

Arkansas Medicaid DUR Board Meeting Minutes

DUR Board Meeting
January 15, 2020
Department of Human Services
Donaghey Plaza South
700 Main Street
Little Rock, AR 72201
Conference Room A

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.

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
Annette Jones, B.S.
Michael Munnerlyn, MBA
Jordan Brazeal, Pharm. D. (RDUR—HID)
Lynn Boudreaux, Pharm. D. (Magellan)

Board Members and Others Absent

Cynthia Neuhofel, Pharm. D.
Karen Evans, P.D. (ProDUR—Magellan)
Lana Gettman, Pharm. D.
1 pharmacist vacancy
1 physician vacancy (oncologist)

Meeting held in Conference Room A of the Department of Human Services Donaghey Plaza South Building at 700 Main Street in Little Rock, Arkansas. A quorum was present, and the chair called the meeting to order at 8:35am.

I. SPEAKERS

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

Trikafta™ (Joseph Truong Pharm. D. with Vertex); Oxbryta™ (Laura Pridgen, PhD from Global Blood Therapeutics); Nayzilam® (Brenda Wood, Pharm. D. from UCB) and Ofev® (Michael Horton, Pharm. D. from Boehringer-Ingelheim). Public comments in the form of letters were provided to the Board members prior to the meeting. Board members asked for a demonstration and utilization information for the Nayzilam® nasal spray.

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) Introduction of Magellan pharmacist, Christina Drummond, Pharm. D.
- 3) Chair announced that we are still needing a pharmacist and an oncologist to fill vacant seats on the Board.
- 4) Update on meeting location

B. REVIEW MINUTES FROM THE OCTOBER 2019 QUARTERLY MEETING

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

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 October 2019 Board meeting

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2) IMPLEMENTATION INFORMATION FORM OCTOBER 16, 2019 DUR BOARD MEETING AND NOVEMBER 13, 2019 DRC MEETING

Preferred Drug List changes were effective January 1, 2020; DUR PA manual review drugs were effective immediately; Therapeutic duplication edits for Truvada®, Descovy®, Viread® and Emtriva® will be effective April 1, 2020.

3) LAB INTEGRATION

Chair informed the Board that Magellan now has lab integration technology which enables the prior authorization reviewing pharmacist to view lab work submitted by LabCorp and Quest Diagnostics. Access to lab data allows point-of-sale criteria to be implemented based on lab values.

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

1) Entresto® (sacubitril and valsartan) tablets

This medication was previously reviewed by the Arkansas Medicaid DUR Board in October 2015 and July 2016.

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

CRITERIA CHANGE:

- Remove manual review status and change status to preferred with criteria
- Make point-of-sale (POS) approval criteria
 - Diagnosis in Medicaid medical history in previous 2 years of congestive heart failure; **AND**
 - Recipient not pregnant meeting **BOTH** criteria below:
 - No billed diagnosis in Medicaid medical history of a pregnancy in the last 9 months; **AND**
 - No positive pregnancy test results billed in lab values in the last 9 months

**If a pregnancy diagnosis is billed or a positive lab test is billed in the last 9 months, the system will look further for a delivery. If the recipient has delivered a baby and is no longer pregnant, the claim will process without a PA. If there is no indication of delivery, the claim will deny at POS and require a PA request to be submitted. **

DISCUSSION:

Dr. Podrazik asked if PA's are currently being submitted exclusively by cardiologists. Chair affirmed that most requests are received from cardiologists but not all. Dr. Boudreaux commented that most of initial requests come from the cardiologists and some continuation come from PCP. Dr. Johnson asked if there was a way to prevent an overlap of ACEI/ARBs with Entresto. Chair stated that there is a therapeutic duplication edit in place to prevent concomitant use.

ACTION:

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

2) Sensipar® (cinacalcet hydrochloride) 30mg, 60mg and 90mg tablet

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

SUGGESTED CRITERIA: (Highlighted includes the changes to current criteria)

APPROVAL CRITERIA:

Criterion 1: POS PA approval criteria for Treatment of Secondary Hyperparathyroidism (HPT) In Adult Patients with Chronic Kidney Disease (CKD) On Dialysis,

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- Diagnosis in Medicaid medical history in previous 2 years of BOTH diagnoses codes for:
 - “Secondary HPT of renal origin” (ICD-10 code N25.81),
AND
 - “ESRD CKD requiring Chronic Dialysis” (ICD-10 code N18.6 or Z99.2).

Manual review PA will be on a case-by-case basis if either diagnoses code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

UPDATED Criterion 2: POS PA approval criteria for Treatment of Hypercalcemia in Adult Patients with Parathyroid Carcinoma.

- Diagnosis in Medicaid medical history in previous 2 years diagnosis code for:
 - “Cancer of the parathyroid gland” (ICD-10 code C75.0)
AND
 - Diagnosis in Medicaid medical history in previous 2 years for: “Hypercalcemia” (ICD-10 code E83.52)
OR
 - Hypercalcemia Level with calcium >10 mg/dL

Manual review PA will be on a case-by-case basis if cancer diagnosis or documentation of hypercalcemia is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

UPDATED Criterion 3: POS approval criteria for Treatment of Hypercalcemia in Adult Patients with primary HPT for whom parathyroidectomy would be indicated based on serum calcium levels, but who are unable to undergo parathyroidectomy:

- Absence of a Parathyroidectomy in the Patient’s Medical History
- NO Procedure Code for **Parathyroidectomy** in the past 2 years: (ICD-10 code Z90.89)
AND
 - Diagnosis in Medicaid medical history in previous 2 years for: “Hypercalcemia” (ICD-10 code E83.52)
OR
 - Hypercalcemia Level with calcium >10 mg/dL

Manual review PA will be on a case-by-case basis if above criteria is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

DISCUSSION:

Dr. Mancino asked if there was a timeframe on the lab. Chair stated there would be a 30 day look back timeframe. Chair stated that lab updates take a week to load into Magellan system. Chair added the 30 days look back to the criteria.

ACTION:

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

3) Erythropoiesis Stimulating Agents

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

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Chair stated that this change would not include Aranesp® or Mircera® as these products are nonpreferred and would continue to require a PA. Epogen® and Procrit® would be impacted by this POS lab integration.

APPROVAL CRITERIA:

- Remove manual review status and change status to preferred with criteria.
- System reviews labs in the past 30 days for Hemoglobin level. If Hgb level is ≤ 10 g/dL, a claim will process at POS without a PA.

DISCUSSION:

Dr. Johnson asked if the system would be looking for anything else, such as indication. Chair stated that was discussed but would not be implemented at this time. Dr. Johnson doesn't see utilization changing much as the population she deals with gets while in clinic for dialysis as a medical bill.

ACTION:

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

4) Idiopathic Pulmonary Fibrosis Agents

These products were last reviewed by the DUR Board in July 2017.

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

a. Esbriet® (pirfenidone) 267mg capsule

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- Must be at least 18 years of age; **AND**
- Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung; **AND**
- Must be a non-smoker and prescriber must submit documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6 ppm, carboxyhemoglobin (COHb) levels of $<3\%$ OR urine cotinine concentration <200 ng/mL; **AND**
- Must not be pregnant; **AND**
- Prescriber must submit the following
 - Current chart notes with current weight
 - Specific dose requested (PA entered based on specific dose)
 - IPF staging classification
 - Liver Function Tests (LFTs)
 - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of $\geq 50\%$ and carbon monoxide diffusing capacity (%DLCO) of $\geq 35\%$
 - Results of high resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
 - Results of 6-minute walk test (6MWT) at baseline
 - Specific measurable goals for treatment outcomes

DENIAL CRITERIA:

- Does not meet approval criteria; **OR**
- Pregnant or breastfeeding; **OR**
- Currently smoking; **OR**

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- Received lung transplant; **OR**
- Recent MI or stroke; **OR**
- Elevated liver enzymes with ALT and/or AST >3 X ULN with symptoms or hyperbilirubinemia OR ALT or AST >5 X ULN; **OR**
- Child Pugh C or ESRD; **OR**
- Requested dose >2403mg per day; **OR**
- Requested dose >801mg per day if taking concomitant strong CYP1A2 inhibitor; **OR**
- Requested dose >1602mg per day if taking concomitant moderate CYP1A2 inhibitor

CONTINUATION CRITERIA:

- Compliance on prescribed dose will be monitored; **AND**
- Patient should have a positive response to the use for continuation (i.e. improved PFTs or 6MWT); **AND**
- Prescriber should submit the requested dose along with the following for documentation of response to therapy:
 - Current chart notes with current weight
 - Current LFTs
 - Current PFTs
 - Current 6MWT
 - Current documentation of smoking status with either eCO, COHb or urine cotinine concentration
 - Dose requested (PA entered based on specific dose)

QUANTITY EDITS:

267mg--#279/31 days

801mg--#93/31 days

DISCUSSION:

Dr. Miller asked for utilization information. Dr. Brazeal noted that in the last year there were 2 claims for Ofev® and no claims for Esbriet®. Chair asked for input on specific improvement requirements on continuation. Dr. Mancino asked about results from the clinical trials. Dr. Podrazik asked who is referring these patients, assume pulmonologists. Chair recommended not to place specific improvement requirements on continuation given the natural decline of this disease. But if the patient has a rapid decline, then the medical necessity would need to be questioned.

ACTION:

Motion to approve criteria as written with minor change to remove specific continuation numbers made by Dr. Bemberg, seconded by Dr. Mancino. All members present voted in favor of the motion. Motion passed.

b. Ofev® (nintedanib) 100mg and 150mg capsules

SUGGESTED CRITERIA

APPROVAL CRITERIA: (No longer requires previous trial of Esbriet®)

- Manual review on a case-by-case basis; AND
- Must be at least 18 years of age; AND
- Must have one of the FDA approved indications—Idiopathic Pulmonary Fibrosis (IPF) or Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD); AND
- Must be a non-smoker; AND
- Must not be pregnant (provide pregnancy test results when applicable); AND
- Prescriber must submit the following for IPF patients; AND
 - Current chart notes
 - Specific dose requested (PA entered based on specific dose)
 - Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung
 - IPF staging classification

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- Liver Function Tests (LFTs)
- Documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL
- Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥50% and carbon monoxide diffusing capacity (%DLCO) 30%-79% of predicted
- Results of high resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
- Results of 6-minute walk test (6MWT) at baseline
- Specific measurable goals for treatment outcomes
- Prescriber must submit the following for SSC-ILD patients; AND
 - Current chart notes
 - Specific dose requested (PA entered base on specific dose)
 - Chest high resolution computed tomography (HRCT) scan within the last 12 months with ≥10% fibrosis
 - Liver Function Tests (LFTs)
 - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥40% and carbon monoxide diffusing capacity (%DLCO) 30%-89% of predicted
 - Medical necessity over immunosuppressant therapy
 - Results of 6-minute walk test (6MWT) at baseline
 - Specific measurable goals for treatment outcomes

DENIAL CRITERIA:

- Does not meet approval criteria; OR
- Lung transplant; OR
- Pregnant or breastfeeding; OR
- Currently smoking; OR
- Elevated LFTs with ALT, AST or bilirubin >1.5 X ULN; OR
- Child Pugh B or C OR ESRD; OR
- Severe diarrhea, nausea or vomiting despite symptomatic treatment; OR
- Gastrointestinal perforation; OR
- Patient cannot tolerate minimum dose of 100mg twice daily

CONTINUATION CRITERIA:

- Compliance on prescribed dose will be monitored; AND
- Patient should have a positive response to the use for continuation; AND
- Prescriber should submit the requested dose along with the following for documentation of response to therapy:
 - Current chart notes with current weight
 - Current LFTs
 - Current PFTs
 - Current 6MWT
 - Current documentation of smoking status with either eCO, COHb or urine cotinine concentration
 - Dose requested (PA entered based on specific dose)

QUANTITY EDITS:

100mg--#62/31 days

150mg--#62/31 days

DISCUSSION:

Dr. Johnson asked for rationale for removing trial/failure of Esbriet. Chair stated that the clinical information available makes the two products similar in efficacy. Dr. Mancino asked if the cost was similar. The chair confirmed. Dr. Johnson stated that data from 2016 and 2017 indicates better improvement of mortality with Esbriet, but there is no difference in FEV between the two agents.

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ACTION:

Motion to approve criteria as written with minor change to remove specific continuation numbers made by Dr. Johnson, seconded by Dr. Boone. All members present voted in favor of the motion. Motion passed.

5) Asthma Criteria Based on GINA Guidelines

SUGGESTED CHANGE to CRITERIA:

Based on the updated GINA report with ICS or ICS-LABA as Step 1 of treatment, we recommend removing criterion 3 from the current asthma criteria. This would allow ICS-LABA claims to process without previous ICS or oral steroids on file. And we suggested to add an asthma diagnosis billed in the last 2 years as criterion 3.

DISCUSSION:

Dr. Magee stated this recommendation with suggested changes was for patients 12 years of age and older. Removing the original criterion 3 would be a concern for patients <12 years of age. Also, he stated that this would allow the use of a salmeterol product with review which is not supported in the GINA report. Dr. Boudreaux stated that changes can be put in place in the Magellan system to account for the above recommendations. Dr. Magee further stated that the GINA report specifically points out the budesonide/formoterol product as the agent of choice. Dr. Boudreaux stated it would take writing a rule and testing for this change. Dr. Magee wants to leave the old criterion 3 in place for patients <12 years per the GINA report and allow Symbicort without a PA for patients 12 and older. Dr. Boudreaux asked about Dulera. Chair Stated that most places in the report list ICS-formoterol, but the charts list that there is data only for budesonide/formoterol.

ACTION:

Motion to approve criteria as amended was made by Dr. Magee, seconded by Dr. King. 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. Temodar® (temozolomide) 5mg, 20mg, 100mg, 140mg, 180mg and 250mg capsule

SUGGESTED CRITERIA

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; **AND**
- ≥ 18 years of age; **AND**
- Diagnosis consistent with the FDA approved; **AND**
- With diagnosis of Glioblastoma Multiforme, beneficiary must also receive radiotherapy in the initial treatment phase “Concomitant Phase”; **AND**
- Provide current chart notes; **AND**
- Provide current labs including CBC with differential and liver function tests; **AND**
 - Absolute Neutrophil Count ≥ 1.5 X 10⁹/L
 - Platelets ≥ 100 X 10⁹/L
 - May have mild to moderate hepatic impairment
- Provide the body surface area for dosing; **AND**
- If in concomitant phase for treatment of Glioblastoma, beneficiary must also receive *Pneumocystis pneumonia* (PCP) prophylaxis; **AND**
- Approval month-to-month due to continued monitoring of labs

DENIAL CRITERIA:

- Diagnosis not consistent with FDA approved indications; **OR**

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Beneficiary not tolerating the minimum dose of 100mg/m²; **OR**

- Pregnancy or breast-feeding; **OR**
- Severe hepatic impairment; **OR**
- ANC and platelet counts fall outside of dosing requirements; **OR**
- Drug interaction with Valproic Acid—consider medical necessity

CONTINUATION CRITERIA:

- During concomitant phase, CBCs should be drawn at initiation and weekly during treatment. During maintenance phase, CBCs should be drawn on treatment Day 1 and on Day 22 of each cycle. LFTs should be drawn at baseline, midway through first cycle, prior to each subsequent cycle and 2-4 weeks after last dose; **AND**
- Current chart notes with response to therapy; **AND**
- Current body surface area and requested dose

QUANTITY EDITS:

No quantity edits because dosed based on Body Surface Area (BSA).

DISCUSSION:

Dr. Johnson was concerned about our staff micromanaging with lab requests. She is concerned about being late approving if labs are delayed. She suggests focusing on the correct diagnosis and dosing. Dr. Mancino and Dr. Miller reiterated that he didn't want labs to delay treatment. Chair explained the rationale for wanting labs is to see the whole picture in the patient's therapy. Given the concern by the Board, the Chair suggested removing the requirement for ANC and Platelets. Since liver function affects dosing, LFTs would need to be provided.

ACTION:

Motion to approve criteria as amended was made by Dr. Johnson, seconded by Dr. Miller. All members present voted in favor of the motion. Motion passed.

2. Nourianz™ (istradefylline) 20mg and 40mg tablet

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Must be at least 18 years of age; **AND**
- Provide current chart notes; **AND**
- Provide Liver Function Tests; **AND**
- Provide smoking status with average number of cigarettes per day; **AND**
- Should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; **AND**
- Must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting NOURIANZ™; **AND**
- Must be taking at least 3 doses of levodopa per day; **AND**
- NOURIANZ™ will be used in combination with levodopa/carbidopa; **AND**
- Must be experiencing at least 2 hours of OFF time per day; **AND**
- If taking other PD medications, patient must be on a stable dose for at least 4 weeks prior to starting NOURIANZ™ (although patients can be on levodopa/carbidopa without the concomitant use of other PD medications including COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); **AND**
- Medical necessity over the increase in levodopa/carbidopa dose or changing to extended release formulations.

DENIAL CRITERIA:

- Currently taking strong CYP3A4 Inducers; **OR**
- Diagnosed with severe hepatic impairment (Child-Pugh C); **OR**
- Diagnosed with a major psychotic disorder; **OR**
- <2 hours per day of "OFF" time; **OR**

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- Atypical parkinsonism or secondary parkinsonism variants; **OR**
- Pregnant or lactating females (Women of childbearing potential should be advised to use contraception during treatment with NOURIANZ™)

CONTINUATION CRITERIA:

- Chart notes indicating the patient has responded to therapy indicated by the reduction in “off” episodes characterized by tremor, sluggish movements, and gait disturbances and an increase in “on” episodes compared to baseline; **AND**
- Chart notes monitoring for the absence of adverse effects during treatment including new or worsening dyskinesia, development of impulse control disorders, hallucinations and other symptoms of psychosis; **AND**
- NOURIANZ™ will continue to be used in combination with levodopa/carbidopa

QUANTITY EDITS:

20mg tablets #31/31 days

40mg tablets #31/31 days

DISCUSSION:

Dr. Johnson pointed out that there was some benefit by reducing “off” episodes in the clinical trials at 12 weeks, but by 52 weeks the trials indicated a loss of significance. Dr. Johnson agreed with requiring the medical necessity over increasing levodopa/carbidopa dosing. Dr. Johnson would question the medical necessity of the drug and its utility. Dr. Podrazik mentioned no long-term benefit impacting continuation if were approved. Chair stated that part of manual review would be to monitor effectiveness. Dr. Podrazik asked if there was a similar “fall off” period with Inbrija®. Dr. Johnson commented that it is a levodopa product. Chair reminded the Board that we must cover this medication since it is a rebateable outpatient drug, but we can manually review for medical necessity.

ACTION:

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

3. Egaten® (triclabendazole) 250mg tablet

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Patient must be at least 6 years old; **AND**
- The infection must be confirmed by a diagnostic or laboratory test (documented by the presence of parasite eggs in the stool or documented worm-specific antibodies in serum samples)

DENIAL CRITERIA:

- Patients with known hypersensitivity to triclabendazole or other benzimidazole derivatives; **OR**
- Pregnant or lactating females
- Fascioliasis not confirmed

CONTINUATION CRITERIA:

This drug is indicated for short-term acute use

QUANTITY EDITS:

No specific quantity limits except claim approved for 2 doses only based on weight

DISCUSSION:

Dr. Smith noted that this product has been available through the CDC for many years for IND but now FDA approved. Dr. Smith noted that is product is also an acceptable alternative in treating a rare lung fluke, paragonimiasis. The chair stated that if we received a request for this medication for the new indication, the PI and MicroMedex would be consulted. Dr. Johnson noted that currently there is no cost for this medication as it is donated by Novartis until 2022. Even though rebateable, Novartis has not released a cost, so it would not be

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payable as a pharmacy claim at this time per Dr. Boudreaux. Chair noted that we will review by the Board now. Once this product is payable, criteria voted on today will automatically be effective at that time.

ACTION:

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

4. Trikafta™ (elexacaftor, tezacaftor, and ivacaftor) kit

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Must be at least 12 years old; AND
- Must have a diagnosis of Cystic Fibrosis with the presence of mutations in both copies of the gene for the CFTR protein; AND
- Must have at least one (1) F508del mutation in the CFTR gene; AND
- Must have a mutation on the second allele that results in either no CFTR protein or a CFTR protein that is not responsive to ivacaftor (Kalydeco®) or tezacaftor/ivacaftor (Symdeko®) alone; AND
- Provide current chart notes with documentation of previous therapies; AND
- Provide current PFTs and must have forced expiratory volume in 1 second (FEV1) value $\geq 40\%$ and $\leq 90\%$ of predicted; AND
- If the beneficiary failed therapy with Kalydeco®, Orkambi® OR Symdeko® and is requesting a switch to Trikafta™, submit chart notes with documentation of failure; AND
- Beneficiary is adherent to standard of care therapies for treating CF; AND
- Baseline assessments of liver function tests (ALT, AST, and bilirubin) prior to initiating Trikafta™; AND
- For the initial PA approval and continuation reviews, the liver function lab results for ALT or AST must be less than 3 times the upper limit of normal (ULN) with bilirubin elevations less than 2 times the ULN, OR the liver function lab results for ALT or AST must be less than 5 times the upper limit of normal without bilirubin elevation; AND
- Baseline eye exams in younger patients between the age of 12 and 17 prior to initiating Trikafta™; AND
- Must be a non-smoker and prescriber must submit documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) $< 6\text{ppm}$, carboxyhemoglobin (COHb) levels of $< 3\%$ OR urine cotinine concentration $< 200\text{ng/mL}$; AND
- If has been taking another CFTR Modulator Therapy agent for less than 6 months, provide the medical necessity for changing to Trikafta™ without a sufficient trial period; AND
- If has been taking another CFTR Modulator Therapy agent and the beneficiary is stable and otherwise doing well, provide the medical necessity for changing to Trikafta™; AND
- Documentation of dosage change if requires concomitant moderate or strong CYP3A Inhibitors; AND
- Initial approval will be for 3 months. After 6 months of Trikafta™ with documentation of stabilization or improvement, PAs may be entered for 6 months.

DENIAL CRITERIA:

- Severe hepatic impairment (Child-Pugh C); OR
- Does not meet approval criteria; OR
- Beneficiary does not have diagnosis of Cystic Fibrosis (CF) with the presence of mutations in both copies of the gene for the CFTR protein; OR
- Current colonization with organisms associated with a more rapid decline in pulmonary status (i.e. *Burkholderia cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus*); OR
- < 12 years of age; OR
- Pregnancy or breastfeeding; OR
- Tobacco use; OR
- Baseline FEV1 $< 40\%$ or $> 90\%$; OR
- Concomitant use of strong CYP3A inducers

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CONTINUATION CRITERIA:

- Current chart notes with documentation of clinical response (after 6 months of treatment) and prescriber must submit documentation to substantiate the following:
 - Stabilization or improvement in lung function (FEV1);
 - Stabilization or improvement in weight gain;
 - Reduction in exacerbations/hospitalizations.
- Lab results with recent assessment of liver function tests (ALT, AST, CPK, and bilirubin) within 3 months since starting treatment (LFTs should be done every 3 months within the first year of starting Trikafta™ and then yearly afterwards); AND
- Beneficiary remains a non-smoker

QUANTITY EDITS: #84/28 days

DISCUSSION:

Dr. King asked if this is a film-coated product or extended release. The Chair referred to the Vertex Rep for confirmation. Dr. Bemberg was concerned about what happens to the lone Ivacaftor dose when a patient has hepatic impairment and asked the Vertex Rep the incidence of hepatic issues. Dr. Magee introduced Dr. Berlinski, pediatric pulmonologist at Arkansas Children's Hospital. Dr. Magee asked if the FEV1 is 39%, are we going to deny. The Chair stated that requests are reviewed on a case-by-case basis and not black and white, and we are giving our staff some guidelines for review. Dr. Magee was concerned we were micromanaging the pulmonologists, and they can just provide the PFTs. Dr. Berlinski gave some background on CF and prognosis. Dr. Berlinski made the point that he would be required to tell the patient with a FEV1 of 120% that they must lose 30% of their lung function before they can be treated with the proposed criteria. This product does not reverse the damage after exacerbations, and CF affects multiple body functions, not just lungs. He also commented that this medication decreases exacerbations, and there would be no reason to force a patient to stay on a medication that has documented improvement of 4% when this product may improve by 14%. He feels that the sickest patients (FEV1 <40%) are the ones who need it the most. Dr. Berlinski stated that diagnosing CF requires a positive sweat chloride test, not genetic testing. He suggested to use diagnosing requirements consistent with the FDA approved document. There is a new trial that will focus on withdrawing medications (Pulmozyme, Hypertonic Saline) since symptoms are improved. Dr. Boudreaux asked Dr. Berlinski if he ever takes patients off these medications if there has been no improvement. He stated he doesn't, if they remain stable he considers that a win. Chair asked the Board for a recommendation on a specific scenario including a very low FEV1 of 17%, and patient smoked marijuana. Dr. Smith stated that his current physician can fill out marijuana card. Dr. Johnson stated that this low FEV1 has not been studied, and there is no current evidence of benefit. Dr. Johnson supports the criteria for requiring adherence to standard of care therapies. Hypertonic saline is a very effective treatment for decreasing exacerbations. Dr. Magee asked if we need the fourth bullet. Dr. Podrazik asked if the proposed criteria came from FDA approval, the clinical trial or both. The chair replied both were taken into consideration. Dr. Podrazik asked if we could just use the FDA approved criteria. Dr. Magee asked that the diagnosis of CF and the presence of one F508 del mutation be sufficient. Chair stated that the proposed criteria was not obtained any differently than any other new drug on the market. Chair reiterated the Board recommendations: 1. To remove requirement for proof of second mutation 2. To remove requirement of specific FEV1 levels 3. To remove the requirement concerning previous therapy and medical necessity for this product over those others.

ACTION:

Motion to approve criteria as amended was made by Dr. Magee, seconded by Dr. Podrazik. All members present voted in favor of the motion. Motion passed.

5. FEIBA (anti-inhibitor coagulant complex) 500, 1000 and 2500-unit kit

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Diagnosis of congenital factor VIII or IX deficiency has been confirmed by blood coagulation testing; AND

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- Confirmation the patient has high Factor VIII or factor IX titer inhibitors (≥ 5 Bethesda Units); AND
- Used as treatment in at least one of the following:
 - Control and prevention of bleeding episodes; OR
 - Perioperative management; OR
 - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- Patient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy and emicizumab-kxwh (Hemlibra®) - Hemophilia A only; AND
- Patient has a documented trial and failure of combination of Immune Tolerance Induction (ITI) therapy and highly immunosuppressive regimens – Hemophilia B only (see explanation below**); AND
- If doses above 100 units/kg or daily doses of 200 units/kg are required, provide the treatment plan to monitor for Disseminated Intravascular Coagulation (DIC) or signs of ischemia and thromboembolic events; AND
- Chart notes with history of bleeds and treatment for the last 24 weeks, current labs and current weight for dosing; AND
- Provide requested dose as PA will be entered for specific dosing requirements

DENIAL CRITERIA:

- Documented previous severe allergic reaction to FEIBA or tendency to develop allergic reactions or hypersensitivity to any human plasma-derived product; OR
 - No medical necessity provided over ITI therapy or emicizumab for Hemophilia A patients; OR
 - Diagnosis of Disseminated Intravascular Coagulation (DIC); OR
 - Acute thrombosis or embolism (such as angina, myocardial infarction, heart attack or stroke); OR
 - Pregnant or breastfeeding women
- Use of FEIBA during pregnancy or breastfeeding is not recommended, due to insufficient information being available. FEIBA should be administered to pregnant women only if clearly needed

CONTINUATION CRITERIA:

- Record of clinical response to treatment (evidence of hemostasis) with chart notes and appropriate labs; AND
- Absence of unacceptable toxicity from the drug (thromboembolic events which includes venous thrombosis, pulmonary embolism, myocardial infarction, and stroke)

QUANTITY EDITS: Quantity entered of time of PA; no specific quantity edits

DISCUSSION:

Dr. Johnson asked to explain the second denial bullet. The Chair explained that ITI therapy and emicizumab have proven more effective than FEIBA. Dr. Johnson stated that the patient could still need FEIBA while on emicizumab in less amounts. FEIBA should not be excluded altogether if on emicizumab.

ACTION:

Motion to approve criteria as amended was made by Dr. Johnson, seconded by Dr. Podrazik. All members present voted in favor of the motion. Motion passed.

6. NOVOSEVEN RT (coagulation factor VIIa-recombinant) kit

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Chart notes with history of bleeds and treatment for the last 24 weeks, current labs and current weight for dosing; AND
- Provide requested dose as PA will be entered for specific dosing requirements

Hemophilia A or B with Inhibitors

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- Diagnosis of congenital or acquired hemophilia A or B with inhibitors confirmed by blood coagulation testing; AND
- Used for treatment of at least one of the following:
 - Control and prevention acute of bleeding episodes; OR
 - Perioperative management; AND
- Patient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy and emicizumab-kxwh (Hemlibra®) - Hemophilia A only
- Patient has a documented trial and failure of combination of Immune Tolerance Induction (ITI) therapy and highly immunosuppressive regimens – Hemophilia B only

Congenital Factor VII Deficiency

- Diagnosis of congenital factor VII deficiency confirmed by blood coagulation testing; AND
- Documentation of prothrombin time and factor VII coagulant activity prior to administration as baseline; AND
- Used for treatment of at least one of the following:
 - Control and prevention of acute bleeding episodes; OR
 - Perioperative management

Glanzmann's Thrombasthenia

- Diagnosis of Glanzmann's thrombasthenia; AND
- Condition is refractory to platelet transfusions; AND
- Used for the treatment of one of the following:
 - Control and prevention of bleeding episodes; OR
 - Perioperative management

Acquired Hemophilia

- Diagnosis of Acquired Hemophilia; AND
- Used for the treatment of one of the following:
 - Control and prevention of bleeding episodes; OR
 - Perioperative management

DENIAL CRITERIA:

- Known hypersensitivity to NovoSeven or any of the components of NovoSeven; OR
- Hypersensitivity to mouse, hamster, or bovine proteins; OR
- Prothrombin time (PT) and activated partial thromboplastin time (aPTT); AND
- Continued use of coagulation factor VIII

CONTINUATION CRITERIA:

- Record of clinical response to treatment (evidence of hemostasis); AND
- Absence of unacceptable toxicity from the drug (thromboembolic events which includes venous thrombosis, pulmonary embolism, myocardial infarction, and stroke); AND
- Factor VII clotting activity – for Congenital Factor VII Deficiency

QUANTITY EDITS:

Quantity entered of time of PA; no specific quantity edits

DISCUSSION:

Dr. Smith asked how the manual review process work for someone with an acute bleed. The Chair commented that these patients should start treatment in the hospital which allows time for a PA submission. Dr. Boone asked the reason for wanting to move it to manual review. The Chair stated that patients on Hemlibra® will not need NovoSeven as much and manual review would be consistent with FEIBA. Dr. Johnson requested to remove the denial criteria concerning PT and aPTT because the levels change so fast preventing accurate lab levels being provided for review.

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ACTION:

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

7. Pretomanid 200mg tablet

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Diagnosed with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); AND
- Age \geq 18 years; AND
- Taking Sirturo[®] (bedaquiline) and Zyvox (linezolid) concomitantly; AND
- Provide current labs including CBCs, BMPs (abnormal calcium, potassium or magnesium must be corrected prior to treatment) and LFTs; AND
- Provide baseline ECG if also taking other medications that prolong QT interval

DENIAL CRITERIA:

- Bedaquiline and/or Linezolid are not being taken; OR
- Does not meet FDA approved diagnosis; OR
- Abnormal LFTs; OR
 - Aminotransferase elevations are accompanied by total bilirubin elevation greater than 2 times the upper limit of normal.
 - Aminotransferase elevations are greater than 8 times the upper limit of normal.
 - Aminotransferase elevations are greater than 5 times the upper limit of normal and persist beyond 2 weeks.
- Clinically significant ventricular arrhythmia or QTcF interval >500 ms; OR
- Coadministration of moderate or strong CYP3A4 inducers

CONTINUATION CRITERIA:

- CBCs and LFTs at baseline, at two weeks and then monthly while on treatment; AND
- Positive cultures to continue beyond week 26; AND
- Current chart notes

QUANTITY EDITS: #31/31 days

DISCUSSION:

Dr. Smith asked if we had received a PA request for any 3 of these drugs from any provider other than the Health Department TB program. The Chair stated only Zyvox. Dr. Smith stated that all TB cases are reviewed, and regimens approved by the ADH TB control officer/medical director—Dr. Patil. ADH should be the only one requesting these medications in the state of Arkansas. Dr. Smith asked if PA requests could be restricted to a physician and not require the rest of the information. Dr. Smith asked for notification if we receive a request from another physician outside of the Health Department. Dr. Mancino questioned the first denial bullet. “Or” should be removed. Dr. Smith stated that ADH orders patient specific regimens that may not be exactly as presented in the package inserts based on individual needs. Dr. Smith and Dr. Podrazik suggested to put in criteria requiring consultation with the Arkansas Department of Health. Chair stated the lab requirements would be removed and the requirement to be submitted by ADH will be added. A notation is made that therapy chosen by ADH will be patient specific.

ACTION:

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

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8. Nayzilam® (midazolam) spray

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Diagnosis of partial or generalized epilepsy; AND
- Must be at least 12 years old; AND
- Provide current chart notes and current labs to monitor renal function; AND
- Experiencing stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures, recurrent seizures;) AND
- Currently on a stable regimen of antiepileptic drugs (AEDs); AND
- Medical necessity over the use of Diazepam Gel; AND
- Must be ordered by a neurologist

DENIAL CRITERIA:

- Has a neurological disorder that is likely to progress in the next year; OR
- Has severe chronic cardio-respiratory disease; OR
- Has a history of their stereotypical seizure cluster progressing to status epilepticus within the last 2 years; OR
- Has a history of acute narrow-angle glaucoma; OR
- Taking moderate or strong CYP3A4 inhibitors; OR
- Pregnancy or breastfeeding

CONTINUATION CRITERIA:

- Patient is responding positively to therapy (termination of seizure(s) within 10 minutes after drug administration, and no recurrence of seizure(s) for up to 6 hours after drug administration; AND
- Patient is not exceeding maximum allowable dose of 2 doses per single episode; AND
- Provide current chart notes with overall response to therapy

QUANTITY EDITS: Max of 5 packs (10 doses) per month

DISCUSSION:

Dr. Mancino asked why the medical necessity over Diazepam gel is required given similar cost. The Chair stated that rebates have an impact on the difference in cost. Dr. Johnson suggested on continuation criteria to question baseline maintenance epileptic agents if this medication is filled monthly at maximum quantities also diversion is a concern. Dr. Miller asked about a billed diagnosis of benzodiazepine poisoning causing this medication to deny at point-of-sale. Dr. Boudreaux stated that this medication can be removed from this rule.

ACTION:

Motion to approve criteria as amended was made by Dr. Bemberg, seconded by Dr. Johnson. All members present voted in favor of the motion. Motion passed.

9. Oxbryta™ (voxelotor) 500mg tablet

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Manual review on a case-by-case basis; AND
- Must be at least 12 years old; AND
- Must have a diagnosis of Sickle Cell Disease; AND
- Must not be pregnant; AND
- Has had from 1 to 10 vasoocclusive crisis (VOC) events in the last 12 months; AND
- Must have hemoglobin (Hb) level ≥ 5.5 to ≤ 10.5 g/dL; AND

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- If taking hydroxyurea, the dose of HU must be stable for at least 3 months; AND
- Prescriber should submit the following:
 - Chart notes
 - History of Sickle Cell treatment including VOC events and hospitalization in the last 12 months
 - Documentation of Hydroxyurea usage
 - Current labs including CBC and LFTs

DENIAL CRITERIA:

- Does not have a diagnosis of Sickle Cell Disease; OR
- Received an RBC transfusion in the last 60 days or erythropoietin within the last 28 days; OR
- Pregnancy or breastfeeding; OR
- Severe hepatic impairment

CONTINUATION CRITERIA:

- Compliance on therapy; AND
- Documentation of positive response to therapy including an improvement in Hb level AND decrease in VOC events; AND
- Prescriber should submit the following:
 - Current chart notes
 - Current labs including CBC and LFTs

QUANTITY EDITS: #90/30 days

DISCUSSION:

Dr. Johnson stated Medicaid would need to decide if wanted a required trial or intolerance to Hydroxyurea usage prior to approval. Hydroxyurea has been shown to decrease pain crises in those with at least 3 crises per year. Dr. Johnson noted that since inexpensive and as long as not toxic to the patient, Hydroxyurea can be required and can take concurrently. Dr. Johnson noted that it is difficult to document failure of Hydroxyurea as patients should take for about a year to account for its success. The Chair stated that we see compliance issues with Hydroxyurea in our population. Board voted to require a trial of Hydroxyurea or documentation of a contraindication.

ACTION:

Motion to approve criteria as amended was made by Dr. King, seconded by Dr. Mancino. All members present voted in favor of 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 November 2019—all members approved
- Criteria recommendations for December 2019—all members approved
- Criteria recommendations for January 2020—all members approved
- Criteria revisions 4Q19—all members approved
- RetroDUR Quarterly Summary report 3Q19

F. Meeting adjourned at 12:00pm.

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