Arkansas Medicaid DUR Board Meeting Minutes

DUR Board Meeting
July 15, 2020
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.
Brian King, Pharm.D.
James Magee, M.D.
Clint Boone, Pharm. D.
Michael Mancino, M.D.
Paula Podrazik, M.D.

Non-Voting Board Members Present
William Golden, M.D. (advisor)
Kristen Pohl, Pharm.D. (ATC)
Christopher Page, Pharm.D. (Empower)
Lauren Jimerson, Pharm.D. (Summit)

Medicaid Pharmacy Representatives Present
Cinnamon Pearson, Pharm.D., Chair
Cynthia Neuhofel, Pharm.D. (DHS)
Annette Jones, B.S. (DHS)
Karen Evans, P.D. (Magellan)
Scott Donald, Pharm.D. (RDUR—HID)
Lynn Boudreaux, Pharm.D. (Magellan)
Elizabeth Pitman, J.D. (DHS)
Jacqueline Dodwell, UAMS pharmacy student

Board Members and Others Absent
Nate Smith, M.D. (advisor)
1 pharmacist vacancy
1 physician vacancy

Meeting held in a ZOOM webinar due to COVID-19. A quorum was present, and the chair called the meeting to order at 8:45 a.m.

I. SPEAKERS

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

a. Palforzia® (Laura Odom, DNP, FNP-BC with Aimmune Therapeutics)
b. Repatha® (Mandi Champ, Pharm.D. with Amgen)

Public comments in the form of letters were provided to the board members prior to the meeting. Dr. King and Dr. Johnson asked the Palforzia speaker questions. There were no questions for the Repatha speaker.

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. Chair announced that we are still needing a pharmacist and a physician to fill vacant seats on the board.

B. REVIEW MINUTES FROM THE JANUARY 2020 QUARTERLY MEETING

Motion by Dr. Mancino to approve the minutes as written; Dr. Gettman 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 15, 2020 DUR BOARD MEETING AND May 13, 2020 DRC MEETING**

Preferred Drug List changes were effective July 1, 2020; DUR PA manual review drugs' criteria were effective immediately; POS edits for leucovorin and Lovaza® were effective July 15, 2020; Revlimid® became manual review on July 15, 2020; Gabapentin quantity/dose edits became effective July 15, 2020; TIMs age edits and inclusion of Spravato® were effective May 1, 2020; Lysteda® POS edits will be effective August 18, 2020.

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

1) PCSK9 Agents (Repatha® and Praluent®)

Chair gave background information from ICER reports, previous criteria from the provider memo and cholesterol treatment guidelines as well as dosing information.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis consistent with FDA approved indications; **AND**
- Provider must submit current chart notes; **AND**
- Provider must submit chart notes during trials of statins **AND** ezetimibe **OR** bile acid sequestrants; **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**
- Provider should submit current labs including lipids as well as labs corresponding with previous trials of statins AND ezetimibe OR bile acid sequestrants taken concomitantly; **AND**
- Recipient should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after 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 have a diagnosis consistent with FDA approved indications; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**
- Recipient has not compliantly trialed concomitant therapy of statins with either ezetimibe or bile acid sequestrants

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:

- Repatha® 140 mg syringe/autoinjector—2 injections per month

- Repatha® 420 mg injection—1 injection per month
- Praluent® 75 mg syringe/pen—2 injections per month
- Praluent® 150 mg syringe/pen—2 injections per month

DISCUSSION:

Dr. Johnson corrected a mistake in the presentation that 50% reduction was referring to LDL not to stroke and MI as presented. This information does not support using this medication first line. Dr. Podrazik asked if bile acid sequestrants require a PA. The generic cholestyramine does not. Drs. Johnson, Podrazik, and Golden suggested to remove bile acid sequestrants as a requirement. Statins and ezetimibe usage would be required unless contraindicated as a prerequisite to adding PCSK9s.

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.

2) ACTHAR® Gel

Chair gave background information on infantile spasms along with dosing information and a proposed Acthar form.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≤ 2 years of age; **AND**
- Recipient must have a diagnosis for infantile spasms (West Syndrome) as indicated by:
  - Epileptic spasms; **AND**
  - Developmental problems; **AND**
  - Hypsarrhythmia on electroencephalography (EEG)
- Prior authorization request should be submitted prior to beginning Acthar® if being hospitalized and sent again upon discharge; **AND**
- Provider must submit admission clinical notes with initial prior authorization request and discharge summary notes prior to discharge; **AND**
- Provider must submit current body surface area (BSA); **AND**
- Recipient has a history of previous vigabatrin(Sabril®) and corticosteroid usage with failure; **AND**
- Provider must complete the Acthar® form with initial request and resubmit the form at time of discharge with specific taper directions; **AND**
- PA will be approved at the time of discharge for the amount needed for completion of the taper. Recipients cannot fill Acthar® as a pharmacy benefit and use during hospitalization.

DENIAL CRITERIA:

- Recipient has not trialed vigabatrin (Sabril®) and corticosteroids; **OR**
- Provider has not submitted all of the required information as outlined on the Acthar® form; **OR**
- Provider intends to use Acthar® purchased as a pharmacy benefit during an inpatient stay

DISCUSSION:

Dr. Magee asked if this was a criterion change or just submitting requests upon admission and discharge. Chair confirmed that previously the criteria alone stated manual review, but our staff had been reviewing using these criteria. We felt it would be easier to communicate needed information and requirements with this form and criteria outlined. Dr. Magee stated he would assume that no adult neurologists would prescribe this medication for IS. Chair agreed with that assumption.

ACTION:

Motion was made to accept criteria as presented by Dr. Magee; seconded by Dr. King. All members present voted by roll call to accept as written. 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) Isturisa® (osilodrostat) 1 mg, 5 mg and 10 mg tablets

Chair gave background information on Cushing's Disease and Cushing Syndrome along with dosing information and MOA of Isturisa.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient ≥ 18 years of age; **AND**
- Diagnosis of Cushing's disease and pituitary surgery is not an option or has not been curative **OR** diagnosis consistent with FDA indication; **AND**
- Prescriber must provide the following:
  - Current chart notes with documentation of surgery status; AND
  - Current labs including
    - Urine free cortisol levels (normal is <150nmol/24 hours OR 3.5-45mcg/24 hours); **AND**
    - Liver function tests; **AND**
    - Comprehensive metabolic panel; **AND**
  - Baseline electrocardiogram; **AND**
- Prescriber should provide a letter of medical necessity for the use of this medication over adrenal enzyme inhibitors such as ketoconazole (small studies and retrospective reviews); **AND**
- Current labs should indicate the recipient does not have hypokalemia or hypomagnesemia; **AND**
- Recipients with risk factors for QT prolongation should have more frequent ECG monitoring

DENIAL CRITERIA:

- Recipient does not meet the approval criteria; **OR**
- Dose requested is > 30 mg twice daily; **OR**
- Recipient is showing symptoms of adrenal insufficiency

CONTINUATION CRITERIA:

- Prescriber should submit current chart notes; **AND**
- Previously requested labs; **AND**
- ECG results of any recent tests; **AND**
- Recipient should indicate a positive response with a decrease in urine free cortisol levels and decrease in symptoms

QUANTITY EDITS:

- Due to titration and variety of doses, do not recommend quantity edits on 1 mg and 5 mg
- 10 mg tablets — #180/30 days

DISCUSSION:

Since pituitary irradiation is a treatment option, Dr. Johnson suggested to amend the 2nd bullet to read "Diagnosis of Cushing's Disease and pituitary surgery and/or pituitary irradiation is not an option or has not been curative". Dr. Podrazik asked about making ketoconazole a requirement prior to this medication, and Dr. Johnson agreed. Dr. Johnson suggested to require a failure or intolerance to ketoconazole and mitotane since both lower urinary cortisol levels. Dr. Johnson suggested an evaluation for adrenalectomy. Chair stated this was beyond her knowledge. Dr. Golden stated he would have to review. Dr. Johnson suggested that this be limited to an endocrinologist.

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.

2) Koselugo™ (selumetinib) 10 mg and 25 mg capsules

Chair gave background information on Neurofibromatosis Type 1 and Plexiform Neurofibromas along with dosing information for Koselugo.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 2 years of age; **AND**
- Recipient must have a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **OR** diagnosis consistent with FDA indications; **AND**
- Recipient must have at least one measurable PN measuring at least 3 cm **AND** either a positive genetic test for NF1 or have at least one other diagnostic criterion listed below
    - 6 or more café-au-lait macules; **OR**
    - Freckling in axilla or groin; **OR**
    - Optic glioma; **OR**
    - 2 or more Lisch nodules; **OR**
    - Distinctive bony lesion; **OR**
    - First-degree relative with NF1
- Provider should submit the following:
    - Current chart notes with status of plexiform neurofibromas; **AND**
    - Documentation of current baseline left ventricular ejection fraction (LVEF); **AND**
    - Documentation of comprehensive ophthalmic assessment; **AND**
    - Documentation of current labs including serum CPK, baseline INR, CBC, and LFTs; **AND**
        - ANC ≥ 1500/µL
        - Hemoglobin ≥ 9g/dl
        - Platelets ≥ 100,000/ µL
    - Current body surface area (BSA)—no recommended dosage for recipients with BSA < $0.55m^2$.
- Prescriber should provide plan for monitoring patients that require coadministration with vitamin-K antagonists or platelet antagonists.

DENIAL CRITERIA:

- Recipient does not meet age requirement; **OR**

- Recipient does not have a diagnosis consistent with FDA approved indications; **OR**
- Recipient has disease progression or unacceptable toxicity and is unable to tolerate after 2 dose reductions; **OR**
- Recipient has retinal vein occlusion; **OR**
- Recipient is unable to swallow a whole capsule; **OR**
- Recipient's BSA is < 0.55m^2 ; **OR**
- Recipient has symptomatic or Grade 3 or 4 decreased LVEF; **OR**
- Recipient has Grade 4 diarrhea or Grade 3 or 4 colitis; **OR**
- Recipient has rhabdomyolysis; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is pregnant; **OR**
- Recipient is not using birth control when has reproductive potential; **OR**
- If recipient requires strong or moderate CYP3A4 inducers, Koselugo™ should be avoided; strong or moderate CYP3A4 inhibitors require dose decrease for Koselugo™.

CONTINUATION CRITERIA:

- Provider should submit the following:
  - Documentation of ejection fraction assessed every 3 months for the first year; **AND**
  - Documentation of current labs including serum CPK, INR, CBC and LFTs; **AND**
  - Current chart notes with documentation of response to therapy; **AND**
  - Documentation of current BSA ; **AND**
  - Current required dosage
- Recipient should continue contraception unless have no reproductive potential; **AND**
- Recipient should show improvement with the plexiform neurofibromas

QUANTITY EDITS:

- 10 mg capsule — #270/30 days
- 25 mg capsule — #120/30 days

DISCUSSION:

Dr. Podrazik asked if there was a specific provider type who would be prescribing this medication. Dr. Golden and Dr. Magee stated that there is always a debate if the provider would be a genetic specialist. Chair stated that given the need for genetic testing, this request would be coming from the specialist. No recommendations for changes made by board members.

ACTION:

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

3) Tukysa™ (tucatinib) 50 mg and 150 mg tablets

Chair provided MOA and dosing information for Tukysa.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have the diagnosis of advanced unresectable or metastatic HER2-positive breast cancer with at least one treatment in history and taking trastuzumab with capecitabine **OR** diagnosis consistent with FDA indications; **AND**

- Recipient must have previously received trastuzumab (Herceptin®), pertuzumab (Perjeta®) and ado-trastuzumab emtansine (T-DM1) (Kadcyla®) separately or in combination; **AND**
- Prescriber should submit the following:
  - Current chart notes with documentation of previous therapies; **AND**
  - Documentation that the recipient is taking trastuzumab (Herceptin®) and capecitabine (Xeloda®); **AND**
  - Current labs including CBC, renal function, and LFTs; **AND**
  - Pregnancy test results for recipient with child-bearing potential;
- Prescriber should add anti-diarrheal medication to recipient medication list for use as needed (81% of patients develop some grade of diarrhea); **AND**
- Prescriber should advise females of reproductive potential to use effective contraception as wells as female partners of male patients

DENIAL CRITERIA:

- Recipient does not meet the above approval requirements; **OR**
- Recipient cannot tolerate the minimum dose of 150 mg twice daily; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient must be able to swallow pills; **OR**
- Recipient has Grade 4 diarrhea; **OR**
- Recipient has either one of the following:
  - Grade 4 ALT or AST (>20X ULN) **OR** Grade 4 Bilirubin (>10X ULN); **OR**
  - ALT or AST >3X ULN **AND** Bilirubin >2X ULN
- Recipient requires a strong CYP3A inducer (e.g. rifampin or phenytoin), moderate CYP2C8 inducer (e.g. rifampin) or a strong CYP2C8 inhibitor (e.g. gemfibrozil)—if unavoidable, dose may need to be adjusted; **OR**
- Recipients with severe renal impairment (CrCl < 30mL/min) because these patients should not take capecitabine

CONTINUATION CRITERIA:

- Recipient has no evidence of disease progression or unacceptable toxicity; **AND**
- Provider should submit the following:
  - Current chart notes with documentation of response to therapy; **AND**
  - Documentation that recipient continues taking trastuzumab and capecitabine; **AND**
  - Current labs including CBC, renal function, and LFTs; **AND**
- Recipient is not pregnant or breastfeeding.

QUANTITY EDITS:

- 50 mg tablets — #120/30 days
- 150 mg tablets — #120/30 days

DISCUSSION:

Dr. Johnson questioned whether previous trial of other TKI's specific for HER2-positive breast cancer (i.e. lapatinib and neratinib) would be a denial criterion. There are no comparative efficacy or sequencing trials to date. We don't know how tucatinib would work in patients previously failed on other TKIs. Dr. Golden states that most chemotherapy criteria look at whether patient had a similar class of treatment prior. If failed a medication in a similar class (TKI), then tucatinib would possibly fail. Dr. Johnson clarified that would not include just any TKIs, but the TKIs that specifically target HER2. Dr. Mancino asked about patients with an intolerance to another TKI specific to HER2. Dr. Johnson stated that they

may not be intolerant to all medications in a class, and this question is different than failure. Intolerance to previous TKI therapy should not be considered as a denial criterion.

ACTION:

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

4) Pemazyre™ (pemigatinib) 4.5 mg, 9 mg, and 13.5 mg tablets

Chair provided background information on cholangiocarcinoma, MOA, and dosing information for Pemazyre.

SUGGESTED CRITERIA:

APPROVAL 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 prior systemic therapy. 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 >7mg/dL with reduction in dose), CBC, LFTs; **AND**
    - Documentation of comprehensive ophthalmological exam; **AND**
    - Pregnancy test results for recipient with child-bearing potential

DENIAL CRITERIA:

- Recipient does not meet the above approval requirements; **OR**
- Recipient is unable to tolerate 4.5 mg once daily; **OR**
- Recipient has persistent symptoms for Retinal Pigment Epithelial Detachment (RPED); **OR**
- Recipient has continued serum phosphate >10mg/dL despite 2 dose reductions; **OR**
- Recipient requires concomitant strong or moderate CYP3A inhibitors (e.g. itraconazole, erythromycin, verapamil); if cannot be avoided, reduce Pemazyre™ dose; **OR**
- Recipient is pregnant

CONTINUATION CRITERIA:

- Recipient must lack disease progression or unacceptable toxicity; **AND**
- Prescriber should submit the following:
    - Follow-up ophthalmological exam every 2 months for first 6 months and every 3 months thereafter; **AND**
    - Current chart notes with response to therapy; **AND**
    - Current labs including serum phosphate; **AND**
- Recipient is not pregnant or breastfeeding

QUANTITY EDITS:

- 4.5 mg tablets — #14/21 days
- 9 mg tablets — #14/21 days

- 13.5 mg tablets — #14/21 days

DISCUSSION:

Dr. Johnson states primary treatment for unresectable and metastatic disease is gemcitabine with cisplatin. If there is disease progression, the preferred medication is FOLFOX per NCCN guidelines. FOLFOX is not specific for the FGFR2 fusions or rearrangements. Pemigatinib was in a single arm trial with overall response rate of 36%. Given NCCN recommendations and efficacy data, Dr. Johnson recommended previous trial of FOLFOX for those who progressed on previous therapy prior to moving to pemigatinib. There is an ongoing trial comparing pemigatinib with current therapy. Dr. Mancino asked if patient had the FGFR2 fusion or rearrangement, why should they try another therapy that is not specific for their mutation? Dr. Mancino questions why we would force two failures before testing for the FGFR2 fusion or force treatment with a second therapy that does not have data for the FGFR2 fusion. Dr. Podrazik states that FOLFOX appears to be therapy of 2nd choice regardless of mutations with better response rate. Chair stated that the criteria should explain NCCN guidelines and request documentation of medical necessity of pemigatinib over FOLFOX for patients having disease progression after previous treatment.

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.

5) Palforzia™ 0.5 mg, 1 mg, 10 mg, 20 mg, and 100 mg powder capsules/sachets

Chair provided dosing information on Palforzia.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 4 years of age and ≤ 17 years of age to initiate treatment; **AND**
- Recipient must have a confirmed diagnosis of a peanut allergy; **AND**
- Prescriber must be an allergy and immunology specialist; **AND**
- Prescriber, clinic, pharmacy and recipient must be enrolled in the Risk Evaluation and Mitigation Strategy (REMS) program and remain compliant with program requirements. REMS pharmacy must deliver the up-dosing packs directly to the REMS certified provider; **AND**
- Prescriber must attest that the recipient has been counseled to continue a peanut-avoiding diet as this medication is for accidental exposure to peanuts; **AND**
- Recipient must continue to have injectable epinephrine on hand with a pharmacy claim within the last year; **AND**
- Prescriber must require initial dose escalation and up-dosing to occur in the office to monitor for anaphylaxis and provide a plan on how to manage potential anaphylaxis reactions while in the office; **AND**
- Prescriber should provide the following:
    - Current chart notes; **AND**
    - Documentation of peanut allergy based on:
        - Serum immunoglobulin E (IgE) to peanuts ≥ 14 kUA/L (kilos of allergen-specific units per liter) within the past 12 months; **OR**
        - Skin prick test (SPT) to peanut with a mean wheal diameter of ≥ 8 mm compared to control; **OR**
        - Documented reaction to peanut upon supervised oral food challenge at a dose of ≤ 100 mg peanut protein (≤ 200 mg peanut flour)

- PAs will be approved for each up-dosing pack individually based on progression of dose. Until recipient has titrated to 300 mg maintenance daily dose, PAs should be for one (1) 15-day supply only. Prescribers **OR** pharmacies can call with dose needed for taper escalation.

DENIAL CRITERIA:

- Recipient has uncontrolled asthma, markedly compromised lung function, severe mast cell disorder or cardiovascular disease (decreased ability to survive anaphylaxis); **OR**
- Recipient has suspected eosinophilic esophagitis and/or other eosinophilic gastrointestinal disease; **OR**
- Recipient cannot tolerate doses up to and including the 3 mg dose during Initial Dose Escalation; **OR**
- Recipient had a severe or life-threatening anaphylaxis within the previous 60 days.

CONTINUATION CRITERIA:

- Recipient's Medicaid profile will be reviewed for compliance for PA renewal; **AND**
- Prescriber should submit current chart notes with response/tolerance to medication; **AND**
- PA renewals for maintenance dosing may be approved for 3-6 months depending on length of proven tolerance.

QUANTITY EDITS:

- Each up-dosing pack— #1 pack/15 days
- Maintenance pack of 300 mg daily— #1 pack (30 powder packs)/ 30 days

DISCUSSION:

Dr. Magee asked to define uncontrolled asthma and markedly compromised lung function since so vague. Chair stated that the wording provided was the exact language for exclusion criteria in the clinical trial. Chair stated that if having multiple exacerbations and multiple claims of rescue inhalers, that may be a consideration, but defining these for all patients would not be black and white. Dr. Podrazik stated that this medication is for desensitization which requires lots of staff and education. Who would be doing this? Chair stated that the patient would be going to an allergy and immunology specialist that is REMS certified. The REMS program has guidelines to follow. Dr. Johnson questioned medical necessity of this treatment at all as the trials didn't show a reduction in anaphylaxis. Epi-pen usage was higher in the Palforzia group over the placebo group. EBRx excludes this medication from their formulary. Dr. Golden questioned the technique for the drug versus current clinical practice. Dr. Bemberg voiced a concern over the 15 day packs and what happens when the patient needs to start a new pack on the weekend or a holiday. How can this be handled to ensure compliance? Chair stated that is a good point, and she had no answer. Dr. Miller asked if we should have the providers try other methods before trying this medication. Chair stated that this would not be first line approved treatment. Dr. Odom from Aimmune Therapeutics wanted all strengths approved at the same time. Chair voiced concern that there could be confusion on the current dose needed, especially with children in the Arkansas Medicaid population. Dr. Podrazik states it is unclear in the trials of the number needed to treat versus the number needed to harm. Dr. Miller asked if other states have more experience with this. Dr. King said that ACH pharmacy is trying to get REMS certified, and Dr. Magee said that ACH has peanut allergy experts. Dr. Neuhofel made a point that if a patient lived far from a REMS provider, they may not be a candidate due to distance to travel. Dr. Miller asked if we need to table this discussion. Chair and board agreed to table for further review. Dr. Boudreaux asked if this could be a medical claim only drug. Chair stated she would contact the medical review department for that discussion.

ACTION:

Discussion was tabled for a future meeting.

6) Tabrecta™ (capmatinib) 150 mg and 200 mg tablets

Chair provided MOA and dosing information for Tabrecta.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient has been diagnosed with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber should submit the following:
    - Current chart notes with previous therapies tried; **AND**
    - Current labs including LFTs and CBCs; **AND**
    - Documentation of MET exon 14 skipping mutation
- Recipient must have a negative status for epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; **AND**
- If Tabrecta™ must be co-administered with a P-gp substrate (e.g. digoxin) or BCRP substrate (e.g. rosuvastatin), prescriber should submit a plan for dosage decreases of the substrates; **AND**
- Initial PA may be approved for 3 months

DENIAL CRITERIA:

- Recipient is unable to tolerate the minimum dose of 200 mg twice daily; **OR**
- Recipient has EGFR mutations or ALK-positive rearrangement; **OR**
- Recipient has Interstitial Lung Disease/Pneumonitis; **OR**
- Recipient has Grade 4 increase in AST and/or ALT without elevated bilirubin **OR** ALT and/or AST >3X ULN with bilirubin >2X ULN **OR** Grade 4 increase in bilirubin without elevated AST and/or ALT; **OR**
- Recipient is pregnant or breastfeeding; **OR**
- Recipient requires coadministration with a moderate or strong CYP3A inducer (e.g. bosentan, rifampin or phenytoin); **OR**
- Recipient has disease progression on this medication

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:

- 150 mg tablet — #120/30 days
- 200 mg tablet — #120/30 days

DISCUSSION:

Dr. Gettman asked if we should have the chest X-ray report required as a part of criteria. Dr. Podrazik stated that we would get an oncologist report with documentation of X-ray report and staging documented. Dr. Gettman was referring to determining if the medication should be stopped due to ILD based on X-ray. No changes to criteria were made.

ACTION:

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

7) Retevmo™ (selpercatinib) 40 mg and 80 mg capsules

Chair provided MOA and dosing information on Retevmo.

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient with diagnosis of NSCLC must be ≥ 18 years of age and with diagnosis of thyroid cancer must be ≥ 12 years of age; **AND**
- Recipient must have a diagnosis of either metastatic RET Fusion-positive NSCLC, advanced or metastatic RET-Mutant Medullary Thyroid Cancer requiring systemic therapy or advanced or metastatic RET Fusion-Positive Thyroid Cancer who are refractory to radioactive iodine (if radioactive iodine is appropriate) **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
- Current chart notes with documentation of diagnosis and previous therapies including radioactive iodine in RET Fusion-Positive Thyroid Cancer; **AND**
    - Current labs including CBC, BMP, LFTs and TSH; **AND**
    - Documentation with the presence of a RET gene fusion or RET gene mutation; **AND**
    - Baseline ECG; **AND**
    - Current blood pressure; **AND**
- Recipient must be able to swallow pills; **AND**
- Hypokalemia, hypomagnesemia and hypocalcemia should be corrected prior to treatment and if developed during treatment; **AND**
- Initial PA would be approved for 1 month; once recipient demonstrates tolerability the PA can be approved for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria; **OR**
- Recipient has been unable to tolerate Retevmo™ after 3 dose reductions (40 mg per day if <50kg and 40 mg twice daily if >50kg); **OR**
- Recipient has Grade 4 or uncontrolled hypertension; **OR**
- Recipient has Grade 4 QT interval prolongation; **OR**
- Recipient has severe or life-threatening hemorrhagic events; **OR**
- Recipient should avoid strong and moderate CYP3A inhibitors (e.g. ketoconazole, clarithromycin or verapamil); Retevmo™ dose must be decreased if concomitant use is required; **OR**
- Recipient requires concomitant use of a proton pump inhibitor, histamine-2 receptor antagonist or locally acting antacid that cannot be taken at a separate time from Retevmo™; **OR**
- Recipient with severe hepatic impairment requires dose decrease; **OR**
- Recipient is pregnant or breastfeeding

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 CBC, BMP and LFTs; **AND**
    - TSH levels and repeated ECG provided periodically; **AND**
    - Current blood pressure; **AND**

- Recipient is not pregnant or breastfeeding

QUANTITY EDITS:

- 40 mg capsules — #180/30 days
- 80 mg capsules — #120/30 days

DISCUSSION:

No comments by board.

ACTION:

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

8) Narcolepsy Agents

Chair provided background information on narcolepsy, OSA, and cataplexy. Chair also provided current criteria and treatment recommendations for the multiple narcolepsy agents.

a. Sunosi™ (solriamfetol) 75 mg and 150 mg tablets

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA) **OR** diagnosis consistent with FDA indications. Diagnosis of narcolepsy is based on International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria; **AND**
- Recipient profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy; **AND**
- Prescriber should submit the following for initial request for narcolepsy:
    - Most recent polysomnogram (PSG) results; **AND**
    - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
        - Mean sleep latency of less than 8 minutes per nap; **AND**
        - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT); **AND**
    - Current chart notes; **AND**
    - Baseline Epworth Sleepiness Scale (ESS) ; **AND**
- Prescriber should submit the following for initial request for obstructive sleep apnea (OSA)
    - Most recent polysomnogram (PSG) results; **AND**
    - Current chart notes; **AND**
    - Documentation of plan for monitoring compliance of positive airway treatment; **AND**
    - CPAP or BiPAP usage report for documentation of compliance for at least 1 month; **AND**
- Recipient must have a documented trial and failure of CII and CIII stimulants in the last year; **AND**
- Requests for any other diagnosis will be reviewed on a case-by-case basis

DENIAL CRITERIA:

- Recipient does not have a confirmed diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea based on sleep study results; **OR**

- Recipient has not had a PSG for OSA diagnosis **OR** PSG and MSLT for narcolepsy diagnosis; **OR**
- Prescriber has not demonstrated the medical necessity over preferred CII or CIII stimulants; **OR**
- Recipient has not been compliant in using their CPAP or BiPAP before beginning therapy for excessive daytime sleepiness or after beginning therapy

CONTINUATION CRITERIA:

- Prescriber should submit the following:
  - Current chart notes with documentation of response to therapy; **AND**
  - Current Epworth Sleepiness Scale (ESS); **AND**
  - Current CPAP or BiPAP usage report if has OSA diagnosis (recipient must remain compliant on positive airway pressure treatment); **AND**
- Recipient must demonstrate improvement in excessive daytime sleepiness and decreased ESS score

QUANTITY EDITS:

- 75 mg tablet — #30/30 days
- 150 mg tablet — #30/30 days

DISCUSSION:

Dr. Podrazik asked would be considered adequate CPAP usage as it is the treatment for OSA. Chair stated that complete compliance is rarely seen. We consider usage most days per month with multiple hours per day as adequate with continued language to provider about compliance on CPAP. Dr. Podrazik is concerned about the use of stimulants with other comorbidities such as hypertension. Dr. Miller stated that we look at all aspects very thoroughly and on an individual basis. Chair stated that comorbidities are taken into account. No changes made.

ACTION:

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

b. Wakix® (pitolisant) 4.45 mg and 17.8 mg tablets

SUGGESTED CRITERIA:
APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of excessive daytime sleepiness associated with narcolepsy **OR** diagnosis consistent with FDA indications. Diagnosis of narcolepsy is based on International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria; **AND**
- Recipient profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy; **AND**
- Prescriber should submit the following for initial request for narcolepsy:
  - Most recent polysomnogram (PSG) results; **AND**
  - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
    - Mean sleep latency of less than 8 minutes per nap; **AND**

        - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT); **AND**
    - Current chart notes; **AND**
    - Current labs including those for liver and renal function; **AND**
    - Baseline Epworth Sleepiness Scale; **AND**
    - Baseline ECG; **AND**
- Recipient must have a documented trial and failure of CII and CIII stimulants in the last year; **AND**
- Recipient must have a documented trial of solriamfetol in the last year; **AND**
- If recipient is of child-bearing potential and on hormonal contraceptives, they should use alternative non-hormonal contraception; **AND**
- Requests for any other diagnosis will be reviewed on a case-by-case basis

DENIAL CRITERIA:

- Recipient does not have a confirmed diagnosis of excessive daytime sleepiness associated with narcolepsy; **OR**
- Recipient has not had a PSG and MSLT for narcolepsy diagnosis; **OR**
- Prescriber has not demonstrated the medical necessity over preferred CII or CIII stimulants; **OR**
- Recipient has severe hepatic impairment; **OR**
- Recipient has end stage renal disease; **OR**
- Recipient has known QT interval prolongation or requires other medications that prolong the QT interval

CONTINUATION CRITERIA:

- Prescriber should submit the following:
    - Current chart notes with documentation of response to therapy; **AND**
    - Current Epworth Sleepiness Scale; **AND**
- Recipient must demonstrate improvement in excessive daytime sleepiness and decreased ESS score

QUANTITY EDITS:

- 4.45 mg tablets— #60/30 days
- 17.8 mg tablets— #60/30 days

DISCUSSION:

Dr. Johnson asked if we should include not allowing concurrent benzos and other medications that would add to excessive daytime sleepiness. Dr. Podrazik requested the addition of narcotics as well.

ACTION:

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

c. Xyrem® (sodium oxybate)

SUGGESTED CRITERIA:

APPROVAL CRITERIA:

- Recipient must be ≥ 7 years of age; **AND**

- Recipient has a diagnosis of narcolepsy with cataplexy or narcolepsy with excessive daytime sleepiness (EDS); **AND**
    - Recipient ages ≥ 7 years and < 18 years must have a trial of a CII stimulant in the last year
    - Recipient ≥ 18 years
        - Trial and failure of CII stimulant in the last year; **AND**
        - Trial and failure of CIII stimulant (modafinil or armodafinil) in the last year; **AND**
        - Trial and failure of solriamfetol (Sunosi™) in the last year; **AND**
        - Trial and failure of pitolisant (Wakix™) in the last year
- Prescriber should submit the following for initial request:
    - Most recent polysomnogram (PSG) results; **AND**
    - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
        - Mean sleep latency of less than 8 minutes per nap; **AND**
        - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT) ; **AND**
    - Current labs including LFTs; **AND**
    - Current chart notes; **AND**
    - Baseline Epworth Sleepiness Scale (ESS) Score for recipients with excessive daytime sleepiness associated with narcolepsy; **AND**
    - Baseline description of cataplexy events for recipients with cataplexy diagnosis; **AND**
    - Letter explaining the medical necessity of receiving Xyrem®; **AND**
- Prescriber, pharmacy and recipient must be enrolled in the Xyrem® REMS program; **AND**
- Requests for any other diagnosis will be reviewed on a case-by-case basis

DENIAL CRITERIA:

- Recipient does not meet the above approval criteria; **OR**
- Recipient has pharmacy claim(s) for sedative hypnotic agents in the last 30 days; **OR**
- Recipient has a documented diagnosis of drug or alcohol abuse in the last two (2) years; **OR**
- Recipient has a documented history of a suicide attempt in the last two (2) years; **OR**
- Recipient does not have a documented response to this medication

CONTINUATION CRITERIA:

- Recipient must have a documented positive response
    - For narcolepsy with cataplexy—must demonstrate a decrease in cataplexy events
    - For narcolepsy with excessive daytime sleepiness—must have an improvement in daily function and ESS
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current ESS for recipients with EDS; **AND**
    - Current description of cataplexy events (if applicable); **AND**
    - Current labs

QUANTITY EDITS:

- 540 ml (3 bottles) per 30 days

DISCUSSION:

No comments made.

ACTION:

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

C. PROPOSED NEW CLAIM EDITS—none

D. ProDUR Report

Dr. Karen Evans from Magellan gave the ProDUR reports for April-June 2020. There seems to be a decrease in claims and alerts possibly due to COVID-19. Early refill edits and refill-too-soon accumulation logic were removed for noncontrolled drugs on March 23, 2020. This allows the pharmacist to enter an override at POS. The percentage of total overrides remained roughly the same. High Dose, Drug-Drug Interaction, Early Refill, Incorrect Duration and Therapeutic Duplication overrides were similar to the previous quarter with small differences. Early refill override was decreased this quarter due to edits being removed. Incorrect duration and high dose overrides were increased over last quarter which was directly related to the edits removed for COVID-19 based on pharmacist overrides in POS system. The ProDUR system appears to have aided pharmacists in making appropriate decisions on overrides.

E. RDUR Report

Chair notified the board that RDUR services moved from HID to Magellan effective July 1, 2020.

1. Dr. Scott Donald from HID gave a presentation on the department's Retrospective Drug Utilization Review Report for first quarter of calendar year 2020 (January 2020-March 2020) including a RetroDUR Process Overview, Case Summary Report, Program Evaluation Report, ICER Section Detailed Report, Intervention Outcomes Report, Lock-In Program Report, Cost Report by Category, Cost Report by Claim and Program Summary Report.

2. Dr. Lynn Boudreaux from Magellan presented potential intervention criteria to be discussed by the DUR board for August 2020, September 2020, and October 2020. The board made recommendations to perform intervention review on the following:
   - Benzos without SSRIs AND concomitant utilization of opioids with gabapentin for August 2020
   - Atypical antipsychotics in children for September 2020
   - Aripiprazole overuse for October 2020

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

F. Meeting adjourned at 12:02 p.m.