterium avium* complex (MAC) lung disease
- Receiving ATS/IDSA guideline-based treatment with a multi-drug regimen for at least 6 months with persistently positive cultures
- Provide documentation of previous multi-drug MAC regimen
- Patient must be diagnosed with non-tuberculosis mycobacterial lung disease in accordance with the 2007 ATS/IDSA criteria: *
 - Patient must have pulmonary symptoms with evidence of nodular bronchiectasis via radiograph and/or cavitary disease by CT
 - Appropriate exclusion of other diagnoses
 - Positive culture results from at least 2 separate sputum samples or positive culture via bronchial lavage or wash or via transbronchial lung biopsy
- Provide current labs including CBC and basic metabolic panel
- If child-bearing age, recommend a pregnancy test due to risk of congenital deafness

DENIAL CRITERIA:

- Patients with non-refractory MAC lung disease
- Currently takes medications associated with neurotoxicity, nephrotoxicity, and ototoxicity.
- Currently takes ethacrynic acid, furosemide, urea, or intravenous mannitol due to increased aminoglycoside toxicity.
- Pregnancy due to potential birth defects.
- FEV1 < 30% predicted*
- Active pulmonary malignancy or active pulmonary TB*
- Lung transplant recipient*
- Conditions requiring continuous oxygen supplementation*
- Smoking within the last 6 months*

CONTINUATION CRITERIA:

- Adherent to multi-drug MAC regimen
- Conversion to negative monthly cultures by end of month 4 (requires 3 consecutive monthly negative sputum cultures by Month 6)
- No reported ototoxicity or nephrotoxicity
- Current labs including CBC and basic metabolic panel
- Monitor cultures periodically to ascertain if remains negative

QUANTITY EDITS: #28 vials/ 28 days

12) [PRIMAQUINE AND KRINTAFEL \(tafenoquine\)](#)

a. PRIMAQUINE

Primaquine phosphate is indicated for the radical cure (prevention of relapse) of vivax malaria

Quantity of #14 per claim

b. KRINTAFEL

KRINTAFEL is indicated for the radical cure (prevention of relapse) of Plasmodium vivax malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection. KRINTAFEL is NOT indicated for the treatment of acute P. vivax malaria.

Quantity of #2 per claim

FRIENDLY REMINDERS:

1. **Effective March 1, 2019**, Arkansas Medicaid will implement **PASSE (Provider-Led Arkansas Shared Savings Entity)**, a new Medicaid program to address the needs of individuals who have intensive behavioral health and intellectual and developmental disabilities service needs. The PASSE organizations will administer all medical needs *and all pharmacy prescription drug needs* for all PASSE members. **Any questions about prescription drugs or drug claims for PASSE members must be directed to the specific PASSE organization taking care of that member.** For more information about PASSE, please refer to the website: <https://humanservices.arkansas.gov/about-dhs/dms/passe>. For questions about each PASSE organization, please refer to this website for contact information: <https://humanservices.arkansas.gov/about-dhs/dms/passe/contact-us>

2. **MAT (Medication Assisted Treatment) with Buprenorphine/naloxone and psychosocial treatment or counseling:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: “**Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care.** As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. **Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities.** In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such patients for appropriate counseling and other nonpharmacological therapies.”
<http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf>

Per ASAM National Practice Guideline, in Part 5: Buprenorphine, Summary of Recommendations, # (5) “**Psychosocial treatment should be implemented in conjunction with the use of buprenorphine in the treatment of opioid use disorder.**” <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

3. **Chronic Pain Patients Who Do Not Need Treatment for Addiction:** Per the TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: Treatment Improvement Protocol (TIP) Series 40*: “Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. *They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids during their medical treatment.*” Substance Abuse and Mental Health Services Administration ([SAMHSA](http://www.samhsa.gov)) Center for Substance Abuse 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>

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 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. **Suboxone Film (buprenorphine/naloxone) once daily dosing:** as stated in the Suboxone Film package insert, the FDA approved dose for treating opioid addiction is **prescribing the total daily dose as one single daily dose.** “After treatment induction and stabilization, the maintenance dose of SUBOXONE sublingual film is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient and clinical response. The recommended target dosage of SUBOXONE sublingual film during maintenance is 16 mg/4 mg buprenorphine/naloxone/day **as a single daily dose.** Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage.”

Per ASAM National Practice Guidelines, the bold and italics were added for emphasis, but the following statement is pulled from the “At Induction” section of “Part 5: Buprenorphine”, under Dosing, “Once it has been established that the initial dose is well tolerated, the buprenorphine dose can be increased fairly rapidly to a **dose that provides stable effects for 24 hours and is clinically effective**”.
<https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

6. **CIRCUMVENTING MEDICAID LIMITS FOR OPIOIDS AND BENZODIAZEPINES:**

Beneficiaries who pay *cash* for opioids to avoid Medicaid dose and quantity limits *or pay cash in addition to* the opioids paid for by Medicaid, result in a much higher daily MME than what is calculated in the Medicaid system edits, are above the CDC recommendations, and could *put the patient at risk for overdose.* **According to the CDC, the number of Arkansas deaths due to drug overdose increased 10.2% from December 2016 to December 2017.**

7. **The Maximum Daily Morphine Milligram Equivalent (MME) Dose WAS DECREASED on NOVEMBER 14, 2018 to ≤ 90 MME/day for non-cancer chronic pain beneficiaries.** Incoming opioid claims that cause the total MME/day to exceed the existing limit of ≤ 90 MME/day will *deny at point of sale* whether prescription is from same prescriber or different prescriber(s).
8. **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, the use of 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.***
9. **“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.
10. **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.
11. **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.
12. **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* 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/>.

13. **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.

- 14. 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.

Effective August 8, 2018, the RTS logic with Early Refill Accumulation Limited edit was revised for the **non-controlled drugs** which now **allow an accumulation of 12 days' supply during the previous 180-day period.**

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

- 15. 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.
- 16. ANTIPSYCHOTIC AGENT CRITERIA FOR CHILDREN < 18 YEARS OF AGE have an ongoing requirement for labs** for metabolic monitoring every 6 months. When any provider sends a patient, who is less than 18 years of age for the required metabolic labs for the antipsychotic agents, the provider must include the PCP's name and Medicaid ID number on the lab order request form. It does not have to be the PCP ordering the labs. Please refer to the Physician/Independent Lab/CRNA/Radiation Therapy Center Provider Manual, Section II, 245.000 B.
- 17. 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.
- 18. 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.
- 19. FOR NON-PDL DRUGS AND FOR NON-ANTIPSYCHOTIC 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.
- 20. 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

AR MEDICAID DUR BOARD MEETING APRIL 17, 2019

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.

- 21. 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
- 22. 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.