DUR Board Meeting
April 21, 2021
Department of Human Services
Zoom Webinar

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

Medicaid Pharmacy Representatives Present
Cinnamon Pearson, Pharm.D., Chair
Cynthia Neuhofel, Pharm.D. (DHS)
Karen Evans, P.D. (Magellan)
Lynn Boudreaux, Pharm.D. (Magellan)

Non-Voting Board Members Present
William Golden, M.D. (advisor)
Kristen Pohl, Pharm.D. (ATC)
Shannon Burke, Pharm.D. (Empower)
Lauren Jimerson, Pharm.D. (Summit)
Shane David, Pharm.D. (in place of Dr. Romero (advisor))

Board Members and Others Absent
1 physician vacancy
1 pharmacist vacancy
Elizabeth Pitman, J.D. (DHS)

*Denotes left prior to the end of meeting due to conflict.

Meeting held in a ZOOM webinar due to COVID-19. A quorum was present, and the chair called the meeting to order at 8:35 a.m.

I. SPEAKERS

The Chair stated there were 2 speakers present to give public comment today on 2 medications:

1. Aimee Metzner, Pharm. D.—ViiV Healthcare
   Cabenuva™
2. Tom Parmelee, Pharm. D.—Aurinia Pharmaceuticals
   Lupkynis™

Public comments in the form of letters were provided to the board members prior to the meeting. Board members had no questions for the speakers.

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. Reimbursement rates are based on WAC, FUL, or NADAC and do not include rebate information.

B. REVIEW MINUTES FROM THE JANUARY 2021 QUARTERLY MEETING

Motion by Dr. Mancino to approve the minutes as written; Dr. Podrazik seconded the motion. All members present voted by roll call 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. **IMPLEMENTATION INFORMATION FROM JANUARY 20, 2021 DUR BOARD MEETING AND FEBRUARY 10, 2021 DRC MEETING**

   Preferred Drug List changes were effective April 1, 2021: Anticoagulants, Antihyperuricemics, Estrogen Agents, GI Motility Agents, and Hepatitis C Agents

   DUR PA manual review drugs' criteria was effective immediately: Isotretinoin, GnRH Receptor Antagonists (Orilissa® and Oriahnn™), Thrombopoiesis Stimulating Proteins (Promacta®, Mulpleta®, Doptelet®, and Tavalisse™), Immunomodulators for Asthma (Fasenra®, Dupixent®, Xolair®, and Nucala®), Xpovio® (Selinexor), Gavreto™ (pralsetinib), Ongentys™ (opicapone), Onureg® (azacitidine), and Zokinvy (lonafarnib).

   Point-of-sale and claim edit updates: None for January 2021 meeting; ADHD updates were implemented February 10, 2021 (reviewed in October DUR meeting).

2. **DUR BOARD BYLAWS REVIEW**—due to pending legislation, the review of DUR Board bylaws has been postponed until the July 2021 meeting.

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

1. **OTEZLA® (apremilast) 30 mg tablets**

   Chair discussed estimated reimbursement rate, indication, information on psoriatic arthritis, information on psoriasis, information on Behçets disease, treatment recommendations, dosing, and recommended approval/denial criteria.

   SUGGESTED CRITERIA: POINT-OF-SALE EDIT

   APPROVAL CRITERIA FOR OTEZLA:

   Must meet one of the following criteria:

   Criterion 1:

   - Recipient has a submitted diagnosis of psoriasis in the past two years; **AND**
   - Recipient is ≥ 18 years of age; **AND**
   - During days 180 to 395 days ago, a total of >180 days of topical drug therapy with:
     - Calcipotriene; **OR**
     - Corticosteroids; **OR**
     - Tazarotene; **AND**
   - During days 1 to 210 ago, a total of >180 days of systemic drug therapy with:
     - Cyclosporine; **OR**
     - Methotrexate; **OR**
     - Acitretin; **AND**
   - Topical drug therapy trial occurred before systemic drug therapy

Criterion 2:

- Recipient has a submitted diagnosis of psoriatic arthritis in the past two years; **AND**
- Recipient is ≥ 18 years of age; **AND**
- ≥ Six (6) claims for any of the following in the past 365 days:
    - Methotrexate; **OR**
    - Hydroxychloroquine; **OR**
    - Sulfasalazine; **OR**
    - Leflunomide

Criterion 3:

- Recipient has a submitted diagnosis of psoriasis or psoriatic arthritis in the past two years; **AND**
- Recipient is ≥ 18 years of age; **AND**
- Paid drug claim for apremilast (OTEZLA) in the past 45 days

NOTE: Before moving to a non-preferred option, the patient must have a documented trial and failure of at least adalimumab (HUMIRA) and/or etanercept (ENBREL) AND apremilast (OTEZLA) for patients with psoriasis and psoriatic arthritis.

Manual Review for Behçet's Disease with manifestation of oral ulcers:
(Manual Review for any new FDA approved indications)

APPROVAL CRITERIA:

- Recipient must be ≥ 18 of age; **AND**
- Recipient must have a diagnosis of Behçet's Disease **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient with oral ulcers has tried and failed topical corticosteroids (i.e., triamcinolone acetonide cream 0.1% in Orabase); **AND**
- Recipient has tried and failed at least 3 months of treatment with colchicine or immunosuppressant; **AND**
- Prescriber must submit current chart notes; **AND**
- Disease manifestation besides oral ulcers will be reviewed on a case-by-case basis; **AND**
- Initial PA approved for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia

CONTINUATION CRITERIA:

- Recipient demonstrates ulcer improvement after 3 months of therapy; **AND**
- Prescriber must submit current chart notes with documentation of response.

QUANTITY EDITS:

#62/31 days

DISCUSSION:
No discussion by the Board.

ACTION:
Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Mancino. All members present voted by roll call to accept as presented. Motion passed.

2. GI MOTILITY POS EDIT

Chair discussed irritable bowel syndrome with treatment guidelines, chronic idiopathic constipation with treatment guidelines, opioid induced constipation with treatment guidelines, current preferred drug list with indications, and POS criteria for Amitiza®, Linzess®, and Movantik®.

SUGGESTED CRITERIA:

APPROVAL CRITERIA for AMITIZA:

Criterion 1:

- Recipient must be ≥ 18 years old
- Recipient's Medicaid profile must include a paid drug claim for AMITIZA within the past 60 days

Criterion 2:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule of different strengths, or new agents to market.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age

APPROVAL CRITERIA FOR LINZESS:

Criterion 1:

- Recipient must be ≥ 18 years old
- Recipient's Medicaid profile must include a paid drug claim for LINZESS within the past 60 days

Criterion 2

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**

- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule, or new agents to market.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age; **OR**
- Recipient has a paid claim for an opioid in the last 60 days.

APPROVAL CRITERIA FOR MOVANTIK:

Criterion 1:

- Recipient must be ≥ 18 years old
- Recipient's Medicaid profile must include a paid drug claim for MOVANTIK within the past 60 days

Criterion 2:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MiraLAX, GlycoLax) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule of different strengths, or new agents to market; **AND**
- Recipient has a paid claim for an opioid in the last 60 days.

DENIAL CRITERIA:

- Absence of approval criteria; **OR**
- Recipient has a history of mechanical gastrointestinal obstruction; **OR**
- Recipient is < 18 years of age; **OR**
- Recipient does not have a paid claim for an opioid in the last 60 days.

DISCUSSION:

Dr. Mancino asked if buprenorphine containing products were included for the products indicated for opioid-induced constipation. Chair stated that buprenorphine containing products can be added along with other opioids. Dr. Golden commented that these conditions would have a significant amount of subjective information that would be difficult to parse and concomitant use of other medications that may exacerbate constipation like verapamil should be considered. Dr. Podrazik made a comment that sometimes PEG and lactulose can cause abdominal bloating which may limit the use in IBS-C, but she agrees to include PEG in criteria.

ACTION:

Motion was made to accept criteria as amended by Dr. Mancino; seconded by Dr. Podrazik. All members present voted by roll call to accept as amended. Motion passed.

3. **SGLT-2 INHIBITORS FOR HEART FAILURE (dapagliflozin and empagliflozin)**

Chair discussed the estimated reimbursement rate for Farxiga® and Jardiance®, indications for both agents, information on heart failure, current practices for reviewing in diabetic patients, and treatment guidelines.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Based on current treatment guidelines for treating heart failure without a diabetes diagnosis; **AND**
- Recipient must have New York Heart Association (NYHA) class II-IV heart failure with low left ventricular ejection fraction (LVEF) ≤ 40%; **AND**
- Recipient must be prescribed first-line standard of care therapy titrated to the maximum tolerated or target doses; **AND**
    - Angiotensin Receptor-Neprilysin Inhibitor (ARNI)/ Angiotensin-Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB); **AND**
    - Beta blocker; **AND**
    - Diuretic (as needed)
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapy; **AND**
    - Baseline LVEF; **AND**
    - Current estimated glomerular filtration rate (eGFR)

DENIAL CRITERIA:

- Recipient does not meet approval criteria; **OR**
- Recipient has type 1 diabetes; **OR**
- Recipient is on dialysis; **OR**
- Recipient has eGFR below the following recommendations:
    - JARDIANCE—eGFR <20 mL/min/1.73 m^2
    - FARXIGA—eGFR <30 mL/min/1.73 m^2

CONTINUATION CRITERIA:

If the recipient remains "stable and compliant", the claim will continue to process at point-of-sale without an additional prior authorization. "Stable and compliant" is defined as at least 90 days of medication therapy out of the previous 120 days based on the recipient's Medicaid drug profile.

DISCUSSION:

Dr. Johnson recommended to include empagliflozin due to level A evidence for treatment in heart failure. It is only a matter of time before empagliflozin also has the HFrEF indication. Dr. Johnson also recommends for initial approval to include patients with a high BNP per the DAPA-HF trial and the EMPEROR-reduced trial.

ACTION:

Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Bemberg. All members

present voted by roll call to accept as amended. Motion passed.

4. ANTIPSYCHOTICS INFORMED CONSENT FORM FOR CHILDREN

Chair discussed the updates to the informed consent form for children on antipsychotics.

DISCUSSION:

Dr. Miller stated that we really want to know the final diagnosis and updating the form provides prescribers with guidance on information needed for PA review. Dr. Mancino asked to change DSM V to DSM 5.

ACTION:

Motion was made to accept the form as amended by Dr. Mancino; seconded by Dr. King. All members present voted by roll call to accept as amended. Motion passed.

III. NEW BUSINESS

1. **UKONIQ™ (umbralisib) 200 mg tablets**

Chair discussed the estimated reimbursement rate, FDA indications, information on marginal zone lymphoma with NCCN guidelines, information on follicular lymphoma with NCCN guidelines, dosing information, and monitoring suggestions per MicroMedex.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen **OR** relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must take concomitant prophylaxis for *Pneumocystis jirovecii* pneumonia (PJP) and consider prophylactic antivirals to prevent cytomegalovirus (CMV) infection; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of diagnosis; **AND**
    - Current labs including CBC with differential and liver function tests; **AND**
    - Documentation of previous therapies
- Initial PA request approved for 1 month, once demonstrates stability may approve 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a confirmed diagnosis of PJP; **OR**
- Recipient is pregnant; **OR**
- MZL recipient has not received at least one prior therapy; **OR**
- MZL or FL recipient has prior exposure to a PI3K inhibitor; **OR**

- FL recipient has not received at least three prior systemic therapies; **OR**
- FL recipient has Grade 3b FL, large cell transformation, prior allogeneic transplant, or history of CNS lymphoma; **OR**
- Recipient cannot tolerate the dose of minimum dose of 400 mg per day; **OR**
- Recipient has severe renal impairment or moderate/severe hepatic impairment.

CONTINUATION CRITERIA:

- Recipient has a positive response without disease progression; **AND**
- Recipient must continue PJP prophylaxis; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of response to treatment; **AND**
    - Current labs including CBC with differential and liver function tests

QUANTITY EDITS:
#120/ 30 days

DISCUSSION:
Dr. Mancino asked how tumor response was measured or assessed. Chair was not familiar with the mechanism for monitoring, but she would research and update the criteria to reflect that information. Dr. Johnson stated that each indication only had a single-arm trial that measured overall response instead of complete response. Dr. Johnson stated that after one month we would not see stability of disease, but maybe tolerability. She recommends removing the 5th approval bullet. Dr. Johnson stated that you would treat with a certain medication until disease progression. So, it is implied that there is no progression when the provider continues the patient. The chair agreed.

ACTION:
Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Mancino.
All other members present voted by roll call to accept as amended. Motion passed.

2. NEXLETOL™ (bempedoic acid) 180 mg tablets

Chair discussed the estimated reimbursement rate, the FDA approved indication, information on heterozygous familial hypercholesterolemia, and dosing requirements.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia **or** atherosclerotic cardiovascular disease **OR** a diagnosis consistent with FDA indications; **AND**
- Provider must submit the following:
    - Current chart notes
    - Chart notes during trials of statins **AND** ezetimibe; **AND**

  - Current labs including lipids as well as labs corresponding with previous trials of statins **AND** ezetimibe taken concomitantly; **AND**
  - Uric acid levels for patients with a gout diagnosis; **AND**
- Compliance on previous lipid therapy is required unless contraindicated. Recipient's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance; **AND**
- Recipient must be prescribed concomitant statin therapy; **AND**
- Recipient should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the recipient has a contraindication; **AND**
- Provider must submit diet plan for lowering cholesterol; **AND**
- If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; **AND**
- Initial approval for 2 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has a ruptured tendon; **OR**
- Provider orders concomitant statin therapy with simvastatin dose > 20 mg or pravastatin dose > 40 mg; **OR**
- Recipient has end-stage renal disease (ESRD) receiving dialysis **OR** severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is taking PCSK9 inhibitors; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe.

CONTINUATION CRITERIA:

- Provider should submit current chart notes; **AND**
- Provider should submit current labs; **AND**
- Recipient must have a decline in LDL-C or non-HDL-C; **AND**
- Renewal reviews may be approved for up to 6 months.

QUANTITY EDITS:

#31/ 31 days

DISCUSSION:

Dr. Johnson asked if proposed criteria discusses patients who cannot take statins. Chair stated that she will add in concerning patients with a contraindication to statins. Chair asked for input for those patients who have a contraindication to statins considering Nexletol is indicated as an adjunct to statins. Dr. Podrazik commented that many people state they are intolerant due to muscle aches, but she will typically retrial those patients and find the medication is tolerated. Dr. Podrazik stated that it is rare to see actual myositis diagnosed with muscle biopsy. Chair stated that we may ask for a trial of statins every other day for those complaining of muscle pain. Dr. Golden agreed that it is a rare patient that cannot tolerate statins, but the genetic background on these patients can be very extreme concerning coronary vascular disease. Dr.

Johnson suggested that we consider requiring ezetimibe in those patients that cannot tolerate statins prior to beginning Nexletol. We could require a PCSK9 inhibitor since they have documented proof of reducing cardiovascular events while Nexletol hasn't. Chair stated that she is hesitant to require a trial of PCSK9 inhibitors prior to Nexletol, but she is not opposed to a patient trying a PCSK9 inhibitor before Nexletol. Dr. Podrazik asked if we have a protocol concerning retrials of statins if patient states they cannot tolerate. Many times in her practice they will try the long-acting statins in these patients. Dr. Johnson stated that the clinical trials required a trial of at least 2 different moderate to high dose statins which is how ICER report defined intolerance. Chair stated she would review the ICER report and reword the criteria based on DUR Board recommendation and language in the ICER report.

ACTION:
Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Podrazik. All other members present voted by roll call to accept as amended. Motion passed.

3. CABENUVA (cabotegravir and rilpivirine) injection

Chair discussed the estimated reimbursement rate, FDA indication, dosing, and International antiviral Society treatment recommendations.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**
- Recipient must be virologically suppressed (HIV-1 RNA less than 50 copies per mL); **AND**
- Recipient must be on a stable antiretroviral regimen with no history of treatment failure; **AND**
- Recipient must have taken Vocabria (cabotegravir) and Edurant® (rilpivirine) for at least a month to assess tolerability; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Labs including current RNA documenting viral suppression; **AND**
    - Attestation that recipient has been counseled on the importance of compliance; **AND**
    - PA request must be submitted after trial of oral therapy has begun; **AND**
- Prior authorization will be approved for 12 months.

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires coadministration with any of the following:
    - Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin; **OR**
    - Antimycobacterials: Rifabutin, rifampin, rifapentine; **OR**
    - Glucocorticoid (systemic): Dexamethasone (more than a single-dose treatment); **OR**
    - Herbal product: St John's wort (Hypericum perforatum)

CONTINUATION CRITERIA:

- Recipient has been compliant on injections; **AND**
- Recipient remains virologically suppressed; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including RNA documenting viral suppression; **AND**
- Renew PA for an additional 12 months.

QUANTITY EDITS:

600 mg/ 900 mg kit—1 per year
400 mg/ 600 mg kit—1 per 28 days

DISCUSSION:

Dr. Johnson raised a concern that this could be considered a convenience kit and costs a lot more than oral therapies. Trials for this medication indicate non-inferiority to other standard treatment options and is not superior for viral suppression. Since the trials required compliance and virological suppression on once daily regimens, Dr. Johnson suggested that we ask for the medical necessity of Cabenuva over other oral standard of care treatment options. Chair did agree about the similar efficacy between the treatment options, but she thought that the costs were comparable between Cabenuva and Biktarvy. Dr. Golden asked if we have any policies pertaining to therapeutic equivalence versus financial impact. Chair suggested to add that the prescriber should provide the medical necessity of Cabenuva over their current oral therapy since they are stable.

ACTION:

Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Miller. All members present voted by roll call to accept as presented. Motion passed.

4. BRONCHITOL® (mannitol) 40 mg inhalation powder capsule

Chair discussed estimated reimbursement rate, FDA indication, information on cystic fibrosis, dosing, and information on the Bronchitol Tolerance Test.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Cystic Fibrosis **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have passed a BRONCHITOL Tolerance Test (BTT). Chiesi provides the 10 capsules requested for the BTT free of charge (NDC# 10122-216-01 – WAC Price $0.00). However, if a facility cannot accept "samples" then the work around is the BTT with NDC# 10122-212-04 – WAC Price $62.18. Both NDCs come with 10 capsules. Failure would include bronchospasms, a decrease in FEV_1, or a decrease in oxygen saturation with administration of BRONCHITOL; **AND**
- Recipient must have a recent claim for a short-acting bronchodilator; **AND**
- Recipient must continue other standard of care treatments; **AND**

- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous and current medications; **AND**
    - Current pulmonary function tests results with baseline FEV_1 > 40% and < 90% predicted; **AND**
    - Results from a recent BTT; **AND**
    - Medical necessity over hypertonic saline and Dornase alfa

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient failed the BTT; **OR**
- Recipient has an episode of hemoptysis (>60 mL) in the previous 3 months or develops hemoptysis during treatment; **OR**
- Recipient does not remain compliant on therapy with PA renewal request.

CONTINUATION CRITERIA:

- Recipient demonstrated an improvement in their FEV_1 from baseline; **AND**
- Recipient remains compliant on the medication; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current pulmonary function tests

QUANTITY EDITS:

One (1) four week treatment pack per 28 days (#560/ 28 days)

DISCUSSION:

Dr. Mancino asked if the BTT was performed in the provider's office. The chair confirmed that the BTT was given in the provider's office. Dr. Mancino commented about the adherence to hypertonic saline. If literature has a concern of adherence to hypertonic saline due to time of administration, Dr. Mancino is concerned the same would be true for Bronchitol considering it requires inhalation of 10 capsules with each dose. Chair stated that hypertonic saline is considered the standard of care for mucus in CF patients which is why the criteria to provide the medical necessity of Bronchitol over hypertonic saline was included despite the length of administration. Dr. Johnson stated that hypertonic saline has been proven to reduce pulmonary exacerbations which is more clinically relevant.

ACTION:

Motion was made to accept criteria as presented by Dr. Johnson; seconded by Dr. Mancino. All members present voted by roll call to accept as presented. Motion passed.

5. TEPMETKO® (tepotinib) 225 mg tablet

Chair discussed the estimated reimbursement rate, FDA indication, mechanism of action, information on NSCLC with NCCN guidelines, and dosing.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of metastatic non-small lunch cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapies; **AND**
    - Documentation of the presence of MET exon 14 skipping alterations; **AND**
    - Current labs including liver function tests and CBCs; **AND**
    - Attestation that patient has been counseled on contraception (both male and female); **AND**
- Recipient should not take concomitant dual strong CYP3A inhibitors and P-gp inhibitors (e.g., clarithromycin, itraconazole, verapamil) **OR** strong CYP3A inducers (e.g., phenytoin, rifampin); **AND**
- Recipient must have a negative status for epidermal growth factor receptor(EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; **AND**
- Initial PA may be approved for 3 month

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is diagnosed with interstitial lung disease/pneumonitis; **OR**
- Recipient cannot tolerate the minimum dose of 225 mg daily; **OR**
- Recipient is pregnant; **OR**
- Recipient has severe renal impairment; **OR**
- Recipient has Grade 4 increase in ALT and/or AST without increased total bilirubin **OR** ALT and/or AST >3X ULN with total bilirubin >2X ULN **OR** Grade 4 increase in total bilirubin without increased ALT and/or AST; **OR**
- Recipient requires coadministration with dual strong CYP3A inhibitors and P-gp inhibitors **OR** strong CYP3A inducers.

CONTINUATION CRITERIA:

- Recipient does not demonstrate disease progression or unacceptable toxicity; **AND**
- Prescriber should submit the following:
    - Current chart notes with response to therapy; **AND**
    - Current labs including LFTs and CBCs

QUANTITY EDITS:

#62/ 31 days

DISCUSSION:
No discussion

ACTION:
Motion was made to accept criteria as presented by Dr. Mancino; seconded by Dr. Bemberg. All members present voted by roll call to accept as presented. Motion passed.

6. LUPKYNIS™ (voclosporin) 7.9 mg capsule

Chair discussed the estimated reimbursement rate, FDA approved indication, information on lupus nephritis, and dosing.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of biopsy-proven active lupus nephritis (Class III, IV or V) **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must also take mycophenolate mofetil (MMF) and corticosteroids(minimum length of trial prior?); **AND**
- Recipient must have an elevated urine protein to creatinine (UPCR) ratio; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including liver function tests, urine protein to creatinine (UPCR) ratio, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR). eGFR must be assessed every two weeks for the first month, and every four weeks thereafter; **AND**
    - Current blood pressure; **AND**
    - Medical necessity over supported immunosuppressive therapy alone (i.e., mycophenolate mofetil or azathioprine).

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient has a baseline eGFR ≤ 45 mL/min/1.73m^2; **OR**
- Recipient has a baseline blood pressure >165/105 mmHg or with hypertensive emergency; **OR**
- Recipient is not taking concomitant mycophenolate mofetil and corticosteroids; **OR**
- Recipient is taking cyclophosphamide; **OR**
- Recipient requires concomitant strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin); **OR**
- Prescriber orders a dose > 23.7 mg twice daily **OR** < 7.9 mg twice daily; **OR**
- Recipient has severe hepatic impairment; **OR**
- If approved, recipient has not experienced therapeutic benefit by 24 weeks.

CONTINUATION CRITERIA:

- Recipient must be a responder with a decrease in prednisone usage/dosage **AND/OR** improved UPCR **AND/OR** improved eGFR; **AND**
- Recipient must be compliant on therapy; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including eGFR and UPCR; **AND**
    - Current blood pressure

QUANTITY EDITS:

#180/ 30 days

DISCUSSION:

Dr. Mancino asked for the response time rates for mycophenolate mofetil and corticosteroids. Chair did not know the answer. Dr. Podrazik referenced trials and guidelines that recommend decrease in proteinuria by ≥ 25% in 3 months, ≥ 50% in 6 months, and proteinuria < .1-.7gm in 12 months after induction. Chair stated that she will do additional research on response time rates. Dr. Mancino suggested maybe 6 months for mycophenolate and corticosteroids to match the trials for voclosporin. Dr. Johnson stated that it may be better to start voclosporin initially rather than after 6 months of other therapy. Data supports improved outcomes concerning complete renal remission with voclosporin plus mycophenolate and corticosteroids vs placebo (which includes mycophenolate and corticosteroids). The ICER report supports the usage. Dr. Podrazik agreed with Dr. Johnson. Dr. Golden mentioned to take into consideration the severity of disease presentation. Chair deferred until after the Benlysta discussion to make the final decision on both products.

ACTION:

Motion was made to accept criteria as amended by Dr. Mancino; seconded by Dr. Podrazik. All members present voted by roll call to accept as amended. Motion passed.

7. BENLYSTA® (belimumab) 200 mg/mL SQ injection

Chair discussed estimated reimbursement rate, FDA indication, mechanism of action, information on systemic lupus erythematosus, treatment guidelines for lupus, and dosing.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age (for subcutaneous injection); **AND**
- Recipient must have a diagnosis of either active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy **OR** active lupus nephritis (LN) who are receiving standard therapy **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient with SLE must have:
    - Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of ≥ 8; **AND**
    - Positive autoantibody test (anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA)); **AND**
- Recipient with LN must have:

  - Clinical diagnosis of SLE; **AND**
  - Biopsy confirmed active lupus nephritis
- Recipient must take concomitant standard therapy which could include corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), NSAIDs, and immunosuppressives (e.g., azathioprine, methotrexate, mycophenolate); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBC with differential, urine protein to creatinine (UPCR) ratio for LN recipient, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR) for LN recipient. eGFR must be assessed every two weeks for the first month, and every four weeks thereafter; **AND**
  - Current blood pressure; **AND**
  - Medical necessity over supported immunosuppressive therapy alone (i.e., mycophenolate mofetil or azathioprine).

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient has progressive multifocal leukoencephalopathy (PML); **OR**
- Recipient has a SELENA-SLEDAI score of < 8 and does not have a positive autoantibody test; **OR**
- Recipient has been prescribed biologic therapies, anti-tumor necrosis factor therapy, cyclophosphamide, interleukin-1 receptor antagonist, IVIG, or plasmapheresis in the previous 3 months; **OR**
- Recipient has severe active CNS lupus; **OR**
- Recipient is pregnant; **OR**
- Recipient is not taking concomitant standard therapy.

CONTINUATION CRITERIA:

- Recipient must be a responder with a decrease in prednisone usage/dosage **AND/OR** improved SELEMA-SLEDAI score (for SLE) **AND/OR** improvement in UPCR or eGFR (for LN); **AND**
- Recipient must be compliant on therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including eGFR and UPCR; **AND**
  - Current blood pressure

QUANTITY EDITS:

4 syringes/ 28 days

DISCUSSION:

Chair asked Dr. Johnson her thoughts concerning lupus nephritis patient's treatment with either Benlysta or Lupkynis. Dr. Johnson stated that the endpoints evaluated with Benlysta were clinical and would be

justifiable to use in LN patients. Dr. Podrazik noted that UptoDate includes these products in induction therapy but short term and long term outcomes are still not clear. Dr. Johnson noted to review the BLISS-LN and AURORA trials and comparative effectiveness in the ICER report for LN. Dr. Podrazik understands the difficulty in determining the criteria since induction periods vary from 3 months to a year. Dr. Mancino made the point that corticosteroids should be tapered and would need to be started earlier to allow time for tapering after starting these agents. Dr. Mancino commented that if all agents were started at the same time, how would we know if the mycophenolate and/or steroids were effective. Dr. Johnson made the suggestion to allow patients with lupus nephritis access to these agents sooner, but SLE patients without nephritis should wait to start these agents. Chair gave an overview of the discussion for a motion. Lupus nephritis patients could start either Benlysta or Lupkynis along with mycophenolate mofetil and corticosteroids as induction. SLE patients must trial standard of care therapy with immunosuppressants and corticosteroids prior to beginning Benlysta.

ACTION:

Motion was made to accept criteria as amended by Dr. Mancino; seconded by Dr. Podrazik. All members present voted by roll call to accept as amended. Motion passed.

8. ORGOVYX™ (relugolix) 120 mg tablet

Chair discussed estimated reimbursement rate, FDA indication, mechanism of action, information on prostate cancer, treatment options for prostate cancer with NCCN guidelines, and dosing.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be a male; **AND**
- Recipient must have a diagnosis of advanced prostate cancer **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient requires at least a year of Androgen Deprivation Therapy (ADT); **AND**
- Recipient has a baseline testosterone level > 50 ng/dL; **AND**
- Prescriber must submit the following:
    - Chart notes; **AND**
    - Current labs including baseline prostate-specific antigen (PSA) and testosterone; **AND**
    - Previous therapies; **AND**
    - Medical necessity over other options for ADT; **AND**
    - Baseline ECG if patient is a risk for QT prolongation

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient is a female; **OR**

- Recipient has end-stage renal disease with or without hemodialysis or severe hepatic impairment (Child-Pugh C); **OR**
- Recipient requires a P-gp inhibitor or combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, separate dosing for those requiring P-gp inhibitors and increase the ORGOVYX dose for those requiring combined P-gp and strong CYP3A inducers; **OR**
- Baseline testosterone level (without ADT) is not above castration level (>50 ng/dL); **OR**
- Testosterone level does not remain at castration level on renewal request (<50 ng/dL).

CONTINUATION CRITERIA:

- Recipient has not developed castrate-resistant or hormone-refractory prostate cancer; **AND**
- Recipient remains compliant on ORGOVYX; **AND**
- Recipient's PSA remains low; **AND**
- Recipient's serum testosterone level remains at castrate level; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including PSA and testosterone; **AND**
    - Response to current chemotherapy or radiation

QUANTITY EDITS:
#31/ 31 days

DISCUSSION:
Dr. Johnson stated that this drug class is one of two for ADT; with GnRH receptor antagonist or LHRH agonist. Standard of care for prostate cancer is giving ADT. There is comparison data between relugolix and leuprolide, but there is no comparison data between relugolix and degarelix. Relugolix was better than leuprolide at suppressing testosterone for ADT, and relugolix has lower CV risks than leuprolide. Degarelix also shows less CV risk. Dr. Johnson states that our options are oral relugolix or injection degarelix. Degarelix is quite a bit less expensive than relugolix. Dr. Johnson asked, "With the lack of comparative data, how do we justify using relugolix over degarelix?" Chair stated DMS is working on collaboration with the medical department on classes of drugs that have options payable on both pharmacy and medical side. Relugolix and degarelix would be a good example. At this point, we cannot require degarelix since that is covered only on the medical side. Medical and pharmacy have two completely different processes on criteria review that are mandated. Dr. Johnson stated she was glad that we are looking into collaborations between pharmacy and medical. There is a huge cost difference just in these 2 products and one disease state; imagine multiplying that for many other examples. Chair stated that we can require the prescriber to provide the medical necessity of relugolix over degarelix, but we cannot require the use of degarelix. Dr. Johnson agreed with adding the comment about medical necessity. Dr. Podrazik stated that the question for ADT is whether a patient has surgical or medical castration, and most of the time leuprolide is used every 3 months.

ACTION:
Motion was made to accept criteria as amended by Dr. Johnson; seconded by Dr. Podrazik. All members present voted by roll call to accept as amended. Motion passed.

9. ORLADEYO™ (berotralstat) 110 mg and 150 mg capsules

Chair discussed estimated reimbursement rate for multiple HAE products, FDA indication, information on hereditary angioedema, and dosing.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥12 years of age; **AND**
- Recipient must have a laboratory diagnosis of Type 1 or Type 2 hereditary angioedema **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks; **AND**
- Provider (allergist/immunologist/hematologist) must submit the following:
    - Current chart notes with documentation of previous therapies tried with disease history and description of typical angioedema attack; **AND**
    - Proposed treatment plan for both acute attacks and prophylaxis treatment; **AND**
    - Documentation of attack frequency, comorbidities, and access to emergency care for the previous 12 months on the initial request; **AND**
    - Documentation of expected angioedema triggers (Trigger avoidance is crucial); **AND**
    - IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation; **AND**
        - 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
        - Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
    - Provide the following labs:
        - Complement C1 esterase inhibitor level; **AND**
        - Complement C4 level; **AND**
        - Functional C1 inhibitor activity; **AND**
- Initial PA maximum 3-month trial if approved

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Prescriber intends for recipient to use for the treatment of acute attacks of HAE; **OR**
- Prescriber requests a dose of >150 mg per day; **OR**
- Recipient is prescribed an ACEi, estrogen, or other drugs that can possibly be angioedema triggers; **OR**
- Prescriber requests a therapeutic duplication with 2 or more preventative agents

CONTINUATION CRITERIA:

- Recipient must provide updated diary of events documenting any angioedema events; **AND**
- Recipient must be compliant on maintenance medication; **AND**

- If there is no response from prophylaxis in severity and frequency, considering changing the medication and/or question diagnosis of Type I or Type II. It may be Type III. Question triggers or accuracy of diagnosis; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of response to therapy with attack frequency and severity

QUANTITY EDITS:

#31/ 31 days for each strength

DISCUSSION:

No discussion

ACTION:

Motion was made to accept criteria as presented by Dr. King; seconded by Dr. Miller. All members present voted by roll call to accept as presented. Motion passed.

IV. REPORTS

A. ProDUR Report

1. Dr. Karen Evans from Magellan gave the quarterly ProDUR reports. The ProDUR system sends alert messages through Point-of-Sale to Arkansas Medicaid Pharmacy Providers. As we have seen in the past, the ProDUR numbers are consistent with hardly any variation.

Using First Data Bank, the Magellan Pro-DUR system sends these alert messages in the following categories:

- High Dose (HD)
- Therapeutic Duplication (TD)
- Drug-Drug (DD) Interactions
- Incorrect Duration (IC)
- Early Refill (ER)

The 3rd Quarter encompasses the months of January, February, and March 2021. We continue to see a decline in paid claims. In the past months we attributed this to the COVID Pandemic. There were less paid claims and therefore, less alerts sent during the 3rd Quarter than there were during the 2nd Quarter. The percentage of total overrides and cancellations, however, remains the same.

More than 75% of those that are sent an alert are NOT overridden or the pharmacist does not send a Pharmacy Professional Service Codes to request an override at the POS in response to alerts. Because a Professional Service Code is not sent, these alerts are then cancelled by the POS system.

As has been stated previously, one of the positive outcomes of the ProDUR System is that the information sent to Pharmacy Providers at POS is actually being utilized. 75% of the time, Pharmacists chose not to override the alert.

Due to the COVID-19 Pandemic on March 23rd, Arkansas Medicaid POS pharmacy providers were allowed to bypass the early refill ProDUR alert for non-controlled prescriptions. Currently, this change allows the pharmacy provider to enter an override for an early refill ProDUR alert. Once the Professional Service Codes are entered by the pharmacist to override the alert, the claim will then pay at Point-of-Sale (POS) as long as all additional criteria for that drug is met.

In addition, on March 23rd, the update to the POS system also included the removal of the "Refill Too Soon" Accumulation Logic from all non-controlled medications. The Refill Too Soon Accumulation Logic removed the requirement to only allow an accumulation of up to 12 days of non-controlled medications every 186 days.

The Early Refill numbers are less, due to the removal of the requirement for Non-Controlled medications to require a Prior Authorization for Early Refill. But we still see Early Refill overrides for Controlled Drugs. The Early Refill Hard Halt for Controlled Drugs was set at 75%. We have increased the Early Refill Hard Halt for Controlled drugs to a 90% tolerance at the DUE level. Ninety percent of a Controlled Substances must be expended before an Early Fill is allowed. The Pharmacy does not have the ability to override an Early Refill DUR alert for a controlled drug.

Less than 50% of the high dose and incorrect duration alerts were overridden by the Point of Sale Pharmacists. It seems that the Pharmacist paid attention to the alert that was sent and depended on the system to determine the need for the override. And maybe we can conclude, that the ProDUR system helped them to make this professional decision even though the was a lifting of the rule.

2. Dr. Cinnamon Pearson gave the combined PASSE ProDUR report for 2nd quarter of SFY2021 (October-December 2020). The PASSEs had a combined 265,673 paid claims with 50,115 ProDUR alerts resulting in 27,222 cancelled claims or 54.3% of alerts cancelled at POS.

B. RDUR Report

Dr. Lynn Boudreaux from Magellan presented intervention letter data for January-March 2021, the quarterly lock-in report, and potential intervention criteria to be discussed by the DUR board for May 2021, June 2021, and July 2021. Also, Dr. Boudreaux provided a list of the top 25 products by total claims, top 25 products by pharmacy reimbursement, and top 25 products by net net expenditures. The Board made recommendations to perform intervention review on the following:

May 2021—7742 CNS Polypharmacy
June 2021—6804 Use of antibiotics for URI-antibiotic overutilization and resistance
July 2021—7737 Females 15-50, claims for narcotics, no BC

Alternative where needed—7968 ADHD medication in women ages 15-44_CDC report concerns

- Motion to accept the recommended intervention criteria was made by Dr. Podrazik; seconded by Dr. Mancino. All other members present voted by roll call to accept as presented. Motion passed.

C. Meeting adjourned at 12:01 p.m.