

# Arkansas Medicaid DUR Board Meeting Minutes

## DUR Board Meeting

October 16, 2019

Magellan Medicaid Administration Office  
#1 Allied Drive, Suite 1120  
Building #1  
Little Rock, Arkansas 72202

### Voting Board Members Present

Paula Podrazik, M.D.  
Jill Johnson, Pharm. D.  
Laurence Miller, M.D.  
Brian King, Pharm. D.  
James Magee, M.D.  
Clint Boone, Pharm. D.  
Michael Mancino, M.D.  
Geri Bemberg, Pharm. D.  
Lana Gettman, Pharm. D.

### Non-Voting Board Members Present

Kristen Pohl, Pharm. D. (ATC)  
Christopher Page, Pharm. D. (Empower)  
Suzanne Trautman, Pharm. D. (Summit)  
Nate Smith, M.D. (advisor)

### Medicaid Pharmacy Representatives Present

Cinnamon Pearson, Pharm. D., Chair  
Cynthia Neuhofer, Pharm. D.  
Elizabeth Pitman, JD  
Michael Munnerlyn, MBA  
Jordan Brazeal, Pharm. D. (RDUR—HID)  
Karen Evans, P.D. (ProDUR—Magellan)  
Annette Jones, B.S.

### Board Members and Others Absent

None absent  
1 pharmacist vacancy  
1 physician vacancy (oncologist)

Meeting held in the Magellan Health Boardroom located at #1 Allied Drive, Suite 1120 in Little Rock, Arkansas. A quorum was present, and the chair called the meeting to order at 8:32am.

## I. **SPEAKERS**

The Chair stated there are 3 speakers present to give public comment today as well as a letter read aloud by the chair:

Ingrezza® (Sean Hinton, PhD from Neurocrine Biosciences); Austedo® (Dave Miley, Pharm. D. from Teva Neurosciences); Cablivi® (Jomy Joseph, Pharm. D. from Sanofi Genzyme) and a letter read by the chair from the National Hemophilia Foundation. Public comments in the form of letters were provided to the Board members prior to the meeting. Board members did not ask questions after any speaker comment.

## II. **UNFINISHED/OLD BUSINESS AND GENERAL ORDERS**

### A. **ANNOUNCEMENTS BY THE CHAIR**

- 1) Chair read the disclosure of conflict of interest statement. Chair has no conflicts, and none noted by Board members.
- 2) Resignations--none
- 3) Introduction of new board member—Geri Bemberg, Pharm. D.
- 4) Introduction of State Health Officer from the Arkansas Department of Health—Nate Smith, M.D.
- 5) Update on meeting location

All 2020 meetings will be held in conference room A/B in the DHS Donaghey South Building at 700 Main Street in Little Rock

### B. **REVIEW MINUTES FROM THE JULY 2019 QUARTERLY MEETING**

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

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### C. UPDATE ON SYSTEM EDITS, IMPLEMENTATIONS FROM THE PREVIOUS DUR BOARD MEETINGS AND OTHER UNFINISHED BUSINESS OR FOLLOW-UP ITEMS:

1) No further correspondence needed for July 2019 Board meeting

#### 2) IMPLEMENTATION INFORMATION FROM JULY 17, 2019 DUR BOARD MEETING AND AUGUST 14, 2019 DRC MEETING

Preferred Drug list changes were effective October 1, 2019; DUR PA manual review drugs were effective immediately; Quantity edits for osteoporosis agents and changing Alpha-1 proteinase inhibitors to manual review were effective October 1, 2019.

#### 3) REVIEW AND VOTE ON AMENDMENT TO THE BYLAWS

Occasionally, the DHS medical director or the state health officer attend DUR Board meetings. The composition of the Board was updated to reflect their attendance as follows.

**7.02 Composition**—Pursuant to 42 CFR 456.716(b), the composition of the DUR Board shall include licensed professionals from a cross-section of healthcare practice who are recognized for their knowledge and expertise in the appropriate prescribing, dispensing, and/or monitoring of Medicaid-covered outpatient prescription drugs, including drug use review, evaluation, intervention, and medical quality assurance. Additionally, the State Health Officer and DHS Medical Director may attend the meeting in an advisory capacity only. The State Health Officer and the DHS Medical Director may not send a designee as a substitution.

Motion to approve the changes to the DUR Board bylaws as written was made by Dr. Johnson; Seconded by Dr. Podrazik; all members present voted for the motion. Motion passed.

4) UPDATE ON OPIOID USAGE—postponed allowing time for review of PASSE encounter data

#### 5) MEDICATION-ASSISTED TREATMENT UPDATE

Beginning January 1, 2020, Arkansas Medicaid will remove prior authorization requirements for preferred buprenorphine products on the Arkansas Medicaid evidence-based preferred drug list. Only the preferred agents on the preferred drug list will be impacted by this change. Non-preferred medications will continue to require a PA. Review the pharmacy vendor website for current preferred medications.

- With a valid prescription for opioid use disorder and compliance with the medication-assisted treatment guidelines, the preferred MAT medications will not require a PA.
- Prescriptions for MAT medications will not take up a Medicaid slot.
- Prescriptions for MAT medications will not require a copay by the beneficiary.
- Maximum quantity edits apply per FDA dosing recommendations.
- Therapeutic duplication limitations will continue to apply. When a prescription for an opioid is submitted at the pharmacy, the system will look back 90 days for a drug claim for a buprenorphine product. If buprenorphine products have been dispensed in the last 90 days, the opioid prescription will deny and require a prior authorization.

#### 6) Truvada® (emtricitabine and tenofovir disoproxil fumarate) 100-150mg, 133-200mg, 167-250mg and 200-300mg tablets

##### SUGGESTED APPROVAL CRITERIA:

\*\*\*Remove manual review criteria for PrEP and remove Point-of-sale (POS) approval criteria to prevent barriers to HIV/AIDS treatment. Keep POS denial criteria concerning therapeutic duplication.

Therapeutic duplication edits for Truvada®, Descovy®, Emtriva® and Viread®:

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- If there is a paid claim within previous 30 days for Descovy®, Emtriva® or Viread®, Truvada® will deny at POS.
  - If there is a paid claim within previous 30 days for Descovy®, Emtriva® or Truvada®, Viread® will deny at POS.
  - If there is a paid claim within previous 30 days for Descovy®, Truvada® or Viread®, Emtriva® will deny at POS.
  - If there is a paid claim within previous 30 days for Truvada®, Viread® or Emtriva®, Descovy®, will deny at POS.
- \*\*\*Keep quantity edits for Truvada®, Descovy®, Emtriva® and Viread® of 1 dose per day.

\*\*\*Any generics that become available will have the same criteria.

### **DISCUSSION:**

Chair stated that Descovy® now carries the PrEP indication as well and should follow the above criteria. Dr. Johnson raised a concern for adherence since there is already documentation of lack of compliance. Chair asked Dr. Smith his thoughts on compliance and resistance in those patients on PrEP and those starting HIV treatment prior to resistance test results. Dr. Smith stated the standard of care is moving to beginning newer products while waiting on resistance testing due to efficacy of drugs. PrEP is a different issue and a negative HIV test is imperative. If the patient is HIV negative, then there would not be a resistance issue. Dr. Johnson asked if taking for PrEP intermittently was a problem. Dr. Smith stated that this should be taken continuously during the period of risk. Chair mentioned the new HIV task force.

### **ACTION:**

Motion to approve as amended with the addition of Descovy made by Dr. Miller; seconded by Dr. Johnson. All members present voted in favor of the motion. Motion passed.

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

### **1) Ingrezza® (valbenazine) 40mg and 80mg capsules**

This medication was previously reviewed by the Arkansas Medicaid DUR Board in October 2017.

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CHANGES TO CRITERIA**

#### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Beneficiary must be 18 years of age or older; **AND**
- Prescriber must submit chart notes with documentation on the impact of TD symptoms with activities of daily living; **AND**
- Beneficiary must have a diagnosis of moderate to severe tardive dyskinesia meeting the following DSM-5 criteria:
  - Involuntary athetoid or choreiform movements; **AND**
  - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); **AND**
  - Symptom duration lasting longer than 4 to 8 weeks; **AND**
- Ingrezza® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage. Ingrezza® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage; **AND**
- Beneficiary must not be suicidal or have violent behavior; **AND**
- Prescriber must submit the completed Medicaid "Ingrezza® / Austedo® Statement of Medical Necessity" form with the initial request as part of the manual review; **AND**

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### Proposed updated form



ARRx\_SMN\_Form\_In  
grezza\_Austedo2.pdf

- Prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual review; **AND**
- Female beneficiary must not be pregnant or breastfeeding; **AND**
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or concomitant strong CYP3A4 inducers (e.g. rifampin, carbamazepine, and phenytoin); **AND**
- Beneficiary must not exceed Ingrezza® 40mg daily if also taking strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, and clarithromycin); **AND**
- Beneficiary must not exceed Ingrezza® 40mg daily if has moderate or severe hepatic impairment (Child-Pugh score 7 to 15); **AND**
- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; **AND**
- If beneficiary has taken benztropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; **AND**
- Beneficiary must not have severe renal impairment (creatinine clearance <30 mL/min) and prescriber must provide attestation; **AND**
- Initial PAs not to exceed 3 months; once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

### **DENIAL CRITERIA:**

- Beneficiary is <18 years of age; **OR**
- Beneficiary is not compliant on prescribed dose after previous approval; **OR**
- Prescriber requests a dose > 80mg/ day; **OR**
- Prescriber requests a dose > 40mg/ day for beneficiaries with moderate or severe hepatic impairment or beneficiary takes strong CYP3A4 inhibitors; **OR**
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy; **OR**
- Beneficiary does not meet the approval criteria

### **CONTINUATION CRITERIA:**

- Beneficiary must be compliant on prescribed dose; **AND**
- Prescriber must submit current chart notes; **AND**
- Prescriber must provide an updated AIMS form and documentation of clinical response to therapy every 6 months; **AND**
- Beneficiary must show an improvement from baseline AIMS score and/or have a positive clinical response to therapy; **AND**
- Beneficiary must continue to meet approval criteria

### **QUANTITY EDITS:**

40mg capsules = #30 per 30 days (The initial PA will be approved for #60 capsules for titration for 1 month only.)  
80mg capsules = #30 per 30 days

### **DISCUSSION:**

Dr. Johnson mentioned that Benztropine is ineffective for tardive dyskinesia and suggested the use not be a requirement. Dr. Johnson asked if the use of Gingko Biloba for tardive dyskinesia which reduces AIMS scores was considered. Chair stated that it would be difficult to require an OTC product. Dr. Hailey stated that Gingko Biloba is not

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a covered product. Dr. Podrazik asked how knowing if the patient has tried Benztropine effects the approval decision. Chair and Dr. Miller stated that our reviewers need to see an overall treatment background. Dr. Podrazik asked about allowing gastroenterologists to request this medication and stated that typically the patient would be referred to an internalist or neurologist. Dr. Miller replied that recently the staff reviewed a request from a gastroenterologist, and the provider made a good review with all required documentation. With the quality of the request, the staff did not see the rationale for making the patient attend another appointment with the neurologist.

### **ACTION:**

Motion to approve updated criteria as written made by Dr. Mancino; seconded by Dr. Gettman. All members present voted for the motion. Motion passed.

### **2) Austedo® (deutetrabenazine) 6mg, 9mg and 12mg tablets**

This medication was previously reviewed by the Arkansas Medicaid DUR Board in October 2017. Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CHANGES TO CRITERIA**

#### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Beneficiary must be 18 years of age or older; **AND**
- Prescriber must submit chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living; **AND**
- Beneficiary must either have a diagnosis of moderate to severe tardive dyskinesia or chorea associated with Huntington's Disease. If has tardive dyskinesia, beneficiary must meet the following DSM-5 criteria:
  - Involuntary athetoid or choreiform movements; **AND**
  - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); **AND**
  - Symptom duration lasting longer than 4 to 8 weeks; **AND**
- Beneficiary with chorea associated with Huntington's Disease must not be suicidal or have untreated or inadequately treated depression; **AND**
- Austedo® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage or Huntington's disease. Austedo® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage; **AND**
- Prescriber must submit the completed Medicaid "Ingrezza® / Austedo® Statement of Medical Necessity" form with the initial request as part of the manual review; **AND**

#### **Proposed updated form**



ARRx\_SMN\_Form\_In  
grezza\_Austedo2.pdf

- For treating Tardive Dyskinesia, prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual PA review; **AND**
- Female beneficiary must not be pregnant or breastfeeding; **AND**
- If beneficiary has taken benztropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; **AND**
- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; **AND**

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- If beneficiary takes a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) OR the beneficiary is a poor CYP2D6 metabolizer, maximum daily dose is reduced to 36mg; **AND**
- Beneficiary must not have hepatic impairment and prescriber must provide attestation; **AND**
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or reserpine; **AND**
- Provider must provide the Austedo® tapering plan with each PA request until beneficiary reaches a stable, maintenance dose; **AND**
- The initial Austedo® PA will be approved for two(2) months to allow time for titration. Austedo® 6mg can be approved up to a maximum of #240 tablets (8 tablets per day) during the initial two(2) months of treatment for titration. If additional titration time is needed beyond the original two(2) months, another PA with quantity override would be required. Once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

### **DENIAL CRITERIA:**

- Beneficiary is <18 years of age; **OR**
- Beneficiary is not compliant on prescribed dose after previous approval; **OR**
- Prescriber requests dose > 48mg/ day; **OR**
- Prescriber requests a dose > 36mg/ day for beneficiaries taking a strong CYP2D6 inhibitor or is a poor CYP2D6 metabolizer; **OR**
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy on renewal request; **OR**
- Beneficiary with a diagnosis of chorea associated with Huntington's Disease is suicidal or has untreated or inadequately treated depression; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary has congenital long QT Syndrome or cardiac arrhythmias associated with prolonged QT interval; **OR**
- Beneficiary has documented hepatic impairment; **OR**
- Beneficiary develops Neuroleptic Malignant Syndrome; **OR**
- Beneficiary takes reserpine, MAOIs or any other VMAT2 inhibitor; **OR**
- Beneficiary does not meet the approval criteria

### **CONTINUATION CRITERIA:**

- Beneficiary must be compliant on prescribed dose; **AND**
- Prescriber must submit current chart notes; **AND**
- Prescriber must provide an updated AIMS form and documentation of clinical response to therapy every 6 months; **AND**
- Beneficiary must show an improvement from baseline AIMS score and/or have a positive clinical response to therapy; **AND**
- Beneficiary must continue to meet approval criteria.

### **QUANTITY EDITS:**

6mg tablets = #60 per 30 days (The initial PA will be approved for a maximum of #240 tablets for titration for 2 months only.)

9mg tablets = #120 per 30 days

12mg tablets = #120 per 30 days

### **DISCUSSION:**

Dr. Mancino asked for verification concerning benztropine. No further comments.

### **ACTION:**

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Motion to approve updated criteria as written made by Dr. Mancino; seconded by Dr. Boone. All members present voted for the motion. Motion passed.

### 3) Hemlibra® (emicizumab) 30mg/mL, 60mg/0.4mL, 105mg/0.7mL and 150mg/mL Subcutaneous injections This medication was previously reviewed by the Arkansas Medicaid DUR Board in January 2018.

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

#### SUGGESTED UPDATES TO CRITERIA

##### **APPROVAL CRITERIA for Hemophilia A WITH Inhibitors:**

- Manual review on a case-by-case basis; **AND**
- Beneficiary must have a diagnosis of congenital hemophilia A with high factor VIII inhibitor titer ( $\geq 5$  Bethesda units per mL (BU)); **AND**
- Documentation Hemlibra® is prescribed for the prevention of bleeding episodes; **AND**
- Provide documentation of previous treatment with episodic and prophylactic bypassing agents for at least the last 24 weeks; **AND**
- Provide chart notes for the last 24 weeks and current labs (CBCs and LFTs); **AND**
- Provide clarification that beneficiary will NOT be receiving concurrent prophylactic treatment with bypassing agents or have ongoing/plan to receive immune tolerance induction therapy while taking Hemlibra®. Beneficiary may receive episodic treatment with bypassing agents as need for breakthrough bleeding episodes; **AND**
- Provide beneficiary's bleed history for the last 24 weeks and include description of bleed episode and treatment required; **AND**
  - Did beneficiary have  $\geq 6$  bleeds on episodic treatment only? **OR**
  - Did beneficiary have  $\geq 2$  bleeds on prophylactic treatment with bypassing agents?
- Provide documentation of treatment plan concerning episodic products (Feiba or NovoSeven); **AND**
- Provide beneficiary's weight with each PA request; **AND**
- Provide a letter of medical necessity outlining rationale for changing therapy from existing treatment; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis (see continuation below).

##### **APPROVAL CRITERIA for Hemophilia A WITHOUT Inhibitors:**

- Manual review on a case-by-case basis; **AND**
- Beneficiary must have a diagnosis of severe congenital hemophilia A with endogenous factor VIII levels  $< 1\%$  of normal OR documentation of  $\geq 5$  bleeding episodes in the last 24 weeks; **AND**
- Documentation Hemlibra® is prescribed for the prevention of bleeding episodes; **AND**
- Provide documentation of the details of previous prophylactic and/or episodic FVIII treatment. Beneficiary must have received episodic or prophylactic factor VIII infusions for at least 24 weeks; **AND**
- Provide beneficiary's bleed history for the last 24 weeks and include description of bleed episode and treatment required; **AND**
- Provide chart notes for the last 24 weeks and current labs (CBCs and LFTs); **AND**
- Provide clarification that beneficiary will discontinue prophylaxis factor VIII; **AND**
- Provide documentation of treatment plan concerning episodic factor products; **AND**
- Provide beneficiary's weight with each PA request; **AND**
- Provide letter of medical necessity outlining rationale for changing therapy from existing treatment; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis (see continuation below).

##### **DENIAL CRITERIA:**

- Beneficiary does not have a diagnosis of congenital hemophilia A; **OR**

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- Beneficiary continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents); **OR**
- Beneficiary is not compliant on prescribed Hemlibra® dose; **OR**
- Prescriber requests dose above FDA-approved dose or prescribes the use of Hemlibra® for PRN dosing; **OR**
- No positive response in the decrease of bleeding episodes or decrease of episodic agent use.

### **CONTINUATION CRITERIA:**

- Provide all of beneficiary's chart notes and labs since previous approval; **AND**
- Provide beneficiary's current weight; **AND**
- Documentation of compliance on Hemlibra®; **AND**
- Provide documentation of beneficiary's bleeding episodes including frequency, drug used and dose since previous approval; **AND**
- If beneficiary continues to need episodic treatment and pharmacy records indicate that prescriptions are billed monthly, provide the medical necessity to continue Hemlibra®; **AND**
- Continued renewal requires a positive response to Hemlibra® (decrease in bleeding episodes and/or decrease in episodic agent requirements); **AND**
- Provide dosing/frequency requirements of Hemlibra® with each renewal request; **AND**
- Once beneficiary is stable on Hemlibra® and indicates a positive response, PA's may be approved for 3 months at a time.

### **QUANTITY EDITS:**

None since weight-based dosing

### **DISCUSSION:**

Dr. Johnson asked how we would know if factor VIII is being used prophylactically or episodically. Chair stated that we would review pharmacy claims. Dr. Magee asked about endogenous factor VIII level of <1%. Dr. Johnson confirmed that <1% was considered severe. Dr. Podrazik verified that the PAs would be a month at a time until stable. Chair confirmed. Dr. Johnson spoke on using Hemlibra for those with inhibitors without barriers as would be more cost effective than using Feiba and Novoseven. Those patients without inhibitors have a huge response with a decrease in bleeding episodes of 97% per clinical trials. Factor VIII consumption would decrease. Dr. Johnson stated that while Hemlibra is very effective, it might not be cost effective due to much lower cost of factor VIII products. Dr. Johnson stated that she agrees with leaving the requirement for factor VIII <1% of normal, and we should consider requiring dosing frequency of factor CIII products be increased before considering Hemlibra. Chair stated that our staff can ask about the medical necessity of Hemlibra over increasing the frequency of factor products.

### **ACTION:**

Motion by Dr. Johnson to approve updated criteria with amendments; seconded by Dr. Mancino. All members present voted in favor of the motion. Motion passed.

## **III. NEW BUSINESS**

- A. PROPOSED NEW CLINICAL POINT OF SALE CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS. NONE**
- B. MANUAL REVIEW PROPOSED CRITERIA WITH OR WITHOUT ADDITIONAL CLAIM EDITS**

### **1) Cablivi® (caplacizumab-yhdp) intravenous or subcutaneous injection**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

✱ *Denotes pulled from clinical trial NCT02553317 (HERCULES)*

### **APPROVAL CRITERIA:**



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- Must be ≥ 18 years of age; **AND**
- Beneficiary has a clinical diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) (initial or recurrent) ; **AND**
- Provide the medical necessity over high dose glucocorticoids and rituximab with PEX; **AND**
- Beneficiary is currently taking immunosuppressive therapy; **AND**
- Beneficiary has initiated plasma exchange; **AND**
- Provide chart notes/hospitalization notes with treatment plan; **AND**
- Provide current labs with minimum of the following: CBCs with platelets, LFTs, and ADAMTS13 activity level (may not have immediately but should be drawn and pending results); **AND**
- Provide treatment plan if beneficiary has clinically significant bleeding; **AND**
- Beneficiary should not be pregnant or breastfeeding (until at least 2 months after last dose) \* ; **AND**
- Beneficiary considered high-risk and hospitalized and has at least one of the following (per UpToDate):
  - Neurologic abnormalities
  - Decreased level of consciousness
  - Elevated serum troponin level
  - Other signs of critical illness
- Approve 1 month at a time (max quantity would be 58 plus number of days getting PEX)

### **DENIAL CRITERIA:**

- Diagnosed with congenital thrombotic thrombocytopenic purpura or has other cause for thrombocytopenia; **OR**
- Pregnant or breastfeeding \* ; **OR**
- Not receiving PEX or immunosuppressive therapy; **OR**
- Beneficiary is classified as standard risk and responds to PEX/glucocorticoids
- Interrupt treatment if clinically significant bleeding occurs \* ; **OR**
- Concomitant use with anticoagulant?? (or require INR/PT and close monitoring); **OR**
- Discontinue if more than 2 recurrences of aTTP while on Cablivi®; **OR**
- ADAMTS13 activity level >10%; **OR**
- Platelet count ≥ 100X10<sup>9</sup>/L \*

### **CONTINUATION CRITERIA:**

- Patients with suppressed ADAMTS13 enzyme activity level indicates persistent underlying disease after initial treatment course. Treatment may be extended to a total of 28 extra days. Discontinue treatment if ADAMTS13 activity is above 20-30% (per UpToDate) ; **AND**
- Provide current chart notes and previously requested labs; **AND**
- Verify last date of PEX; **AND**
- Documentation of compliance with Cablivi® and immunosuppressive therapy.

### **QUANTITY EDITS:**

Maximum of 58 days after plasma exchange is complete.

### **DISCUSSION:**

Dr. Mancino commented that if the patient is sick enough to need to be hospitalized then most likely are high risk. Dr. Mancino stated there is a delay in billing from inpatient stay. How would our staff quantify that? Chair stated that we would not see the inpatient billing, but we would review the treatment in the notes from hospitalization. Chair stated that if patient is sick enough to be hospitalized, there will probably be no problem with approval. It would be a matter of how long the patient would be treated. Dr. Mancino asked how common is ADAMTS13 activity testing availability? Chair asked the manufacturer rep for a response. He stated that testing is available, but it may

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need to be sent out. There would be a variability to length of time for results. Dr. Mancino asked how many patients would be affected in Arkansas. The rep stated that likelihood is 4-5 cases per million.

### ACTION:

Motion to approve criteria as written made by Dr. Mancino, seconded by Dr. King. All members present voted in favor of the motion. Motion passed.

### 2) Piqray® (alpelisib) 50mg, 150mg and 200mg tablet

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### SUGGESTED CRITERIA:

✱ Denotes pulled from clinical trial NCT02437318 (SOLAR-1)

#### APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- If woman, provide documentation that postmenopausal; **AND**
- Provide documentation that beneficiary has HR positive and HER2 negative, PIK3CA-mutated, advanced or metastatic breast cancer; **AND**
- Beneficiary has relapsed after previous treatment with documented evidence of progression; **AND**
- Provide CBCs, BMPs, HbA1c, LFTs; **AND**
- Provide documentation of previous or current endocrine-based therapy—requires current fulvestrant use; **AND**
- Provide documentation that patient was advised to start antidiarrheal treatment and educated on the symptoms of hyperglycemia and educated about signs of severe cutaneous reactions; **AND**
- Beneficiary has either measurable disease or at least one predominantly lytic bone lesion present ✱; **AND**
- ECOG score ≤2 (exclusion criteria in trial was for ≥2)??; **AND**
- Initial approval for 1 month due to significant adverse reaction potential.

#### DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- History of or current diagnosis of severe cutaneous reactions including Stevens-Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis; **OR**
- Beneficiary has inflammatory breast cancer ✱; **OR**
- Beneficiary has diabetes mellitus Type 1 or uncontrolled Type 2 ✱; **OR**
- Beneficiary has Child-Pugh score B or C ✱; **OR**
- Beneficiary has history of acute pancreatitis within 1 year of screening or past history of chronic pancreatitis ✱; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary taking strong CYP3A4 inducers

#### CONTINUATION CRITERIA:

- Provide current chart notes with documentation of response to therapy; **AND**
- Provide current labs including HbA1c obtained every 3 months; FPG should be checked once every week for the first 2 weeks then at least once every 4 weeks; **AND**
- Verify that beneficiary is not experiencing intolerable toxicity including severe cutaneous reactions, severe hyperglycemia and diarrhea

#### QUANTITY EDITS:

200mg/day pack #28/28 days

250mg/day pack #56/28 days

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300mg/day pack #56/28 days

## **DISCUSSION:**

Dr. Podrazik asked how often patients experience hyperglycemia. Chair clarified that 64% experience hyperglycemia. Dr. Podrazik asked if the side effect of hyperglycemia is treated to allow for continuation of this medication. Chair stated that documentation of FPG > 500mg/dL has recommendation of discontinuing this medication. Dr. Podrazik and Dr. Mancino agreed that there are many medications used to treat hyperglycemia, and hopefully the hyperglycemia is recognized early to allow treatment before discontinuing this medication. Dr. Johnson asked if the PIK3CA-mutation is required. Chair confirmed.

## **ACTION:**

Motion to approve as written was made by Dr. Johnson; seconded by Dr. Podrazik. All members present voted for the motion. Motion passed.

### **3) Xpovio™ (selinexor) 20mg tablets**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

## **SUGGESTED CRITERIA:**

✱ *Denotes pulled from clinical trial NCT02336815 (STORM)*

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary must have diagnosis of relapsed or refractory multiple myeloma; **AND**
- Beneficiary must have received at least four prior therapies; refractory to at least 2 proteasome inhibitors (e.g., bortezomib, ixazomib and carfilzomib), at least two immunomodulatory agents (e.g., lenalidomide, pomalidomide and thalidomide), and an anti-CD38 monoclonal antibody (e.g. daratumumab); **AND**
- Beneficiary must be prescribed concomitant dexamethasone; **AND**
- Provider must submit chart notes with documentation of previous treatment; **AND**
- Provide current labs including complete blood count and standard blood chemistry along with body weight as a baseline. Monitor platelet, sodium and neutrophil counts at baseline, during treatment, and as clinically indicated. Monitor more frequently during the first two months of treatment; **AND**
- Provide treatment plan for potential nausea and dehydration; **AND**
- Beneficiary must not be pregnant or breastfeeding; **AND**
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

### **DENIAL CRITERIA:**

- Beneficiary does not meet the approval criteria; **OR**
- Beneficiary has active smoldering multiple myeloma ✱; **OR**
- Beneficiary has active plasma cell leukemia ✱; **OR**
- Beneficiary has documented systemic amyloid light chain amyloidosis ✱; **OR**
- Beneficiary has active CNS multiple myeloma ✱; **OR**
- Adverse effects that require dose modifications do not meet recommendations; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary is not prescribed dexamethasone to take concomitantly.

### **CONTINUATION CRITERIA:**

- Provider must submit current chart notes with documentation of response to therapy; **AND**
- Provide at a minimum the following labs: basic metabolic panel (especially need sodium level), CBC with differential (especially need neutrophil and platelet count); **AND**

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- Current beneficiary weight; **AND**
- Documentation of dose requested for renewal; **AND**
- Once stable, PA's may be approved 3 months at a time.

### **QUANTITY EDITS:**

60mg once weekly= 12 tablets per 28 days  
80mg once weekly= 16 tablets per 28 days  
100mg once weekly= 20 tablets per 28 days  
80mg twice weekly= 32 tablets per 28 days

### **DISCUSSION:**

Dr. Johnson asked that we reevaluate this medication in a few months due to high drop-out rate and worse overall survival rate in one study. FDA had voted 8-5 against approving this medication preferring to see Phase III data. Phase III is ongoing with concomitant bortezomib. Overall survival has not been measured in STORM study. FDA approved when positive response was seen with concomitant use of bortezomib. Dr. Johnson stated that based on the data, bortezomib and dexamethasone used concomitantly with this medication may need to be a criteria. Chair stated that we should hold off for now since this combination is not in treatment guidelines. The combination may be added as criteria in the future when more data and FDA input is provided. Dr. Mancino asked if bortezomib would need to be required if patient is allergic to dexamethasone. Chair stated each request would be reviewed on a case-by-case basis, and that requirement should not be added to the criteria at this time. Trial data will continue to be monitored, and this medication will be brought back to the Board if recommendations/indications change.

### **ACTION:**

Motion to approve as written made by Dr. Miller; seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

#### **4) Iressa® (gefitinib) 250mg tablet**

**This medication was FDA approved in July 2015, but the DUR Board never developed criteria.**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

**\* Denotes pulled from clinical trial NCT00770588**

#### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary has diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations; **AND**
- Verify if beneficiary takes strong CYP3A4 inducers since requires higher dose (e.g., rifampicin, phenytoin or tricyclic antidepressant); **AND**
- Verify if beneficiary requires proton pump inhibitors due to decrease plasma concentration of Iressa®; **AND**
- Beneficiary should not be pregnant or breastfeeding; **AND**
- ECOG score ≤ 2; **AND**
- Provide beneficiary's current chart notes; **AND**
- Provide beneficiary's current labs including CBC and LFTs; **AND**
- Initial PA duration decided on a case-by-case basis

### **DENIAL CRITERIA:**

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- Beneficiary does not meet approval criteria; **OR**
- Beneficiary has EGFR mutation other than exon 19 deletions or exon 21 (L858R) substitution mutations; **OR**
- Beneficiary is pregnant and/or breastfeeding; **OR**
- Beneficiary has confirmed diagnosis of interstitial lung disease; **OR**
- Beneficiary has confirmed gastrointestinal perforation; **OR**
- Beneficiary has severe hepatic impairment; **OR**
- Beneficiary has persistent ulcerative keratitis; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Beneficiary has concomitant proton pump inhibitor usage; **OR**
- Beneficiary has severe bullous blistering or exfoliating conditions or has a history of toxic epidermal necrolysis, Stevens Johnson syndrome or erythema multiforme

### **CONTINUATION CRITERIA:**

- Beneficiary has not progressed or had intolerable toxicity; **AND**
- Provider must submit current chart notes and labs; **AND**
- Provider must submit documentation that beneficiary does not have a denial criteria

### **QUANTITY EDITS:**

#30 per 30 days

### **DISCUSSION:**

No comments

### **ACTION:**

Motion to approve as written was made by Dr. Johnson; seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

### **5) Nubeqa™ (darolutamide) 300mg tablet**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

✳ *Denotes pulled from clinical trial NCT02200614 (ARAMIS)*

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case; **AND**
- Must be ≥ 18 years of age; **AND**
- Beneficiary must have the diagnosis of non-metastatic castration-resistant prostate cancer; **AND**
- Provider must submit current chart notes with documentation of previous treatment history; **AND**
- Provider must submit current labs including CBCs, LFTs, renal function, testosterone level, PSA; **AND**
- Beneficiary must also receive a gonadotropin-releasing hormone analog concurrently or have had a bilateral orchiectomy (provide this documentation); **AND**
- Documentation of castrate level of serum testosterone ✳; **AND**
- ECOG score ≤ 2; **AND**
- Prostate-specific antigen doubling time of ≤ 10 months AND PSA > 2ng/ml ✳; **AND**
- Following labs values required ✳; **AND**
  - Hemoglobin ≥ 9.0 g/dl
  - Absolute neutrophil count ≥ 1500/μl
  - Platelet count ≥ 100,000/μl
  - ALT and/or AST ≤ 2.5 x ULN
  - Total bilirubin ≤ 1.5 x ULN
  - Creatinine ≤ 2.0 x ULN
- Provider must attest to counseling sexually active patients that are not surgically sterile

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- to use condoms
- PA's may be approved for 3 months at a time

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; **OR**
- History of metastatic disease\*; **OR**
- History of the following in the last 6 months: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, CHF NYHA class III or IV\*; **OR**
- Beneficiary is currently taking P-gp and strong or moderate CYP3A4 inducers (rifampicin) due to decreased Nubeqa™ levels; **OR**
- Severe renal impairment and moderate hepatic impairment require dose decreases

### **CONTINUATION CRITERIA:**

- Beneficiary is compliant on Nubeqa™ and GnRH analog; **AND**
- Provide current chart notes and previously requested labs; **AND**
- PSA levels remain stable

### **QUANTITY EDITS:**

#120 per 30 days

### **DISCUSSION:**

Chair asked for comments on requiring specific lab values. Dr. Johnson recommended keeping the requirement of PSA doubling time of  $\leq 10$  months but remove the specific lab values listed in the clinical trials. Dr. Podrazik stated we should be following labs, but we should not use specific labs as approval criteria.

### **ACTION:**

Motion by Dr. Johnson to approve suggested criteria with amendment of removing required specific lab values; seconded by Dr. Boone. All members present voted for the motion. Motion passed.

### **6) Turalio™ (pexidartinib) 200mg capsule**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

\* Denotes pulled from clinical trial NCT02371369 (ENLIVEN)

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case; **AND**
- Must be  $\geq 18$  years of age; **AND**
- Beneficiary has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS)) associated with severe morbidity or functional limitations and not amenable to improvement with surgery; **AND**
- Provide documentation that provider and beneficiary are enrolled in REMS program; **AND**
- Beneficiary should not be pregnant or breastfeeding; **AND**
- Provide beneficiary's current chart notes with description of current range of motion and treatment history (if applicable); **AND**
- Provide MRI results confirming diagnosis; **AND**
- Provide the medical necessity of Turalio™ over surgery and/or radiation; **AND**
- Provide the following labs:
  - LFTs including ALT/AST, ALP, GGT and bilirubin (labs monitored weekly for first 8 weeks, every 2 weeks for the next month and every 3 months thereafter); **AND**
  - Renal function including serum creatinine and BUN; **AND**
  - CBC with differential; **AND**

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- Documentation of stable prescription of analgesic regimen for at least 2 weeks with continued pain and mobility difficulties ✱; **AND**
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; **AND**
- PA's approved month-to-month for at least first 3 months to monitor labs

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**
- Discontinue if cannot tolerate dose of 200mg twice daily; **OR**
- Adequate hematologic, hepatic and renal function required ✱; **OR**
  - Absolute neutrophil count  $\geq 1.5 \times 10^9/L$
  - Aspartate aminotransferase/alanine aminotransferase (AST/ALT)  $\leq 1.5 \times$  upper limit of normal (ULN)
  - Hemoglobin  $> 10$  g/dL
  - Total bilirubin  $\leq 1.5 \times$  ULN
  - Platelet count  $\geq 100 \times 10^9/L$
  - Serum creatinine  $\leq 1.5 \times$  ULN
- Discontinue if the following:
  - ALT and/or AST  $>10 \times$  ULN
  - ALP and GGT  $>2 \times$  ULN
  - Total bilirubin  $\geq 2 \times$  ULN or Direct bilirubin  $>1.5 \times$  ULN
- Concomitant use of proton pump inhibitors; **OR**
- Concomitant use of strong CYP3A inhibitor (e.g., itraconazole) or uridine diphosphoglucuronosyltransferase (UGT) inhibitor (e.g., probenecid)—if unavoidable, reduce Turalio™ dose; **OR**
- Provider or beneficiary are not enrolled in the REMS program; **OR**
- Active or chronic infection with hepatitis C virus, hepatitis B virus or human immunodeficiency virus ✱

### **CONTINUATION CRITERIA:**

- Beneficiary is compliant on therapy; **AND**
- Provide current chart notes; **AND**
- Provide current labs including LFTs, CBC with differential and renal function; **AND**
- Labs must fall within manufacturer's guidelines for renewal; **AND**
- Provide documentation of response to therapy with decrease in tumor size and/or documentation of improvement in range of motion

### **QUANTITY EDITS:**

#120 per 30 days

### **DISCUSSION:**

Chair suggested the specific inclusion labs be removed. Dr. Mancino agreed and should not require specific labs for approval but monitor liver function. Dr. Boone asked what analgesics would be required prior to approval and asked if approval required previous prescription or just documentation if OTC NSAIDs. Dr. King asked if physical therapy would be a requirement. Chair stated that we could ask for that documentation, but TGCT would not resolve with PT. Dr. Brazeal stated that treatment options were surgery, PT, and analgesia with opioids, anti-inflammatories or steroids. Dr. Neuhofer and Dr. Mancino added to request documentation of PT or documentation why PT was not being done. Dr. Johnson and Dr. Podrazik were reviewing data for risk vs. benefit. Dr. Johnson reviewed the liver toxicity data. Data available does not appear to be severely hepatotoxic and efficacy looks promising but not

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conclusive. Dr. Johnson suggests that if approved, reevaluate at some point to determine if patient may be eligible for surgery.

### **ACTION:**

Motion was made by Dr. Mancino to approve suggested criteria with amendments for removing requirement of specific lab values, add documentation of PT, continuation requires reevaluation of surgery eligibility, and clarification of analgesic therapies; seconded by Dr. King. All members present voted for the motion. Motion passed.

### **7) Inrebic® (fedratinib hydrochloride) 100mg capsule**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

✳ *Denotes pulled from clinical trial NCT01437787 (JAKARTA)*

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Must be  $\geq 18$  years of age; **AND**
- Beneficiary has a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF); **AND**
- Provide the following baseline labs:
  - Thiamine (Vitamin B1)
  - CBC with platelets
  - Creatinine and BUN
  - Hepatic panel
  - Amylase and lipase; **AND**
- Beneficiary must have thiamine deficiencies corrected prior to initiating Inrebic®; **AND**
  - The labs should have the following values before initiation of therapy ✳:
    - Absolute Neutrophil Count (ANC)  $\geq 1.0 \times 10^9/L$
    - Platelet count  $\geq 50 \times 10^9/L$
    - Serum creatinine  $\leq 1.5 \times$  Upper Limit of Normal (ULN)
    - Serum amylase and lipase  $\leq 1.5 \times$  ULN
    - AST or ALT  $< 2.5 \times$  ULN
    - Total bilirubin  $< 3.0 \times$  ULN; **AND**
- Beneficiary has an enlarged spleen, palpable at least 5 cm below costal margin ✳; **AND** (Do we require a baseline CT or MRI report?)
- ECOG score  $\leq 2$  ✳; **AND**
- Beneficiary must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant of hydroxyurea; **AND**
- Beneficiary must taper off ruxolitinib prior to initiating Inrebic®; **AND**
- Provider must reduce Inrebic® dose to 200mg once daily if beneficiary has severe renal impairment (CrCl 15mL/min to 29mL/min); **AND**
- Initial PA will be for the specific strength required for dose; approval time will be for 1 month.

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; **OR**
- Beneficiary has a platelet count  $< 50 \times 10^9/L$ ; **OR**



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- Beneficiary has thiamine deficiency; **OR**
- Beneficiary has signs of Wernicke's encephalopathy (ataxia, mental status changes and ophthalmoplegia); **OR**
- Beneficiary has had a splenectomy; **OR**
- Beneficiary has previous history of chronic liver disease; **OR**
- Beneficiary does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; **OR**
- Continued use of strong and moderate CYP3A4 inducers; **OR**
- Continued use with dual CYP3A4 and CYP2C19 inhibitors; **OR**
- Beneficiary unable to tolerate 200mg daily dose

### **CONTINUATION CRITERIA:**

- Beneficiary must be compliant on therapy; **AND**
- Current chart notes and updated labs (including thiamine, CBC with platelets, creatinine and BUN, hepatic panel and amylase/lipase) must be provided; **AND**
- Labs must follow manufacturer's dosing recommendations; **AND**
- Beneficiary must show positive response to Inrebic® by spleen size reduction (Do we require CT or MRI?) or symptom improvement within 6 months of therapy;

### **QUANTITY EDITS:**

#120 per 30 days

### **DISCUSSION:**

Chair suggested that the specific lab value requirements be removed but continue to review the labs for appropriateness. Chair asked for guidance regarding the requirement of a CT or MRI for evaluating the spleen or require palpation only. Dr. Miller suggested that we do not require a CT or MRI. Chair asked the Board if they approve of leaving the Hydroxyurea requirement. The members did not request to change this criteria. Dr. Johnson asked if we could require trial and failure of ruxolitinib. Ruxolitinib has overall survival data, and fedratinib does not at this point. Also Ruxolitinib does not have the adverse effect of Wernicke's encephalopathy and is currently less expensive.

### **ACTION:**

Motion was made by Dr. Johnson to approve the suggested criteria with amendments for removing requirement of specific lab values, removing requirement of CT or MRI, and require a trial of ruxolitinib prior to this medication; seconded by Dr. Podrazik. All members present voted for the motion. Motion passed.

### **8) Nucala® (mepolizumab) 100mg/mL syringe/autoinjector**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

**\* Denotes pulled from clinical trials NCT01000506, NCT01691521, NCT01391508 and NCT02020889**

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; **AND**
- Provide the following documentation for review:
  - Current chart notes
  - Documentation of previous therapies tried with response
  - Baseline blood eosinophilic count

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- Baseline Asthma Control Questionnaire (ACQ-5) OR Asthma Quality of Life Questionnaire (AQLQ) scores (adults only)—For asthma patients
- Current Pulmonary Function Test (PFT) results; **AND**
- No therapeutic duplication with any Interleukins (daclizumab, mepolizumab, or others new to the market) or omalizumab; **AND**

### Criteria specific to Eosinophilic granulomatosis with polyangiitis (EGPA)

- Beneficiary must be ≥18 years of age. (If the indicated ages change, the criteria will reflect that change); **AND**
- Beneficiary must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia (>1.0x10<sup>9</sup>/Liter and/or >10% of leucocytes) \*; **AND**
- Beneficiary has a history of relapsing OR refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids \*; **AND**
- Beneficiary must be on a stable dose of oral prednisolone or prednisone of ≥7.5 mg/day for at least four (4) weeks \*; **AND**
- If beneficiary is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four (4) weeks \*; **AND**
- Provide current liver function tests (if on methotrexate, azathioprine)\*; **AND**
- Medical necessity over corticosteroids and/or immunosuppressive therapy

### Criteria specific to Asthma:

- Beneficiary must be ≥12 years of age (If the indicated ages change, the criteria will reflect the change); **AND**
- Beneficiary must be diagnosed with severe asthma with a history of 2 or more exacerbations in the previous year \*; **AND**
- Beneficiary must be compliant on at least two (2) asthma maintenance medications for at least one (1) year (one must be an inhaled corticosteroid) \*; **AND**
- Blood eosinophil count must be ≥ 150 cells/μL (one trial ≥300 cells/μL) \*; **AND**
- Pre-bronchodilator FEV1 <80% predicted \*; **AND**
- Provide the medical necessity over the use of omalizumab (Xolair®)

### DENIAL CRITERIA:

- Beneficiary does not meet approval criteria; **OR**
- For asthma patients—noncompliance with two (2) asthma maintenance medications for at least 1 year including inhaled corticosteroid; **OR**
- For EGPA patients—not on a stable oral corticosteroid dose for at least four (4) weeks and/or does not have a history of relapse or refractory disease; **OR**
- Current smoker; **OR**
- Beneficiary takes other Interleukins; **OR**
- Beneficiary has life-threatening EGPA \*; **OR**
  - Severe alveolar hemorrhage or hemoptysis requiring transfusion or ventilation, or hemoglobin is <8 g/dL
  - Rapidly progressive glomerulonephritis with creatinine >2.5mg/dL
  - Severe cardiac involvement including life-threatening arrhythmia, LVEF <20%, NUHA Class III/IV or acute myocardial infarction
- Beneficiary has unstable liver disease with presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, varices or cirrhosis (no mention of liver issues in PI) \*
  - ALT ≥ 2 X ULN (≥ 3 X ULN if on methotrexate or azathioprine)
  - AST ≥ 2 X ULN (≥ 3 X ULN if on methotrexate or azathioprine)
  - Alkaline Phosphatase >2 X ULN

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- Bilirubin > 1.5 X ULN

### **CONTINUATION CRITERIA:**

- Beneficiary must be compliant on injections and maintenance asthma medications; **AND**
- Provide current chart notes with documentation of response to therapy; **AND**
- Provide current PFTs—must see improvement in FEV<sub>1</sub> over baseline; **AND**
- Beneficiary must show fewer exacerbations requiring hospitalization and/or emergency department visits; **AND**
- Beneficiary must have a decrease in blood eosinophil count; **AND**
- Beneficiary must have a decrease in oral steroid usage

**QUANTITY EDITS:** #3 prefilled syringes/autoinjectors per 28 days

### **DISCUSSION:**

Chair stated that the Xolair criteria, Dupixent criteria and GINA guidelines were used. Chair stated that response to Nucala may take quite some time before results are seen. Dr. Boone suggested that if approved, PAs should be for 6 months then reevaluation. Dr. Boone suggested requiring a response to therapy for continuation. Dr. Podrazik asked if the other Interleukin products had similar results.

### **ACTION:**

Motion made by Dr. Mancino to approve suggested criteria with the amendment of response to therapy after 6 months; seconded by Dr. Bemberg. All members present voted for the motion. Motion passed.

### **9) Baqsimi™ 3mg (glucagon) powder**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

**\*Denotes pulled from clinical trial NCT03339453, NCT01994746 and NCT01997411**

### **APPROVAL CRITERIA:**

- Must be ≥ 4 years of age; **AND**
- Must have a diagnosis of Diabetes Mellitus; **AND**
- Provider must submit current chart notes; **AND**
- Beneficiary must require daily insulin use; **AND**
- Provider must submit glucose diary for the last 3 months; **AND**
- Provider a letter of medical necessity for Baqsimi™ over Glucagon injection

### **DENIAL CRITERIA:**

- Beneficiary does not have Diabetes Mellitus; **OR**
- Beneficiary is not receiving daily insulin \*; **OR**
- Beneficiary has a history of pheochromocytoma; **OR**
- Beneficiary has a history of insulinoma; **OR**
- Beneficiary uses daily systemic beta-blocker, indomethacin, warfarin or anticholinergic drugs \*
  - *Beta-blockers:* Patients taking beta-blockers may have a transient increase in pulse and blood pressure.
  - *Indomethacin:* In patients taking indomethacin, Baqsimi™ may lose its ability to raise glucose or may produce hypoglycemia.
  - *Warfarin:* Baqsimi™ may increase the anticoagulant effect of warfarin.

**CONTINUATION CRITERIA: ?**

**QUANTITY EDITS: ?**

**DISCUSSION:**

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Dr. Johnson and Dr. Podrazik suggested to remove the denial criteria concerning drug interactions. Dr. King stated his concern for the use of the injection in children per his experience at ACH. Parents find the injection overwhelming. No continuation criteria or quantity edits implemented.

### **ACTION:**

Motion made by Dr. Miller to approve suggested criteria with the amendment to remove the denial criteria for drug interaction; seconded by Dr. Johnson. All members present voted for the motion. Motion passed.

### **10) Rozlytrek™ (entrectinib) 100mg and 200mg capsules**

Chair discussed via a PowerPoint presentation Medicaid estimated reimbursement rates, indication, dosing, dosing modifications, guidelines and suggested criteria.

### **SUGGESTED CRITERIA:**

**\* Denotes pulled from clinical trial NCT02097810 (STARTRK-1) AND NCT02568267 (STARTRK-2)**

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case; **AND**
- Must be  $\geq 18$  years of age for NSCLC diagnosis and  $\geq 12$  years of age for Solid Tumors diagnosis; **AND**
- Beneficiary must have a diagnosis of either ROS1-Positive Non-Small Cell Lung Cancer **OR** neurotrophic receptor tyrosine kinase (NTRK) Gene Fusion-Positive Solid Tumors (sarcoma, lung cancer, salivary gland tumor, secretory breast cancer, thyroid cancer and colorectal cancer); **AND**
- Beneficiaries with diagnosis of NTRK Gene Fusion-Positive Solid Tumors must have one of the following:
  - have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
  - are metastatic or where surgical resection is likely to result in severe morbidity,
  - have either progressed following treatment or have no satisfactory alternative therapy.
- Provider must submit histologically or cytologically confirmed diagnosis of NTRK1, NTRK2, NTRK3, ROS1 or ALK molecular alteration by using tests such as, next generation sequencing (NGS) or fluorescence in situ hybridization (FISH) \*; **AND**
- ECOG  $\leq 2$  \*; **AND**
- Provider must submit current chart notes and documentation of previous treatment (if applicable); **AND**
- Provide current body surface area (BSA) for pediatric patients to adequately verify dosing; **AND**
- Provide current labs including: **AND**
  - Liver Function Tests (LFTs) (monitor every 2 weeks for first month, then monthly)
  - Baseline serum uric acid levels (monitor periodically)
  - Complete Blood Count (CBC) with differential
  - Basic Metabolic Panel (BMP)
- Provide ECG baseline with documentation of QTcF; **AND**
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; **AND**
- Initial PA approve 1 month to monitor for adverse reactions

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria
- Beneficiary has symptomatic CHF, myocardial infarction, unstable angina, or coronary artery bypass graft within 3 months \*; **OR**
- LVEF  $\leq 50\%$  \*; **OR**
- Beneficiary has a history of prolonged QTc interval with repeated values  $> 450\text{ms}$  \*; **OR**
- Beneficiary has risk factors for torsade de pointes \*; **OR**
- Beneficiary has known interstitial lung disease, interstitial fibrosis or history of tyrosine kinase inhibitor-induced pneumonitis \*; **OR**
- Beneficiary has a diagnosis of torsade de pointes, polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia; **OR**
- Beneficiary is pregnant or breastfeeding; **OR**

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- Beneficiary has hepatotoxicity with ALT or AST >3 X ULN with concurrent total bilirubin >1.5 X ULN (in absence of cholestasis or hemolysis); **OR**
- Beneficiary has Grade 4 central nervous system effects; **OR**
- Beneficiary requires moderate or strong CYP3A inhibitors. If requires coadministration, reduce Rozlytrek™ dose and provide documentation of monitoring adverse reactions; **OR**
- Beneficiary requires moderate or strong CYP3A4 inducers as Rozlytrek™ plasma concentrations are decreased; **OR**
- Beneficiary requires another medication that can prolong QT/QTc intervals; **OR**

### **CONTINUATION CRITERIA:**

- Beneficiary is compliant with therapy; **AND**
- Beneficiary has adverse reactions within recommended dosing parameters; **AND**
- Provider must submit current chart notes with response to therapy with tolerability; **AND**
- Provide current labs including LFTs, serum uric acid levels if indicated, CBC with differential and BMP

### **QUANTITY EDITS:**

100mg capsules -- #30 per 30 days

200mg capsules -- #90 per 30 days

### **DISCUSSION:**

Dr. Mancino raised concern of denying for QTc interval values >450ms. Dr. Podrazik confirmed that many patients have a normal QTc interval above this level especially in elderly.

### **ACTION:**

Motion made by Dr. Mancino to approve suggested criteria with the amendment to remove the denial criteria concerning QT interval; seconded by Dr. Podrazik. All members present voted for the motion. Motion passed.

## **C. PROPOSED NEW CLAIM EDITS**

None

## **D. ProDUR Report**

Dr. Evans did not present a ProDUR report during this meeting as data from the PASSEs skewed the numbers generating incorrect reporting. Reporting strategies will be updated for the next meeting.

## **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.

- Criteria recommendations for May 2019—motion by Dr. Mancino; all approved
- Criteria recommendations for June 2019—motion by Dr. Mancino; all approved
- Criteria recommendations for July 2019—motion by Dr. Mancino; all approved
- Criteria revisions 2Q19—motion by Dr. Mancino; all approved
- RetroDUR Quarterly Summary report 1Q19

## **F. Meeting adjourned at 11:58am.**