DUR Board Meeting Minutes April 17, 2019

DUR Board Meeting

April 17, 2019

Voting Board Members Present	**Medicaid Pharmacy Representatives Present**
Lana Gettman, Pharm. D.	Cinnamon Pearson, Pharm. D., Chair
Jill Johnson, Pharm. D.	Cynthia Neuhofel, Pharm. D.
Laurence Miller, M.D.	Jim Richardson, Pharm. D.
Brian King, Pharm. D.	Michael Munnerlyn, MBA
James Magee, M.D.	Jordan Brazeal, Pharm. D. (RDUR—HID)
Ashley McPhee, Pharm. D.	Karen Evans, P.D. (ProDUR—Magellan)

Non-Voting Board Members Present

Kristen Pohl, Pharm. D. (ATC)
Christopher Page, Pharm. D. (Empower)
Jerry Jones, Pharm. D. (Empower)
Suzanne Trautman, Pharm. D. (Summit)

Board Members and Others Absent

Michael Mancino, M.D.
Richard Ward, Pharm. D.

I. SPEAKERS

The Chair stated there are 4 speakers present to give public comment today:

VITRAKVI® (Alima Tchafa, PhD—Bayer), TAKHZYRO™ (David Griffin, MS, Pharm. D.—Takeda), TALZENNA™ (Sara Henson, M.D.—Pfizer), and DAURISMO™ Sam Garas, Pharm. D.—Pfizer). Public comments in the form of letters were received from Dr. Matthew Bell, Dr. Tina Merritt and the HAE Association; letters were distributed to each Board member prior to the meeting and an additional copy was provided during the meeting as the above could not attend the meeting. Manny Nunez from Sanofi-Genzyme for DUPIXENT® was available in the audience for questions.


medicaid hae policy079640201904


Ark MCD HAE Final.pdf


Arkansas Medicaid Testimony for HAE.d

II. UNFINISHED/OLD BUSINESS AND GENERAL ORDERS

a. ANNOUNCEMENTS
   i. Resignation of Lanita White, Pharm. D.
   ii. Introduce new board member—Brian King, Pharm. D.
   iii. Introduce Arkansas Medicaid Clinical Pharmacist—Jim Richardson, Pharm. D.
   iv. New non-voting members—Susanne Trautman, Pharm. D. (Summit); Kristin Pohl, Pharm. D. (ATC); Jerry Jones, Pharm. D. and Christopher Page, Pharm. D. (Empower).
   v. Time for By-laws to be reviewed. Copy of current By-laws and proposed changes were provided to Board members to review next quarterly meeting.

b. Review Minutes from January 2019 quarterly meeting.

Motion by Dr. Miller to approve the minutes as written; Dr. Magee seconded the motion. All members present voted to accept the minutes as written. Motion passed.

c. Update on system edits, implementations form the previous DUR Board meetings, and other unfinished business or follow-up items:
    i. No further correspondence needed for January 2019 Board meeting
    ii. PDL changes from DRC meeting were implemented April 1, 2019; DUR PA manual review drugs were effective immediately; Zortress® edits were updated on April 10, 2019.

d. PROPOSED CHANGES TO EXISTING CRITERIA, INCLUDING POINT OF SALE (POS) CRITERIA, MANUAL REVIEW PA CRITIERIA OR CLAIM EDITS:

1) Hereditary Angioedema Therapy

Chair provided general information on HAE as well as background information on Type I HAE, Type II HAE, and HAE with normal C1 inhibitor (Type III HAE) including the difference in labs.

Chair provide information on all current HAE medications used for either acute attacks or prophylaxis (Berinert ®, Kalibtor ®, Ruconest ®. Firazyr®, Danazol, Oxandrolone, Tranexamic Acid, Aminocaproic Acid, Cinryze®, Haegarda® and Takhzyro™.

1) Current status in Arkansas Medicaid pharmacy program
2) Indication and mechanism of action
3) Recommended dose for adults and pediatrics
4) Route of administration
5) Comparison charts for Cinryze®, Haegarda® and Takhzyro™
6) Treatment information on Type III HAE

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:
    - 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

Discussion:

Dr. Johnson added the need to verify if patient takes estrogens or Ace Inhibitors (should not be taking).
Dr. Magee suggested that we add hematologist to allergist/immunologist that can request. Dr. Golden suggested we take it on a case-by-case basis.

Chair stated that we do not want a provider inexperienced in treating HAE to order these medications.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Gettman seconded the motion. All members present voted for the motion. The motions was approved.

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 has used acute treatment XXXXX times per month, the provider needs to provide a re-assessment and new treatment plan for the patient?

Discussion:

Dr. Golden explained that evolving practice guidelines suggests the addition of on-demand treatment. In the past, we had acute treatment on the medical side with agreements with ERs. Dr. Magee asked if there is difference in treatment of mild or severe. Mild would be observation. Need documentation by a health professional.

Dr. Magee wondered if appropriate in waiting for 3 moderate attacks prior to treatment. Dr. Golden stated it is not a matter of allowing treatment, but whether it will be supplied in the home. Treatment is available in the ER.

Dr. Johnson asked to remove required number of attacks.

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
- Beneficiary tried and had an insufficient response or contraindication to BOTH of the following classes of medication
    - 17α-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 documented failure or contraindication to Androgens or Antifibrinolytic agents
- Does not meet continuation criteria in reference to severity and frequency by XXXXXX months of therapy

CONTINUATION CRITERIA:

- Continues to meet above criteria
- Provide updated diary of events
- Compliance on maintenance medication
- Decrease in frequency and severity of acute attacks by XXXXXX%

Discussion:

Dr. Golden said if using acute treatment multiple times per month, then there may be a need to change to prophylaxis to minimize the number of acute doses needed. Monitor to determine if improvement after prophylaxis. Question if this is truly HAE?

Dr. Johnson suggested to remove androgens and antifibrinolytics as a requirement before moving to these other agents. If they have trialed and failed, then count them as trialed but not require the use. Dr. Golden asked her opinion on Danazol use. Dr. Johnson feels not appropriate in females, but an option in males.

Chair stated we can ask on PA review if they have tried these agents but not require.

Chair asked board for input on how many acute doses would be needed to move to prophylaxis. Dr. Johnson suggested 4 doses in 3 months. Chair states will still be case-by-case.

Based on further discussion by Dr. Johnson and Dr. Neuhofel, the request was made to remove number of attacks. Chair summarized that if patient needs to use acute medications, then on renewal we should reassess on a case-by-case basis. No specific number is needed.

Chair strikes requiring Androgen and Antifibrinolytics.

Dr. Golden stated that if there is no response from prophylaxis, 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.

Chair will remove any amount of attacks or percentage of improvements as required for approval or renewal.

Dr. Magee asked if there was no response, are the providers trying different meds?

Dr. Johnson for manual review—if no improvement in severity and frequency on current medications, on renewal question the provider about changing therapy or reevaluating diagnosis.

Dr. Johnson mentions results of an ICER report.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Gettman seconded the motion. All members present voted for the motion. The motion was approved.

Addendum to proposal—Dr. Golden and Dr. Johnson requested to add no therapeutic duplication of agents.

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
  - Manuel 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
  - Max quantity of XXXX vials per month (no documented max dose)
  - 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

Discussion:

Dr. Johnson requested we do not put a max quantity on Haegarda since weight-based dosing.

Action:

Dr. Gettman made the first motion to accept the proposal as amended and Dr. Magee seconded the motion. All members present voted for the motion. The motion was approved.

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, will be reviewed at the PDL meeting on **May 8, 2019** and selections will be 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
  - Doses above the maximum therapeutic dose 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.
- MAXIMUM DAILY DOSES:
  - Aripiprazole (e.g. Abilify®) Tablet Medicaid Max Daily Dose = 30mg
  - Asenapine (e.g. Saphris®) SL Tablet Medicaid Max Daily Dose = 20mg
  - Brexpiprazole (e.g. Rexulti ®) Tablet Medicaid Max Daily dose = 4mg

- Cariprazine (e.g. Vraylar ®) Capsule Medicaid Max Daily Dose = 6mg
- Clozapine (e.g. Clozaril ®) Tablet Medicaid Max Daily Dose = 900mg
- Iloperidone (e.g. Fanapt ®) Tablet Medicaid Max Daily Dose = 24mg
- Lurasidone (e.g. Latuda ®) Tablet Medicaid Max Daily Dose = 160mg
- Olanzapine (e.g. Zyprexa ®) Tablet Medicaid Max Daily Dose = 20mg
- Olanzapine/Fluoxetine combination (e.g. Symbyax ®) Capsule Medicaid Max Daily Dose = 18mg/75mg
- Paliperidone ER (e.g. Invega ®) Tablet Medicaid Max Daily dose = 12mg
- Quetiapine (e.g. Seroquel®) Tablet Medicaid Max Daily Dose = 800mg
- Quetiapine ER (e.g. Seroquel XR®) Tablet Medicaid Max Daily Dose = 800mg
- Risperidone (e.g. Risperdal®) Tablet Medicaid Max Daily Dose = 16mg
- Ziprasidone (e.g. Geodon®) Capsule Medicaid Max Daily Dose = 160mg
- Chlorpromazine (e.g. Thorazine®) Tablet Medicaid Max Daily Dose = 800mg
- Fluphenazine (e.g. Prolixin®) Tablet Medicaid Max Daily Dose = 40mg
- Haloperidol (e.g. Haldol®) Tablet Medicaid Max Daily Dose = 40mg
- Loxapine (e.g. Loxitane®) Capsule Medicaid Max Daily Dose = 250mg
- Perphenazine (e.g. Trilafon®) Tablet Medicaid Max Daily Dose = 64mg
- Perphenazine-Amitriptyline (e.g. Etrafon®) Tablet Medicaid Max Daily Dose = 16MG/100MG
- Pimozide (e.g. Orap) Tablet Medicaid Max Daily Dose = 10mg
- Thioridazine (e.g. Mellaril®) Tablet Medicaid Max Daily Dose = 800mg
- Thiothixene (e.g. Navane®) Capsule Medicaid Max Daily Dose = 60mg
- Trifluoperazine (e.g. Stelazine®) Tablet Medicaid Max Daily Dose = 40mg

****For specific maximum quantities per strength of each medication, see the provider memo for the full dosing charts****

Discussion:

Chair stated that Dr. Mancino reviewed doses prior to meeting.

Action:

Dr. Miller made the first motion to accept the proposal as written and Dr. Johnson seconded the motion. All members present voted for the motion. The motion was approved.

III. NEW BUSINESS

A. PROPOSED NEW CLINICAL P OINT OF SALE CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS.

NONE

B. MANUAL REVIEW PROPOSED CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS

1) DUPIXENT®

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
- 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) and Asthma Quality of Life Questionnaire (AQLQ) scores
    - 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 FEV_1 over baseline by XXXXX%
- Improvement in ACQ-5 and AQLQ scores by XXXXX%
- Decrease in blood eosinophil count by XXXXX

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.

Discussion:

Dr. Gettman asked we must require a specific number for continuation.

Chair stated that an amount is not required but would help gage response to therapy.

Dr. McPhee stated that clinical trials indicated a 15% improvement on FEV1.

Chair suggested to remove scores for ACQ-5 and AQLQ

Dr. Gettman wanted to remove an improvement number for blood eosinophil count.

Dr. Johnson recommended a therapeutic duplication edit on the Interleukin products.

Dr. Golden adds in continuation criteria that improvement on oral steroid usage.

Dr. Magee states AQLQ does not apply to children. So place OR instead of AND.

Dr. Magee asks if use raw FEV1 or FEV1 % predicted.

Dr. Magee suggests removing specific improvement amount on FEV1—question what would do if patient had a 14% improvement for example.

Dr. Hailey suggested that the medical necessity over Xolair would be required.

Dr. Johnson reviewed ICER report and all Interleukin products work similarly. If price is an issue, recommend Xolair.

Chair stated that Xolair is mentioned in the GINA guidelines.

Dr. Hailey stated that Xolair was approximately 4 times less expensive for the state.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Magee seconded the motion. All members present voted for the motion. The motion was approved.

2) DAURISMO™

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 ≤ 2 or =2 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 ≥ 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
- DAURISMO™ 100MG TABLETS #30/30 DAYS

Discussion:

Dr. Johnson suggested to include ECOG score ≤3

Action:

Dr. Gettman made the first motion to accept the proposal as amended and Dr. Miller seconded the motion. All members present voted for the motion. The motion was approved.

3) XOSPATA®

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

Discussion:

Dr. Johnson feels providers are monitoring labs and should not be burden on Medicaid.

Chair stated that she is aware the providers are monitoring and would like labs sent to allow a complete chart for review.

Action:

Dr. Miller made the first motion to accept the proposal as amended and Dr. Johnson seconded the motion. All members present voted for the motion. The motion was approved.

4) VITRAKVI®

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).*
- Current Body Surface Area (BSA) must be provided. Dosing based on BSA—If BSA < $1m^2$ should be dosed at $100mg/m^2$ twice daily; If BSA is ≥ $1m^2$ 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 3^{rd} 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

Discussion:

Dr. Johnson asks if test for resistance mutation exists.

Chair stated she asked drug rep. Chair addressed Dr. Tchara in audience who answered the question.

Dr. Johnson request addition of need gene mutation for approval with resistance test.

Dr. Gettman as what would be considered intolerable toxicity.

Chair stated it mostly pertains to labs as well as hepatotoxity and neurotoxicity.

Dr. Johnson cannot get on board with this drug (why requesting to add needed verification of gene mutation resistance). Chair stated to remember that this is manual review, and we know not first line. Staff will review NCCN guidelines.

Action:

Dr. Miller made the first motion to accept the proposal as amended and Dr. Magee seconded the motion. All members present voted for the motion. The motion was approved.

5) SYMPAZAN™

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 by XXXXX%

- Current chart notes

QUANTITY EDITS:

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

Discussion:

Chair stated to remove the decrease in seizures from baseline percentage.

Action:

Dr. Magee made the first motion to accept the proposal as amended and Dr. King seconded the motion. All members present voted for the motion. The motion was approved.

6) TALZENNA™

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

Discussion:

No discussion

Action:

Dr. Gettman made the first motion to accept the proposal as written and Dr. Johnson seconded the motion. All members present voted for the motion. The motion was approved.

7) TEGSEDI™

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
- 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 10^9/L on initiation of treatment and stop treatment if platelets are < 100 x 10^9/L during therapy; only resume if platelets rise above 100 x 10^9/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 m^2
    - 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 leptomeningeal amyloidosis*

- Not able to adhere to recommended laboratory monitoring

CONTINUATION CRITERIA:

- Provide current labs
- Platelets must be ≥ 100 x 10^9/L
- eGFR must be ≥ 45 mL/minute/1.73m^2
- UPCR < 1000mg/g
- Updated mNIS+7 composite score and QoL-DN total score with XXX% decrease in score
- Current chart notes

QUANTITY EDITS:

- 4 syringes/ 28 days

Discussion:

Chair removed % decrease in score from continuation criteria to be consistent with other medications reviewed.

Dr. Miller asked if there are other medications for this indication.

Dr. Johnson stated the medication Onpattro®, as a medical benefit is another option.

Dr. Johnson states must have neuropathy along with other body involvement.

Chair asked Dr. Johnson if there is data to support use of other neuropathic pain medications (i.e. gabapentin or pregabalin). Dr. Johnson said due to amyloid build-up these are not helpful. Provide medical necessity of Tegsedi over these neuropathic pain meds. If has definitive diagnosis, would not require other neuropathic pain meds.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Magee seconded the motion. All members present voted for the motion. The motion was approved.

8) INBRIJA™

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.

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

Discussion:

Dr. Johnson suggested adding approval criteria as medical necessity over increasing current Carbidopa/Levodopa oral dose.

Dr. Gettman questioned if problems with inhaling during "off" time.
Chair will research.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Magee seconded the motion. All members present voted for the motion. The motion was approved.

9) ARIKAYCE®

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
- No reported ototoxicity or nephrotoxicity
- Current labs including CBC and basic metabolic panel

QUANTITY EDITS: #28 vials/ 28 days

Discussion:

Dr. Johnson suggested that we continue to monitor the cultures periodically. Monitor maybe yearly to ascertain if remains negative.

Chair states will add this to continuation criteria.

Action:

Dr. Johnson made the first motion to accept the proposal as amended and Dr. Miller seconded the motion. All members present voted for the motion. The motion was approved.

C. PROPOSED NEW CLAIM EDITS

1) PRIMAQUINE

Quantity of #14 per claim per XXXX

2) KRINTAFEL

Quantity of #2 per claim per XXXX

Discussion:

Dr. Magee suggested to leave quantity edits per claim and not have a renewal timeframe.

Action:

Dr. Magee made the first motion to accept the proposal as amended and Dr. Johnson seconded the motion. All members present voted for the motion. The motion was approved.

D. ProDUR Report

Dr. Evans gave a presentation on the departments' Prospective Drug Utilization Review Report. There were no significant changes over the previous quarter.

E. RDUR Report

Dr. Brazeal gave a presentation on the department's Retrospective Drug Utilization Review Report, provided feedback on the impact of RDUR interventions performed 6 months ago, discussed pharmacy lock-ins, and consulted with the Board on RDUR educational intervention criteria recommendations.

Chair shared a slide with upcoming DUR dates. Meeting adjourned at 11:50 a.m.