DUR Board Meeting
October 20, 2021
Department of Human Services
Zoom Webinar

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

Board Members and Others Absent
2 physician vacancies
1-2 pharmacist vacancies
Elizabeth Pitman, J.D. (DHS)
Tonya Robertson, Pharm.D.
Florin Grigorian, M.D.

Non-Voting Board Members Present
William Golden, M.D. (advisor)
Barry Fielder, Pharm.D. (ATC)
Tyler Earley, Pharm.D. (Empower)
Lauren Jimerson, Pharm.D. (Summit)
Turkesia Robertson-Jones, Pharm.D. (CareSource)
Shane David, Pharm.D. (in place of Dr. Romero (advisor))

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

Meeting held virtually by ZOOM webinar. A quorum was present, 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:

1) Itzel Harriott, B.S., RPh, MPA, MSP, MBA, Pharm D, CPHRM—Scynexis
Brexafemme®

2) Karen Evenson, Director and Stacy Sandate, PA—Albireo Pharma
Bylvay™

3) Kirk Culotta, Pharm D—Merck
Welireg™

4) Bashir Kalayeh, Pharm D, RPh—Bayer
Kerendia®

5) Erin Hohman, Pharm D, BCPS—AbbVie
Humira®--Hidradenitis Suppurativa

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 Board members
   a. Tonya Robertson, Pharm. D.
   b. Florin Grigorian, M.D.
   c. Turkesia Robertson-Jones, Pharm. D. (CareSource non-voting member)
   d. Tyler Earley, Pharm. D. (Empower)
4. Chair shared the new quarterly provider newsletter
5. Chair discussed claims and prior authorization metrics.

B. REVIEW MINUTES FROM THE JULY 2021 QUARTERLY MEETING

Motion by Dr. Mancino 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 JULY 21, 2021 DUR BOARD MEETING AND AUGUST 11, 2021 DRC MEETING

Manual review criteria were effective immediately for: Verquvo™, Fotivda®, Lumakras™, Empaveli™, Truseltiq™, Hetlioz®

Point-of-sale and claim edit updates: ADHD update (effective 10/19/21), ICS-LABA update (effective 11/2/21), polypharmacy edits (effective 12/1/21).

Effective October 1, 2021, Preferred Drug List (PDL) therapeutic classes from the August 11, 2021 Drug Review Committee Meeting for the following: Alzheimer's Agents, Benign Prostatic Hyperplasia, Hemorrhoidal Preparations, Opiate Dependence Agents (buprenorphine only), Skeletal Muscle Relaxants

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

1. HIDRADENITIS SUPPURATIVA

Chair discussed current PA criteria for Humira® concerning HS indication, information on HS, and treatment guidelines from American Academy for Dermatology.

SUGGESTED CRITERIA:

- Some medications/treatments recommended in Hidradenitis Suppurativa (HS) guidelines may not be a covered product/procedure by Arkansas Medicaid. Refer to the respective provider manual for additional information.
- Recipient with diagnosis of Hurley Stage I HS should use options from the following list (biologics are not recommended for Hurley Stage I):
  1) Topical clindamycin
  2) Oral tetracyclines (tetracycline, doxycycline, minocycline)
  3) Antiandrogenic agents (combined oral contraceptives, spironolactone, finasteride)
  4) Metformin
  5) Alternatives for refractory patients—clindamycin with rifampin, acitretin, dapsone

6) Laser therapy
7) Intralesional corticosteroids
8) Topical resorcinol
9) Surgical drainage

- Recipient with diagnosis of Hurley Stage II or III HS
  - Recipient should follow treatment guidelines (e.g., *Journal of the American Academy of Dermatology*) https://www.jaad.org/action/showPdf?pii=S0190-9622%2819%2930368-8
  - Prior to beginning biologics, the recipient should have tried the following:
    - Oral tetracyclines for a minimum of 3 months (unless contraindicated); **AND**
    - Combination of rifampin and clindamycin for a minimum of 3 months (unless contraindicated); **AND**
    - Oral contraceptives for a minimum of 3 months (females only); **AND**
    - Oral retinoids for a minimum of 3 months (unless contraindicated); **AND**
    - Refractory after treatment—antibiotic therapy with adjunctive treatment of an antiandrogen, metformin, or oral contraceptives (when choosing adjunctive options, consideration the recipient's comorbidities)
  - Recipients who are refractory after combination therapy may benefit from biologics
    - Adalimumab; **OR**
    - Infliximab (2nd line after adalimumab)
  - Prescriber must submit chart notes with documentation of previous therapies tried including surgery or laser treatment; **AND**
  - Comorbidities that can increase HS severity must be addressed (list not all inclusive)
    - Tobacco use
    - Obesity
    - PCOS

DISCUSSION:

Dr. Golden has seen patients with Stage 3 which is a troublesome condition and would be supportive of new therapies such as biologics. He would be a little more restrictive with Stage 2. Dr. Johnson asked if surgery is definitive. Dr. Golden has seen that surgery can sometimes make it worse, but he would have to check. Dr. Johnson stated she could support a patient starting biologics if they are a Stage 3 especially if there is documented superiority of biologics compared to other treatment. Dr. Pearson stated that there is good data to support the biologics as their efficacy may be superior to other therapies. Dr. Mancino stated he would avoid requiring all proposed therapies for Stage 2 as it would take a year to get through all requirements, and if a Stage 2 fails even one 3-month therapy progressing to Stage 3, they may need the biologics. Dr. Golden stated that some of these conditions flare intermittently and some are continuous. With the possible case variation, it would be difficult to impose a one size fits all criteria. Dr. Johnson made the motion to require Stage 2 patients to try at least 2 therapies for 3 months each prior to moving to a biologic, but if during treatment they progress to Stage 3, then biologics would be an option at that time. If a request is received for a Stage 3 patient, a biologic may be an option at that time.

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.

2. SYNAGIS® (palivizumab) injection

Chair discussed Synagis®, AAP guidance, information on RSV, current Synagis® PA form, RSV data from ADH, PCR/Antigen tests from CDC, Arkansas Medicaid data, and interim AAP guidance.

QUESTIONS:

1. Should we keep the typical November to March season?
2. Should we only consider positivity thresholds? If so, what would that be?
   (VT --The end of the RSV "season" is when the positivity rate on antigen tests is ≤ 10% for 2 weeks or the positivity rate on PCR tests is ≤ 4% for 2 consecutive weeks.)
3. Should we use a combination of both—continue to use the typical season and look at positivity rate for requests outside of season?
4. If positivity rates outside of typical season would indicate possible prophylaxis, do we continue with the AAP guidelines for the maximum of 5 doses?

DISCUSSION:

Dr. Johnson asked about the ease of getting data from the Health Department for PCR and Antigen test results. Dr. Pearson stated that the data would more than likely come from the CDC as this is not typically something our health department monitors. Dr. Pearson stated that it is hard to get the data as there may be a delay in reporting. Dr. Magee stated that this has been difficult time trying to figure out what we should do with the kids with no clear answer. This summer was not considered a new season, just an outlier. Dr. Magee suggested that we continue with our typical season from November to March as in the past and maybe look at positivity rates outside of the normal season. We expect a normal RSV season this winter, but you never know. Dr. Pearson stated that we had recent discussions with the health department. These requests are reviewed on a case-by-case basis, and if there is a surge, we're going to help the high risk children. Our staff needs a little more guidance on how to handle the off-season requests more than anything. Dr. Podrazik asked what the delay time was to get the national statistics. Dr. Pearson commented that there may be about a 2 week delay. Dr. Johnson asked if we should reassess based on one month look-back of positivity rates and be driven by the antigen detection tests. During the non-RSV season, once the positivity rate goes down below set thresholds, we should tighten up the criteria. But if the positivity rates stay up, we need to be generous and provide the drug. Dr. Pearson stated that an Antigen test positivity rate around 10% is what Dr. Romero discussed.

ACTION:

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

3. Intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG)

Chair discussed immunoglobulin products, clinical uses of IVIG, mechanism of action, Medicaid claim and cost for the last 2 years, and FDA approved indications for each product.

SUGGESTED CRITERIA:

- All IVIG and SCIG products will be subject to point-of-sale edits
- For a claim to process at POS, the recipient must have a billed diagnosis for an indication found in Table A in the last 2 years
- Recipients without a billed diagnosis from Table A will require a prior authorization request to be submitted by the prescriber. Each PA request will be reviewed on a case-by-case basis. The prescriber must submit the following:
  - Current chart notes
  - Diagnosis requiring immune globulin

- Criteria does not pertain to medically billed claims; only pertains to pharmacy claims.

FDA approved and non-FDA supported immune globulin indications
FDA approved indications
Primary Humoral Immunodeficiency
•Common variable immunodeficiency •X-linked agammaglobinemia •Congenital agammaglobinemia •Wiskott-Aldrich syndrome •Severe combined immunodeficiency
Chronic Immune Thrombocytopenic Purpura
Chronic Inflammatory Demyelinating Polyneuropathy
Kawasaki Syndrome
Multifocal Motor Neuropathy
B-cell Chronic Lymphocytic Leukemia
Dermatomyositis
Supported non-FDA approved indications
Acquired epidermolysis bullosa
Autoimmune hemolytic anemia
Autoimmune neutropenia
Bone marrow transplant
Bullous pemphigoid
Cytomegalovirus Infection (Treatment and prophylaxis)
Disseminated encephalomyelitis
Guillain-Barre Syndrome
Herpes gestationis
Kidney disease (Severe IgA nephropathy)
Linear IgA dermatosis
Lumbosacral radiculoplexus neuropathy
Lymphoproliferative disorder following transplantation
Myasthenia gravis
Ocular cicatricial pemphigoid
Pemphigus vulgaris
Polyarteritis nodosa
Pyoderma gangrenosum
Renal Transplant
Respiratory Syncytial Virus Infection
Stiff-person syndrome
Toxic shock syndrome
Uveitis
von Willebrand disorder

DISCUSSION:
Dr. Golden stated that this is one of those agents that is often used with less than robust evidence. So we need to be cautious and look at the literature carefully as the potential for use is enormous, but supporting evidence is marginal. Dr. Johnson asked if this class can be placed on the PDL. Dr. Pearson noted that we are considering this.

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 presented. Motion passed.

III. NEW BUSINESS

1. KERENDIA® (finerenone) 10 mg and 20 mg tablets

Chair discussed Medicaid estimated reimbursement rates with comparison to spironolactone, FDA indications, information on CKD with Type 2 diabetes, management of diabetic kidney disease, mechanism of action, dosage, and dose modification.

SUGGESTED CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of Type 2 diabetes mellitus and chronic kidney disease **OR** a diagnosis consistent with FDA indications; **AND**

- Recipient must have been treated with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) unless contraindicated and receiving treatment for diabetes based on treatment guidelines; **AND**
- Recipient must have one of the following to confirm the diagnosis of CKD with T2D:
    - UACR of 30-300 mg/g, eGFR 25-60 mL/min/1.73m^2, and diabetic retinopathy **OR**
    - UACR of ≥ 300 mg/g and eGFR 25-75 mL/min/1.73m^2
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous therapies; **AND**
    - Current labs including Urinary Albumin-to-Creatinine Ratio (UACR), eGFR, and potassium level; **AND**
    - Medical necessity over other mineralocorticoid receptor antagonists available without a PA
- Initial approval for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has eGFR < 25 mL/min/1.73m^2; **OR**
- Recipient's baseline serum potassium is > 5 mEq/L; **OR**
- Recipient is receiving concomitant strong CYP3A4 inhibitors (e.g., fluconazole) and strong or moderate CYP3A4 inducers (e.g., efavirenz, rifampicin); **OR**
- Recipient has been diagnosed with adrenal insufficiency (Addison's disease)

CONTINUATION CRITERIA:

- Recipient must demonstrate a decrease in UACR and sustained or improved eGFR after dose titration; **AND**
- Recipient must have a potassium level that remains < 5.5 mEq/L; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including UACR, eGFR, and potassium
- Approval for 6 months

QUANTITY EDITS:

- 20 mg--#31/ 31 days
- 10 mg--#31/ 31 days

DISCUSSION:

Dr. Golden stated that the eGFR range of 25-75 mL/min/1.73m^2 is an enormous range. Patients may stay in the 50-75 mL/min/1.73m^2 range for years so the risk reduction in these patients may be minimal. Clinical studies for this smaller eGFR range would help determine if most diabetics would benefit from this intervention. Dr. Golden would like to see more risk stratification and benefit for different levels of eGFR. Dr. Pearson asked if this would include patients with a really high UACR. Dr. Golden would have to research. Dr. Podrazik stated that there is also the practicality of dealing with hyperkalemia and if treating per protocol, this drug would be way down on the list. Dr. Pearson stated that she doesn't have that data to review at the moment. Bashir Kalayeh from Bayer was available for questions. Drs. Golden and Podrazik wanted additional data with documentation of absolute risk reduction per CKD group. Discussion was tabled.

ACTION:

Motion was made to table the discussion until January 2022 DUR meeting.

2. BREXAFEMME® (ibrexafungerp) 150 mg tablet

Chair discussed the Medicaid estimated reimbursement rate with comparison to fluconazole, FDA indication, mechanism of action, treatment of uncomplicated vaginal candidiasis, dosage, and dose modification.

SUGGESTED CRITERIA:

- Recipient must be post-menarchal; **AND**
- Recipient must have a diagnosis of vulvovaginal candidiasis (VVC) **OR** a diagnosis consistent with FDA approved indication; **AND**
- Recipient must have failed vaginal antifungal treatment AND fluconazole unless cannot tolerate azole antifungals; **AND**
- Prescriber must submit current chart notes

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber requests total dose greater than 600 mg; **OR**
- Prescriber has not tried an azole antifungal if no contraindication; **OR**
- Recipient is pregnant

QUANTITY EDITS:
#4 tablets / 30 days

DISCUSSION:
Dr. Golden asked if the definition of failed antifungal treatment includes reoccurrence within a short period of time or non-clearance of initial infection. Dr. Pearson clarified the intent is non-clearance. No further discussion

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.

3. REZUROCK™ (belumosudil) 200 mg tablet
Chair discussed the Medicaid estimated reimbursement rate, FDA approved indications, information on chronic GVHD with clinical manifestations, treatment recommendations, dosage, and dose modification.

SUGGESTED CRITERIA:

- Recipient must be ≥ 12 years of age; **AND**
- Recipient must be diagnosed with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient of reproductive potential should use effective contraception; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous therapies tried with response; **AND**
    - Current labs including CBC with differential, LFTs, and CMP; **AND**
    - Negative pregnancy test for female recipient 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 demonstrates disease progression; **OR**
- Recipient develops hepatotoxicity while on the medication with either Grade 4 AST or ALT (20X ULN) or Grade 3-4 bilirubin (3X ULN)

- Recipient has the following labs values at baseline:
  - Platelets < 50 X 10^9/L
  - ANC < 1.5 X 10^9/L
  - AST or ALT > 3X ULN
  - Total bilirubin > 1.5X ULN
  - eGFR < 30 mL/min/1.73m^2
  - FEV1 ≤ 39%

CONTINUATION CRITERIA:
- Recipient demonstrates an improvement in baseline symptoms associated with GVHD; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Response to treatment; **AND**
  - Current labs including CBC with differential, LFTs, and CMP

QUANTITY EDITS:
#30/ 30 days

DISCUSSION:
Dr. Johnson asked for verification on the FEV1—were we requiring PFTs on each patient. Dr. Pearson clarified that we were not, only those with pulmonary manifestations. Dr. Pearson updated criteria to clarify.

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

4. BYLVAY™ (odevixibat) 200 mcg and 600 mcg pellets & 400 mcg and 1200 mcg capsules
Chair discussed the Medicaid estimated reimbursement rate, the FDA approved indication, mechanism of action, information on progressive familial intrahepatic cholestasis, dosage, and dose modification.

SUGGESTED CRITERIA:
- Recipient must be ≥ 3 months of age; **AND**
- Recipient must have a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) with a baseline presence of pruritus **OR** a diagnosis consistent with FDA indication; **AND**
- Recipient has elevated serum bile acid concentration; **AND**
- Recipient has documented failure of ursodeoxycholic acid (Ursodiol) ± cholestyramine; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including serum bile acids, serum levels of vitamins A, D, E, and INR (for vitamin K) and LFTs
- Initial approval for 3 months

DENIAL CRITERIA:
- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); **OR**
- Recipient has decompensated liver disease; **OR**

- Recipient should discontinue BYLVAY if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 120 mcg/kg per day.

CONTINUATION CRITERIA:

- Recipient must have a documented decrease in pruritis and/or a decrease in serum bile acid after dose titration; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Current labs including bile acids, serum levels of vitamins A, D, E, and INR (for vitamin K) and LFTs; **AND**
    - Dose required

QUANTITY EDITS:

200 mcg pellets--#62 per 31 days
600 mcg pellets--#31 per 31 days
400 mcg capsules--#155 per 31 days
1200 mcg capsules--#155 per 31 days

DISCUSSION:

Dr. Golden asked how many patients would we expect as this is a rare disease. Dr. Podrazik stated that there are approximately 10,000 in the US. Dr. Golden stated there is no discussion of the bilirubin level in the blood. Dr. Pearson stated she didn't see that documentation in her research. Dr. Johnson stated the patients with bilirubin >10 ULN were excluded. Dr. Johnson wanted the industry rep to discuss the discordance between the effect of 40 mcg/kg and 120 mcg/kg as there is no statistically significant improvement at higher doses especially when these children may not accurately be able to determine their itch scores. Stacy Sandate provided a comment. Dr. Johnson cannot find Trial 2 results. Dr. Johnson stated that generally in a long term extension trial there is selection bias, because the people who have responded remain in the trial and those people without significant response dropped out. Dr. Johnson asked if we could require a trial of cholestyramine. Dr. Pearson stated she is not opposed to that requirement, but there is an age restriction on cholestyramine. Dr. Johnson stated that data on the 2 trials is not easy to find and poses lots of questions on this very expensive medication. Dr. Johnson wanted the ± cholestyramine to be changed to AND unless there is a contraindication. Dr. Johnson suggested a re-evaluation in 2 quarters. Dr. Mancino asked if there is a requirement around the genetic testing. Dr. Pearson didn't know if ABCB11 variant testing is covered by Medicaid. Dr. Johnson suggested we require the testing since it may prevent this medication being given to a patient where it will not be effective. Dr. Pearson will check if this genetic testing is covered and will include as a requirement if covered. Dr. Johnson questioned the definition of meaningful response. Stacy Sandate provided a response. Dr. Johnson recommended that we update bullet 4 on the approval criteria slide to say documented failure as monotherapy for Ursodiol and require concomitant therapy of Ursodiol if this product is approved.

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.

5. AEMCOLO™ (rifamycin) 194 mg tablet

Chair discussed the Medicaid estimated reimbursement rate, FDA approved indication, information on travelers' diarrhea, CDC treatment recommendations, and dosing requirements.

SUGGESTED CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with travelers' diarrhea caused by non-invasive strains of *Escherichia coli* **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Documentation of previous treatment; **AND**
    - Medical necessity over other antibiotics available without a PA

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber ordered a dosage or therapy duration outside of FDA indication or support on the official Compendia; **OR**
- Recipient has a fever and/or bloody stools

CONTINUATION CRITERIA:

- Recipient continues to have symptoms of travelers' diarrhea; **AND**
- Prescriber must submit the following:
    - Current fecal culture & sensitivity report documenting an E. coli infection

QUANTITY EDITS:
#12/ 23 days

DISCUSSION:
No comments

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.

6. WELIREG™ (belzutifan) 40 mg tablet
Chair discussed the Medicaid estimated reimbursement rate, FDA approved indication, information on von Hippel-Lindau disease, mechanism of action, dosage, and dose modification.

SUGGESTED CRITERIA:

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must be diagnosed with von Hippel-Lindau (VHL) disease and require therapy for renal cell carcinoma, central nervous system hemangioblastoma, or pancreatic neuroendocrine tumor but does not require immediate surgery **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient of reproductive potential should use effective non-hormonal contraception; **AND**
- Prescriber must submit the following:
    - Current chart notes; **AND**
    - Previous therapies tried; **AND**
    - Documentation of diagnosis (i.e., MRI results, fundoscopy report, abdominal US/MRI results, or blood & urinary catecholamine metabolites) with tumor size; **AND**
    - Current labs; **AND**
    - Baseline oxygen saturation; **AND**

  - Pregnancy test results of female recipient of reproductive potential
- Initial PA approved for 1 month

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient with a hemoglobin <9 g/dL should have medication withheld (If possible, resume at reduced dose if Hb increases to ≥9 g/dL.) and permanently discontinue depending on the severity of anemia; **OR**
- Recipient with decreased oxygen saturation (pulse oximeter <88%) should have medication withheld (If possible, resume at same or reduced dose depending on severity.) and permanently discontinue for life-threatening or recurrent symptomatic hypoxia; **OR**
- Recipient has severe renal or hepatic impairment; **OR**
- Recipient requires immediate need for tumor surgery

CONTINUATION CRITERIA:

- Recipient does not have intolerable side effects; **AND**
- Recipient has a positive response on tumor size (timeframe??); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs; **AND**
  - Oxygen saturation if recipient has hypoxia symptoms; **AND**
- Subsequent PAs approved for 3 months

QUANTITY EDITS:
#90/ 30 days

DISCUSSION:
Dr. Mancino asked if we expect a response after the initial 1 month PA. Dr. Pearson stated that short PA is to monitor for side effects. Dr. Kirk Culotta (industry rep) stated that the median time to determine response for RCC tumors was 8 months. Based on the industry rep's comments, Dr. Pearson recommended a positive response with a reduction in tumor size should be seen by a year after beginning therapy.

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

7. Antiepileptic medication quantity edits
Chair discussed the future placement on PDL and maximum quantities based on FDA indication. After reviewing utilization by our Medicaid clients, many times FDA approved doses are exceeded.


Seizure meds max dose draft 2.xlsx

DISCUSSION:
Dr. Golden asked if the outliers have been case reviewed. Dr. Pearson stated that they have not been reviewed. Dr. Golden stated the best option may be to perform systematic review of the outliers to identify potential opportunities for dose reduction instead of grandfathering them in with the outlying dose. Dr. Mancino

suggested that patients with higher doses may require a physician to submit documentation of tolerance with the higher dose, improved efficacy at the higher dose, and lowering the dose has negative effects. Dr. Pearson stated that would be the same as a Letter of Medical Necessity. Dr. Miller stated that many of these drugs have psychiatric uses, and patients may titrate up to higher doses. We would want to have some information on the chronology of how they got to the dose requested. Dr. Miller stated that he is concerned about the lack of blood level monitoring for these medications. Dr. Pearson stated that most products will not be a problem as FDA approved doses are usually adhered to. But for those few drugs that have significant dosing outside of the PI, checking the profiles individually would be cumbersome. Dr. Mancino brought up that some drugs have ideal blood levels that are different based on diagnosis, such as divalproex. Dr. Miller stated that we would take diagnosis in consideration. Dr. Pearson stated that we can accept the FDA approved dosing. For those dosing outlier drugs, we can raise the quantity a bit above the PI dosing to prevent so many needed PAs. Dr. Miller suggested that we perform an RDUR review for these patients.

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 presented. Motion passed.

8. Dose optimization on various drug classes

Chair discussed the benefit of dose optimization for our program with examples of potential savings. The classes reviewed were blood pressure, diabetes, blood modifiers, and cholesterol.

Dose optimization spreadsheet.xlsx

DISCUSSION:

Dr. Golden noted that many of the products in the list are archaic and questioned if we are still required to cover them. Dr. Pearson verified that we must cover them if rebateable, but these classes are on the PDL which allows us to focus on the more effective medications. Dr. Golden asked about supporting the use of combination products like Exforge generic. Dr. Pearson stated that we do have some combination products as preferred which was confirmed by Dr. Boudreaux. Dr. Golden wanted to know if excessive doses (ex: Clonidine 3mg per day) would be flagged for review. Dr. Pearson stated that doses exceeding the allowed through quantity edits would require a review.

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.

IV. REPORTS

A. ProDUR Report

1. Dr. Cinnamon Pearson gave the combined PASSE ProDUR report for 4th quarter of SFY2021 (April-June). The PASSEs had a combined 278,393 paid claims with 44,281 ProDUR alerts resulting in 23,240 cancelled claims or 52.5% 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 1st Quarter encompasses the months of July, August, and September 2021.

Approximately 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 being utilized. 75% of the time, Pharmacists chose not to override the alert.

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 the quarterly lock-in report and potential intervention criteria to be discussed by the DUR board for November 2021, December 2021, and January 2022. 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:

November 2021—7058 APAP with other meds which may have hepatotoxic side effects
December 2021—5167 Tramadol with SSRIs or SNRIs
January 2022—7879 Non-compliance with anticonvulsant medications for seizure patients

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

C. Meeting adjourned at 11:50 a.m.