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

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

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

Meeting held in a hybrid format with no Board members present in-person. A quorum was present with the voting members attending virtually, and the chair called the meeting to order at 8:37 a.m.

I. SPEAKERS

The Chair stated there were 5 speakers present to give public comment today on 2 medications:

1) Vicki Star, MD—Merck & Co. (Virtual)
   Verquvo™
2) Jamie Tobitt, Pharm. D., MSL-BC—Apellis Pharmaceuticals (In-person)
   Empaveli™
3) Teri Jeffers Vancil, MD—Four Seasons Allergy and Asthma Clinic (Virtual)
   Larry Simmons, MD—ACH (Virtual)
   ICS-LABA in asthma
4) Mandi Champ, Pharm. D.—Amgen (Virtual)
   Lumakras™
5) Jacob Mercer, PhD—Helsinn Therapeutics, Inc. (Virtual)
   Truseltiq™

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.
3. Recognition of new PASSE Board member—Barry Fielder, Pharm. D. from ATC

4. Annual CMS Survey report was submitted June 30, 2021.

B. **REVIEW MINUTES FROM THE APRIL 2021 QUARTERLY MEETING**

Motion by Dr. King to approve the minutes as written; Dr. Johnson 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 APRIL 21, 2021 DUR BOARD MEETING AND MAY 12, 2021 DRC MEETING

Preferred Drug List changes were effective July 1, 2021: Colony Stimulating Factors; Lipotropic Agents (statins); Narcolepsy Agents (Provigil/Nuvigil only); Phosphate Binders; and Platelet Aggregation Inhibitors

DUR PA manual review drugs' criteria was effective immediately: Ukoniq™ (umbralisib); Nexletol™ (bempedoic acid); Cabenuva (cabotegravir and rilpivirine); Bronchitol® (mannitol); Tepmetko® (tepotinib); Lupkynis™ (voclosporin); Benlysta® (belimumab); Orgovyx™ (relugolix); Orladeyo™ (berotralstat); SGLT-2 inhibitors for heart failure (Farxiga® and Jardiance®);

Point-of-sale and claim edit updates: (effective July 14, 2021) Otezla® (apremilast); GI motility (Amitiza®, Linzess®, and Movantik®).

2. DUR BOARD BYLAWS REVIEW—

Updates to the DUR Board bylaws were presented to include the following:

1) Update to Board composition to add 2 physicians/APRN currently treating rare diseases
2) Add the capability to attend virtually in addition to in-person
3) Redefined a quorum based on composition
4) Add guidelines in section 3.03 concerning new medication or label expansion

DISCUSSION:

No discussion by the Board.

ACTION:

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

3. UPDATE on ADHD meds

Chair presented PA burden for ADHD claims prior to the addition of the ADHD rule on 2/10/2021 and after the rule was implemented. The initial PA approval rate was 94.7% and the approval rate after implementation was 97.2%

DISCUSSION:

The chair suggested to remove the requirement of a billed ADHD diagnosis for patients 6-18 years of age as the edit did not provide the results expected. Dr. Magee agreed that the ADHD rule has been a burden on newly diagnosed patients.

ACTION:

Motion was made by Dr. Magee to remove the requirement of a billed diagnosis of ADHD; seconded by Dr. King. All members present voted by roll call to accept as presented. Motion passed.

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

1. ASTHMA TREATMENT WITH ICS-LABA

Chair discussed current PA criteria for the preferred ICS-LABA agents, indications and claim counts over the last year for the preferred agents, GINA and NIH guidelines for each age group, and maximum dosing recommendations for SMART therapy.

SUGGESTED CRITERIA: POINT-OF-SALE EDIT

PROPOSED CRITERIA for Symbicort®:

For Criterion 1: COPD diagnosis in the past two years **AND** ≥ 40 years old

OR

For Criterion 2: Paid drug claim in drug history for Advair Diskus, Advair® HFA, Dulera®, or Symbicort® in the last six months

OR

For Criterion 3:

- Age ≥ (4,5,or 6+) years of age; **AND**
- Asthma diagnosis in the past 2 years

OR

For Criterion 4:

- Age (4,5,or 6+) years old; **AND**
- One of the following criteria below:
  - ≥ Three inhaled corticosteroid claims in the last 120 days; **OR**
  - ≥ Three oral steroid claims in the last 120 days; **OR**
  - Combination for ≥ three claims (as defined below) in the last 120 days:
    - o One Inhaled Corticosteroid + 2 Oral Steroids
    - o Two Inhaled Corticosteroids + 1 Oral Steroids

QUANTITY EDITS:

#2 inhalers per month for 120 actuation size (Currently the quantity is #2 inhalers per 53 days). If the recipient needs > 8 puffs per day, a PA can be submitted to approve an additional inhaler.

PROPOSED CRITERIA for Dulera® and Advair Diskus®:

For Criterion 1: COPD diagnosis in the past two years **AND** ≥ 40 years old.

OR

For Criterion 2: Paid drug claim in drug history for Advair Diskus®, Advair® HFA, Dulera®, or Symbicort® in the last six months

OR

For Criterion 3: Do we mimic Symbicort for Dulera?

OR

For Criterion 4:

- Age ≥ 4 y/o for Advair Diskus and Age ≥ 5 y/o for Dulera; **AND**
- One of the following criteria below:
  - ≥ Three inhaled corticosteroid claims in the last 120 days; **OR**
  - ≥ Three oral steroid claims in the last 120 days; **OR**
  - Combination for ≥ three claims (as defined below) in the last 120 days:
    - One Inhaled Corticosteroid + 2 Oral Steroids
    - Two Inhaled Corticosteroids + 1 Oral Steroids

QUANTITY EDITS:
Dulera –#2 inhalers per month (if we allow prn doses); Advair Diskus—#1 Diskus per month

DISCUSSION:
Chair asked the Board to decide the minimum age for SMART therapy for Symbicort. Dr. Magee commented that we should use a minimum of 4 years of age that is in line with NIH guidelines. Dr. Johnson and Dr. Magee agreed to include Dulera in the Symbicort criteria.

ACTION:
Motion was made by Dr. Magee to include patients down to 4 years old for Symbicort; seconded by Dr. Gettman. All members present voted by roll call to accept as amended. Motion passed.

Motion was made by Dr. Magee to include Dulera with the same criteria as Symbicort; seconded by Dr. Johnson. All members present voted by roll call to accept as amended. Motion passed.

2. HETLIOZ® (tasimelteon) 20 mg capsule and 4 mg/mL suspension

Chair discussed estimated reimbursement rate, indications, mechanism of action, information on Non-24 and Smith-Magenis Syndrome, and dosing requirements.

PROPOSED CRITERIA:

- Recipient with Non-24 diagnosis must be ≥ 18 years of age, and recipient with SMS diagnosis must be ≥ 3 years of age; **AND**
- Recipient must have a diagnosis of either Non-24-Hour Sleep-Wake Disorder **OR** Nighttime Sleep Disturbances in Smith-Magenis Syndrome **OR** a diagnosis consistent with FDA indications; **AND**
- Non-24-hour Sleep-Wake Disorder
  - Blind patient
    - Clinical trials provided in the package insert included totally blind patients and reference the Diagnostic and Statistical manual of Mental Disorders 5 (DSM-5) diagnostic criteria
      - A persistent or recurrent pattern of sleep disruption that is primarily due to an alteration of the circadian system or to a misalignment between the endogenous circadian rhythm and the sleep-wake schedule required by an individual's physical environment or social or professional schedule; **AND**
      - The sleep disruption leads to excessive sleepiness or insomnia, or both; **AND**

- The sleep disturbance causes clinically significant distress or impairment in social, occupational, and other important areas of functioning; **AND**
- Recipient must have tried and failed melatonin and other sleep aids

- Sighted patient
  - Recipient must have tried and failed melatonin and other sleep aids; **AND**
  - Recipient must have tried and failed timed light exposure; **AND**
  - Sleep disturbance cannot be explained by other causes (i.e., neurological disorder, mental disorder, medication use, or substance use disorder)

- For Nighttime Sleep Disturbances in SMS requests:
  - Need confirmed diagnosis of SMS; **AND**
  - Need history of sleep disturbances; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of medications and therapies tried to improve sleep patterns; **AND**
  - Documentation as listed above to confirm diagnosis; **AND**
  - Daily sleep logs or actigraphy for confirmation of sleep disruption; **AND**
- Initial PA for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Recipient requires the use of strong CYP1A2 inhibitors or strong CYP3A4 inducers; **OR**
- Recipient has severe hepatic impairment

CONTINUATION CRITERIA:

- Recipient has a positive response with nighttime total sleep time (increase) and daytime nap duration (decrease); **AND**
- Recipient is compliant on therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of response to therapy with daily sleep logs

QUANTITY EDITS:

20 mg capsules #31/ 31 days
Suspension 48 mL—3 bottles/ 31 days
158 mL—1 bottle/ 31 days

DISCUSSION:

Dr. Johnson raised concerns over the effectiveness of Hetlioz.

ACTION:

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

3. General criteria for new-to-market products or products with label expansions

Chair discussed Act 745 of the 2021 Arkansas legislative session and proposed document for posting on the Medicaid/Magellan website.

CRITERIA FOR MEDICATIONS NEW-TO-MARKET OR WITH LABEL EXPANSIONS

MANUAL GUIDELINES: Pertains to new-to-market FDA approved drugs available on the Medicaid drug file or drugs with a label expansion including new indication, dosage change, or age changes prior to being reviewed by the Arkansas Medicaid DUR Board.

PROPOSED CRITERIA:

- Medication must be an outpatient drug with a federal rebate agreement in place
- Medication must be prescribed for an FDA-approved indication with age, dose, and frequency based on manufacturer's packet insert
    - If the FDA-approved indication(s) does not match the client's diagnosis, the medication must have support for the requested diagnosis either in treatment guidelines or the official Compendia (MicroMedex®)
- If the new-to-market medication is included in an existing class/category on the preferred drug list (PDL):
    - The new-to-market medication will be added as a non-preferred option.
    - The new-to-market medication will require a prior authorization with documentation of the medical necessity over preferred options.
    - If the PDL class has multiple preferred options, the client must have documentation of trial and failure of at least 2 different chemical entities unless otherwise noted.
    - If the PDL class has multiple preferred options with multiple mechanisms of action (MOA), the client must have documentation of trial and failure from each MOA unless there is a contraindication.

        Example: Second generation antidepressants have multiple MOA as preferred option (i.e., SSRI, NSRI, and aminoketone).

- If the new-to-market medication's class/category is not on the preferred drug list (PDL), the documentation of medical necessity over older products in the same class is required along with a trial of at least 2 older products unless otherwise noted.
    - An exception—New-to-market antiepileptic drugs require a trial of 3-4 different AEDs available without a PA.
- If the new-to-market medication is the same chemical entity as another medication already on the market but in a different dosage form, the existing dosage form must be tried first. If the original medication was a solid oral dosage form, the following scenarios would require a prior authorization with documentation of the medical necessity for the new formulation.
    - New-to-market is an oral, non-solid dosage form (may be considered in clients <7 years of age or clients identified as NPO).
    - New-to-market is an extended-release formulation.
    - New-to-market is a sprinkle formulation.
- If the new-to-market medication is a novel product and/or requires extensive monitoring, a prior authorization will be required. The prescriber should submit the following for review:
    - Current chart notes and/or discharge summary
    - Documentation of all previous therapies tried with treatment timeframe and responses

  - Current labs if warranted (e.g., oncology and hemophilia)
  - Letter of Medical Necessity outlining the rationale for this medication over others currently on the market
- Once the new-to-market medication has been reviewed by the DUR Board, required criteria for approval will be consistent with the DUR Board vote. All new and renewal prior authorization requests will refer to the DUR Board approved criteria.

DISCUSSION:

No discussion by Board

ACTION:

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

4. REVIEW LYRICA® AND FIBROMYALGIA

Chair discussed Lyrica® indications, current Lyrica® criteria, and Lyrica® utilization.

PROPOSED UPDATED LYRICA® CRITERIA:

Based on utilization and the expanded indications:

- Remove the above pregabalin criteria making it available without a PA and add to the neuropathic pain agent list as a preferred agent.
- Keep therapeutic duplication criteria for all doses of pregabalin and allow one therapeutic duplication (90% overlap of last fill) with different date of service and same prescriber ID between Lyrica® GCNs in previous 93 days
- Add therapeutic duplication criteria with gabapentin.
- Keep previous quantity edits with a maximum daily dose of 600 mg/day for pregabalin IR.
- Pregabalin ER will remain non-preferred with manual review requiring documentation of the medical necessity over the IR formulation.

UPDATE TO NEUROPATHIC PAIN AND FIBROMYALGIA AGENTS:

- Remove fibromyalgia class from PDL and incorporate into the neuropathic pain class
- Criteria for antiepileptic agents will be reviewed during a future DUR meeting

DISCUSSION:

No discussion by Board**.**

ACTION:

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

5. POLYPHARMACY EDITS

Chair discussed the SUPPORT Act, CMS guidance on section 1004, opioid and benzodiazepine edits for other state Medicaid programs, and explanation of the current prospective and retrospective review.

PROPOSED ACTION:

- For the following drug combinations, add a POS prospective review
  - Opioid—benzodiazepine
  - Opioid—sedative hypnotic

  - Opioid—muscle relaxer
  - Opioid—antipsychotics
  - Opioid—gabapentin
- The pharmacist would be required to review the rejection and apply the proper DUR codes if they feel the combination is appropriate.
- Example messages to pharmacists
  - *TOXICITY WARNING- Perform DUR Review; Enter appropriate codes*
  - *DD – Caution Risk of breathing difficulties with combination of these medications. Review & submit appropriate DUR codes*

DISCUSSION:

Dr. Golden was concerned about the burden on the Help Desk. Drs. Boudreaux and Evans explained that these DUR soft edits would not require a PA and just require an input by the dispensing pharmacist.

ACTION:

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

III. NEW BUSINESS

1) VERQUVO™ (vericiguat) 2.5 mg, 5 mg, and 10 mg tablets

Chair discussed the estimated reimbursement rate, FDA approved indications, mechanism of action, treatment of heart failure with secondary agents, and dosing requirements.

PROPOSED CRITERIA

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with symptomatic chronic heart failure (New York Heart Association class II-IV) with an ejection fraction < 45% following a worsening HF event **OR** a diagnosis consistent with FDA-approved indications; **AND**
- Recipient must have previously been hospitalized for heart failure in the last 6 months or required outpatient IV diuretics in the last 3 months; **AND**
- Recipient must remain on standard of care therapy; **AND**
- Recipient of reproductive potential should use contraception and have a negative pregnancy test; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Discharge summary from hospital if recently hospitalized; **AND**
  - Documentation of previous therapies tried with outcomes; **AND**
  - Documentation of ejection fraction; **AND**
  - Negative pregnancy test results for recipients of reproductive potential

DENIAL CRITERIA

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient is taking another soluble guanylate cyclase (sGC) stimulator (i.e., Adempas); **OR**
- Recipient taking a PDE-5 inhibitor is not recommended to take with this product; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C) or severe renal impairment (eGFR <15 mL/min/1.73m^2 or on dialysis)

CONTINUATION CRITERIA

- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of response to therapy; **AND**
- Recipient has an improvement in symptoms (i.e., EF, quality of life)

QUANTITY EDITS
#31/ 31 days for each strength

DISCUSSION:
Dr. Golden commented about ejection fraction of <45% is not necessarily severe, and he suggested to change NYHA class to III-IV. Dr. Johnson suggested that we require a Pro-BNP to confirm HF diagnosis and require continued symptoms on Entresto.

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.

2) FOTIVDA® (tivozanib) 0.89 mg and 1.34 mg capsules
Chair discussed the estimated reimbursement rate, the FDA approved indication, mechanism of action, information on renal cell carcinoma, NCCN guidelines and dosing requirements.

PROPOSED CRITERIA
- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of relapsed or refractory advanced renal cell carcinoma **OR** a diagnosis consistent with FDA-approved indications; **AND**
- Recipient must have had two or more prior systemic therapies including at least one VEGFR kinase inhibitor (e.g., axitinib); **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous therapies tried; **AND**
    - Documentation of current blood pressure (monitor often during therapy); **AND**
    - Current labs including CBCs and LFTs; **AND**
- Initial approval for 1 month

DENIAL CRITERIA
- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has systolic blood pressure ≥ 150 mmHg or diastolic blood pressure ≥ 100 mmHg despite anti-hypertensive therapy; **OR**
- Recipient had a severe or life-threatening venous or arterial thromboembolic event; **OR**
- Recipient had a severe or life-threatening hemorrhagic event; **OR**
- Recipient develops nephrotic syndrome/proteinuria; **OR**
- Recipient develops reversible posterior leukoencephalopathy syndrome; **OR**
- Recipient had a major surgery < 2 weeks prior to request; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient with moderate hepatic impairment requires a dose reduction

CONTINUATION CRITERIA

- Recipient has no unacceptable toxicity; **AND**
- Prescriber must submit the following
    - Current chart notes with documentation of response to therapy; **AND**
    - Current labs including LFTs and CBCs; **AND**
    - Documentation of blood pressure

QUANTITY EDITS
#21/28 day

DISCUSSION:
No discussion by Board

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

3) LUMAKRAS™ (sotorasib) 120 mg tablet

Chair discussed the estimated reimbursement rate, FDA approved indication, mechanism of action, information on the KRAS G12C mutation, NCCN guidelines, and dosing requirements.

PROPOSED CRITERIA
- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer who have received at least one prior systemic therapy **OR** a diagnosis consistent with FDA-approved indications; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including LFTs; **AND**
    - Test results verifying the KRAS G12C mutation from tumor or plasma specimens; **AND**
    - Documentation of previous therapies tried including an immune checkpoint inhibitor (anti-PD-1/PD-L1) (e.g., pembrolizumab, atezolizumab) and/or platinum-based chemotherapy (e.g., cisplatin, carboplatin); **AND**
- Initial PA for maximum of 3 months

DENIAL CRITERIA
- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient requires acid-reducing agents (PPIs or H_2 receptor antagonists) or a strong CYP3A inducer (e.g., phenytoin or rifampin) due to a decrease in sotorasib concentration; **OR**
- Recipient requires a CYP3A4 substrate (e.g., cyclosporin or ketoconazole) due to a decrease in plasma concentration of the substrate or a P-glycoprotein substrate (e.g., digoxin) due to an increase in plasma concentration of the substrate; **OR**
- Recipient cannot tolerate the minimum dose of 240 mg daily; **OR**
- Recipient has confirmed interstitial lung disease/pneumonitis; **OR**
- Recipient is pregnant or breastfeeding

CONTINUATION CRITERIA
- Recipient has no unacceptable toxicity; **AND**
- Prescriber must submit the following

- Current chart notes with documentation of response to therapy; **AND**
- Current labs including LFTs

QUANTITY EDITS
#248/ 30 days

DISCUSSION:
No discussion by Board

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

4) EMPAVELI™ (pegcetacoplan) 1,080 mg/20 mL injection

Chair discussed estimated reimbursement rate, FDA approved indication, information on paroxysmal nocturnal hemoglobinuria, REMS requirements, mechanism of action, and dosing requirements.

PROPOSED CRITERIA

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation of EMPAVELI, and recipient must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy; **AND**
- Prescriber, pharmacy, and recipient must be enrolled in the REMS program; **AND**
- Recipient currently taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must follow the required dose initiation per the package insert; **AND**
- Recipients taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must have been stable for at least 3 months; **AND**
- Female recipients of reproductive potential should use contraception and have a negative pregnancy test prior to starting therapy; **AND**
- Recipient's baseline hemoglobin level is <10.5 g/dL; **AND**
- Treatment naïve recipient's (no previous C5 inhibitor or C3 inhibitor) baseline lactate dehydrogenase (LDH) level is elevated; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapies; **AND**
  - Current labs including CBC and LDH; **AND**
  - Pregnancy test results (if applicable)

DENIAL CRITERIA

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has not been vaccinated according to package insert/REMS requirements; **OR**
- Recipient has an unresolved serious infection caused by encapsulated bacteria; **OR** including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*
- Recipient is pregnant or breastfeeding

CONTINUATION CRITERIA

- Recipient is compliant on therapy; **AND**
- Recipient has an improvement in hemoglobin and/or LDH levels compared to baseline; **AND**
- Recipient with continued LDH > 2X ULN should adjust dose to 1,080 mg every 3 days; **AND**
- Recipient has an improvement in overall clinical presentation (e.g., fatigue, dyspnea); **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs CBC and LDH

QUANTITY EDITS

10 vials/ 30 days

DISCUSSION:

Dr. Tobitt from Apellis spoke again about the study comparing Soliris and Empaveli concerning hemoglobin.

ACTION:

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

5) TRUSELTIQ™ (infigratinib) 25 mg and 100 mg capsules

Chair discussed the estimated reimbursement rate, FDA approved indication, information on cholangiocarcinoma, NCCN guidelines, mechanism of action, and dosing requirements.

PROPOSED CRITERIA

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test **OR** diagnosis consistent with FDA indications; **AND**
- Recipient has progressed after at least 1 failed prior systemic therapy. Provide the medical necessity of infigratinib over FOLFOX. (NCCN guidelines currently recommend FOLFOX as preferred therapy after progression with gemcitabine/cisplatin. But FOLFOX does not have current data about the specific FGFR2 fusion mutation.) Provide documentation of that therapy including any radiation with response; **AND**
- Prescriber should submit the following:
    - Current chart notes with previous therapies tried; **AND**
    - Documentation of FGFR2 fusion or other rearrangement; **AND**
    - Current labs including serum phosphate (initiate phosphate lowering therapy if >7.5 mg/dL with reduction in dose), CBC, LFTs; **AND**
    - Documentation of comprehensive ophthalmological exam; **AND**
    - Pregnancy test results for recipient with child-bearing potential; **AND**
- Initial PA for 2 months.

DENIAL CRITERIA

- Recipient does not meet the above approval requirements; **OR**
- Recipient is unable to tolerate 50 mg once daily; **OR**
- Recipient has persistent symptoms for Retinal Pigment Epithelial Detachment (RPED); **OR**
- Recipient has life-threatening consequences due to elevated serum phosphate; **OR**

- Recipient requires concomitant strong or moderate CYP3A inhibitors (e.g., itraconazole, erythromycin, verapamil); if cannot be avoided, reduce Truseltiq™ dose; **OR**
- Recipient requires strong or moderate CYP3A inducer (e.g., carbamazepine, phenytoin); **OR**
- Recipient is pregnant

CONTINUATION CRITERIA

- Recipient must not experience unacceptable toxicity; **AND**
- Prescriber should submit the following:
  - Follow-up ophthalmological exam at the following intervals—1 month, 3 months, then every 3 months thereafter during treatment; **AND**
  - Current chart notes with response to therapy; **AND**
  - Current labs including serum phosphate; **AND**
- Recipient is not pregnant or breastfeeding

QUANTITY EDITS

25 mg capsules -- #63/21 days
100 mg capsules -- #21/21 days

DISCUSSION:

Dr. Miller asked for the cost of Pemazyre. No further discussion.

ACTION:

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

IV. REPORTS

A. ProDUR Report

1. Dr. Cinnamon Pearson gave the combined PASSE ProDUR report for 3rd quarter of SFY2021 (January-March 2021). The PASSEs had a combined 263,651 paid claims with 47,630 ProDUR alerts resulting in 25,758 cancelled claims or 54.1% of alerts cancelled at POS.

2. 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 4th Quarter encompasses the months of April, May, and June 2021.

More than 73% 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 being utilized. 73% of the time, Pharmacists chose not to override the alert.

Due to the COVID-19 Pandemic on March 23rd, Arkansas Medicaid POS pharmacy providers could 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) if 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. Early Refill Hard Halt for Controlled drugs has been increased 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.

Approximately 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.

B. RDUR Report

Dr. Lynn Boudreaux from Magellan presented intervention letter data for January-July 2021, intervention responses from providers, the quarterly lock-in report, and potential intervention criteria to be discussed by the DUR board for August 2021, September 2021, and October 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. Also, Dr. Boudreaux reported on top 10 prescribers and pharmacies with number and cost of paid claims, and she reported the top 10 prescribers and pharmacies concerning opioids for the last 6 months. The Board made recommendations to perform intervention review on the following:

August 2021—7968 ADHD medication in women ages 15-44 CDC Report Concerns
September 2021—7848 SABA 2 or more in 90 days without a controller medication
October 2021—8008 FDA increased warning about complex sleep behaviors with zaleplon, zolpidem and eszopiclone

Alternative where needed—7970 Fluoroquinolones should be used with caution in diabetics

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

C. Meeting adjourned at 11:55 a.m.