Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	January 19, 2022 8:33 - 12:17 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lynn Boudreaux, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
	X	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.	X	Tyler Earley, Pharm.D.	Empower
	X	Lana Gettman, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Florin Grigorian, M.D.	X	Turkesia Robertson-Jones, Pharm. D.	CareSource
	X	Jill Johnson, Pharm.D.		Elizabeth Pitman	DHS Director
	X	Brian King, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	James Magee, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Michael Mancino, M.D.	X	William Golden, M.D.	DHS advisor
	X	Laurence Miller, M.D.		Jose Romero, M.D.	ADH advisor
	X	Paula Podrazik, M.D.	X	Shane David, Pharm.D.	ADH advisor
	X	Tonya Robertson, Pharm.D.	X	Karen Evans, P.D.	Magellan
		Vacant M.D. position	X	Lynn Boudreaux, Pharm.D.	Magellan
		Vacant M.D. position			
		Vacant Pharm.D. position			
		Vacant Pharm.D. position			

Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:33am.
Public comments		1. Pratik Parikh, Sr MSL, PA—Mirum Pharmaceuticals (Livmarli™) 2. Andrew Howe, Pharm.D.—Novartis (Scemblix®) 3. Matthew Redmann, PhD—UCB (Nayzilam®) 4. Matt Ackermann, PhD—ChemoCentryx (Tavneos™) 5. Sunita Misra, MD, PhD—Neurelis (Valtoco®)
Announcements		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Boudreaux. 2. Reimbursement rates are based on WAC, FUL or NADAC. 3. Recognition of new Board members—Tonya Robertson, Pharm.D. and Florin Grigorian, M.D. 4. Quarterly provider newsletter--  Arkansas Medicaid Quarterly Newsletter .
Minutes		Motion to approve October 2021 meeting minutes was made by Dr. Mancino, seconded by Dr. Miller. All voting members present voted to approve the minutes as written. Motion passed.
Criteria change review		**1. Palforzia® (peanut powder)** Dr. Pearson provided a summary of the ICER 2019 and Prime Therapeutics 2019 reports. Based on the lack of new data since the original review in 2020, Dr. Pearson recommended no change in the current prior authorization criteria.

DISCUSSION:
Dr. Pearson asked Dr. Magee for his comments given that Dr. Jones from Arkansas Children's Hospital had expressed some concerns. Dr. Magee stated that Dr. Jones' concern was the PA approval length of two months was not long enough and should be extended to 6 months. Dr. Pearson commented that the 2 month PA was implemented in part due to a new PA is required for every step of the titration (dose changes approximately every 2 weeks). Dr. Mancino wanted to clarify 2 weeks vs 2 months. Dr. Pearson explained that the dose titrates up every 2 weeks if the patient tolerates the increase, and the pharmacy team must put in 4 separate PAs to cover that 2 month timeframe. Dr. Bemberg made the comment that there would be an edit for therapeutic duplication. The industry representative commented in the chat box that Palforzia has a REMS program, and the specialty pharmacy must verify the dose prior to dispensing. Dr. Pearson commented that we are not receiving PA requests for this medication. Dr. Magee stated that with no patients he is less excited about pushing for a change and asked to revisit the discussion if PAs become a burden.

ACTION:
Motion made to keep current criteria was made by Dr. Magee; seconded by Dr. Miller. All members present voted for the motion. Motion passed.

2. Quetiapine

Dr. Pearson discussed the increasing utilization of quetiapine for off-label uses, and she provided information on schizophrenia and bipolar disorder. Dr. Pearson provided the following as proposed criteria:

POINT-OF-SALE CRITERIA:

- Recipients <18 years of age will not be included in this POS edit
- If the recipient does not meet one of the POS criteria, a prior authorization request must be submitted including the following:
  - Current chart notes
  - Previous medication therapies
  - Medical necessity for the off-label use (If the request is for sedation, provide the medical necessity over other medications that can be used for sleep such as melatonin, trazodone, and alpha blockers.)

Criterion 1: Recipient has a billed diagnosis in the past two years for one of the following:

- Schizoaffective disorder
- Schizophrenia
- Bipolar I disorder
- Bipolar II disorder
- Unspecified bipolar and related disorder
- Unspecified schizophrenia spectrum and other psychotic disorders
- Delusional disorder

Criterion 2: Recipient has a paid pharmacy claim in their Medicaid drug history for quetiapine in the last 120 days

DISCUSSION:
Dr. Johnson wanted to clarify that we would be grandfathering in the patients currently taking for off-label use. Dr. Pearson confirmed as we do not want to cut patients off "cold

turkey". Dr. Miller stated that in his case reviews, he is seeing an increase in the number of adults who've been prescribed low dose Seroquel for sleep without a psychiatric diagnosis and have not been worked up for other causes of insomnia. Dr. Mancino had no comment. Dr. Podrazik commented that Seroquel may be added if the patient is hospitalized with delirium and harm of self, and the medication list is not reviewed afterward.

ACTION:
Motion to approve criteria as presented was made by Dr. Bemberg; seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

3. **Rescue seizure medications (Valtoco® and Nayzilam®)**
Dr. Pearson provided the estimated reimbursement rate, indications, current manual review criteria, and utilization data for Nayzilam®, Valtoco®, and diazepam rectal gel. Dr. Pearson provided the following as proposed criteria:

PROPOSED NEW CRITERIA:

- Recipients with a billed diagnosis of seizures may receive NAYZILAM without a PA if between 12-18 years of age. (If the minimum FDA approved age changes, this rule will be updated to match the package insert.)
- Recipients with a billed diagnosis of seizures may receive VALTOCO without a PA if between 6-18 years of age. (If the minimum FDA approved age changes, this rule will be updated to match the package insert.)
- Recipients that are younger than the FDA approved age will require a prior authorization.
- Recipient ≥ 19 years of age require a PA meeting the following criteria:
    - Diagnosis of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern; **AND**
    - Recipient is currently stable on regimen for antiepileptic drugs (AEDs); **AND**
    - Prescriber must be a neurologist and submit the following:
        - Current chart notes; **AND**
        - Medical necessity over the use of diazepam rectal gel
    - PA request may be denied if the recipient has any of the following:
        - Severe chronic cardio-respiratory disease (NAYZILAM request only); **OR**
        - History of acute narrow-angle glaucoma; **OR**
        - Taking moderate or strong CYP3A4 inhibitors
- Quantity edits will remain the same: NAYZILAM—10 doses per month; VALTOCO—10 doses per month

DISCUSSION:
Dr. Johnson recommended to remove the medical necessity over diazepam rectal gel. Dr. King stated that ACH had been using injectable Versed in the atomized route. Dr. Johnson asked if continuation criteria was an option, and for a patient to continue to get these products you had to have an adjustment in your seizure meds or improvement in compliance. Dr. Robertson agreed that compliance would be expected similar to the rules for asthma/COPD treatment. Dr. Robertson suggested to monitor patients refilling multiple months. Dr. Evans stated that POS edits can be used to require a billed diagnosis for seizures, paid claim in the last 2 months for antiepileptic, and deny rescue medication if

more than 2 months are filled in a row requiring a manual review PA. Dr. Magee asked if we are still requiring the request to come from a neurologist. Dr. Pearson stated that the use of a neurologist could not be monitored at POS. But if the patient did not meet criteria and required a PA, a neurologist's input would be required.

ACTION:
Motion made by Dr. Johnson to approve the amended criteria; seconded by Dr. Robertson. All members voted to approve the amended motion. Motion passed.

New Business

1. **Kerendia® (finerenone)**

Dr. Pearson provided the estimated reimbursement rate, information on CKD with T2D, treatment guidelines, and drug information. Kerendia was tabled during the October 2021 DUR Board meeting for further research. Dr. Pearson provided the following as proposed criteria:

APPROVAL 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 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
- 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 tried and failed an aldosterone inhibitor unless contraindicated; **AND**
- Recipient must be a non-smoker or participating in a tobacco cessation program**; AND**
- Recipient must have controlled diabetes (HbA1c <9%) and blood pressure (BP < 130/85); **AND**
- 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 be a non-smoker; **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 this medication is an investment in prevention, and it is in many ways kind of a second or third line preventative measure to reduce cardiovascular risk as well as renal risk for patients with diabetes and some kidney dysfunction. There are other interventions that are more essential to the prevention of progressive renal failure and cardiovascular disease. A preventative program needs to start with smoking cessation and blood pressure control.

ACTION:

Motion to approve criteria as presented was made by Dr. Johnson; seconded by Dr. King. All other members presented voted for the motion. Motion passed.

2. Tavneos™ (avacopan)

Dr. Pearson provided the estimated reimbursement rate, indications, drug information, information on the disease state, and treatment recommendations. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; **AND**
- Recipient must have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient had previous therapy with an immunosuppressant (i.e., rituximab or cyclophosphamide) and corticosteroids based on treatment guidelines; **AND**
- Recipient must be concomitantly prescribed standard therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapy; **AND**
  - Current labs including positive ANCA test results, anti-PR3 and anti-MPO if available, baseline LFTs, and Hepatitis B serology (HBsAg and anti-HBc); **AND**
  - If available, chest x-ray or CT scan results used for diagnosis confirmation; **AND**

- If available, biopsy reports used for diagnosis confirmation

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has severe hepatic impairment OR AST/ALT >5X ULN OR AST/ALT >3X ULN with bilirubin >2X ULN; **OR**
- Recipient should avoid the use of CYP3A4 inhibitors (e.g., ketoconazole, cyclosporine, erythromycin) if possible. If concomitant use is required, TAVNEOS dose should be decreased to 30 mg once daily; **OR**
- Recipient develops reactivation of HBV while on TAVNEOS; **OR**
- Recipient has an active, serious infection including localized infections; **OR**
- Recipient is pregnant or breastfeeding

CONTINUATION CRITERIA:

- Recipient demonstrates a therapeutic response with disease stability and/or improvement; **AND**
- Recipient has achieved remission by week 52 of therapy (based on length of the clinical trial); **AND**
- Recipient is compliant on TAVNEOS and standard therapy**; AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including LFTs; **AND**
  - Documentation of response to therapy

QUANTITY EDITS:
#180 capsules/ 30 days

DISCUSSION:
No discussion

ACTION:
Motion to approve criteria as presented was made by Dr. Johnson; seconded by Dr. Podrazik. All members present voted to approve the criteria. Motion passed.

3. Exkivity™ (mobocertinib)

Dr. Pearson provided the estimated reimbursement rate, indication, drug information, information on NSCLC, and treatment/NCCN recommendations. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; **AND**
- Recipient must have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (Stage IIIB or IV) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have disease progression on or after platinum-based chemotherapy; **AND**
- Female recipients of reproductive potential must use effective non-hormonal contraception; **AND**
- Recipient must have normal lab values for electrolytes (i.e., sodium, potassium, calcium, and magnesium). Prior to beginning medication, electrolyte abnormalities must be corrected; **AND**

- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapy; **AND**
  - Baseline QTc interval; **AND**
  - Baseline left ventricular ejection fraction; **AND**
  - Baseline labs including CBC and CMP; **AND**
  - Documentation of treatment plan for possible diarrhea

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient is pregnant; **OR**
- Recipient has severe renal impairment or severe hepatic impairment; **OR**
- Recipient requires hormonal contraceptives, strong or moderate CYP3A inducer, or strong or moderate CYP3A inhibitor (EXKIVITY dose may need to be adjusted); **OR**
- Recipient has a prolonged QTc interval (clinical trials included QT intervals of ≤ 450ms for males and ≤ 470ms for females) or being treated with medications known to cause Torsades de Pointes; **OR**
- Recipient has been diagnosed with interstitial lung disease or pneumonitis; **OR**
- Recipient has Grade 2 heart failure or Grade 3 or 4 decreased ejection fraction (EF <39%)

CONTINUATION CRITERIA:

- Recipient must not demonstrate disease progression or unacceptable toxicity; **AND**
- Female recipients of reproductive potential remain on non-hormonal contraception; **AND**
- Recipient's lab values must remain within normal limits; **AND**
- Recipient must not have Grade 2 or greater heart failure or an EF <39%; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of disease response; **AND**
  - Current labs; **AND**
  - Current cardiac function tests if available

QUANTITY EDITS:

#124/31 days

DISCUSSION:

Dr. Johnson noted that the data for this drug and the other NCCN recommended therapy for this mutation are from single arm data with only the outcome of the primary outcome of response rates. There is no comparative data with this drug to anything else, and there are alternative therapies for NSCLC including Keytruda, Opdivo, or docetaxel. Dr. Grigorian feels the criteria is strong enough.

ACTION:

Motion to accept the criteria as presented was made by Dr. Grigorian; seconded by Dr. Johnson. All members present voted for the motion. Motion passed.

4. Opzelura™ (ruxolitinib)

Dr. Pearson provided the estimated reimbursement rate, indication, drug information, and information on atopic dermatitis. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥12 years of age; **AND**
- Recipient should have mild or moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2-3 out of a 0-4 scale **OR** a diagnosis consistent with FDA indications; **AND**
- Recipient must have uncontrolled mild to moderate atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (i.e., tacrolimus, pimecrolimus); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapies; **AND**
  - Current IGA score; **AND**
  - Current baseline Itch Numerical Rating Scale (Itch NRS); **AND**
- If approved, PA will be approved for 2 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has a history of skin cancer; **OR**
- Recipient has severe atopic dermatitis; **OR**
- Recipient's atopic dermatitis affects greater than 20% of BSA; **OR**
- Prescriber requests continuance beyond 8 weeks without improvement; **OR**
- Recipient has been approved for biologics, JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine

CONTINUATION CRITERIA:

- After 8 weeks, recipient has an improvement of IGA score to 0-1 **OR** ≥ 4 point improvement in itch NRS; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of current IGA score and Itch NRS; **AND**
  - Medical necessity to continue beyond 8 weeks

QUANTITY EDITS:

4 tubes (240 gm)/ 30 days

DISCUSSION:

Dr. Johnson noted that patients with moderate atopic dermatitis may be better served to use Dupixent than Opzelura considering the price difference. Dr. Johnson asked if we could decrease the maximum monthly quantity. Dr. Robertson agreed that 4 tubes per month would be excessive given the patients would be mild-moderate in severity with small BSA. Dr. King asked how many recent claims for steroids would we require. Dr. Pearson stated that she would expect to see different potencies of TCS like category 1, clobetasol then topical a calcineurin inhibitor. Dr. Pearson will update bullet 3 to include information on steroids and decrease the quantity edits to 2 tubes per month.

ACTION:

Motion to approve the criteria as amended was made by Dr. Johnson; seconded by Dr. Miller. All members present voted for the motion. Motion passed.

5. Livmarli™ (maralixibat chloride)

Dr. Pearson provided the estimated reimbursement rate, indication, drug information, and information on Alagille syndrome. After discussion with the Board members, Livmarli™ was tabled until the next DUR meeting.

6. Scemblix® (asciminib)

Dr. Pearson provided the estimated reimbursement rate, indication, drug information, information on Ph+ CML, and NCCN recommendations. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; **AND**
- Recipient must have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) previously treated with two or more tyrosine kinase inhibitors (TKIs) (e.g., imatinib, nilotinib, dasatinib, radotinib or ponatinib) **OR** Ph+ CML in CP with the T315I mutation **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBC, serum lipase, and amylase levels; **AND**
  - Genetic test results with confirmation of the Philadelphia chromosome and/or the BCR-ABL gene; **AND**
  - Test results for the T315I mutation, if applicable; **AND**
  - Previous therapy; **AND**
  - Current blood pressure; **AND**
- Initial PA will be approved for 1 month to determine tolerability

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient without the T315I mutation must be able to tolerate the minimum dose of 40 mg daily (or 20 mg twice daily); Recipient with the T315I mutation must be able to tolerate the minimum dose of 160 mg twice daily; **OR**
- Recipient has uncontrolled hypertension; **OR**
- Recipient has baseline platelets <50 X 10^9/L; **OR**
- Recipient has recent history of pancreatitis; **OR**
- Recipient is pregnant

CONTINUATION CRITERIA:

- Recipient has continued response without unacceptable toxicity; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including CBC (CBCs should be reviewed every 2 weeks for the first 3 months then monthly.), serum lipase and amylase levels (Labs must be checked at least monthly for monitoring pancreatitis.) Dosing should be based on these labs per the package insert.; **AND**
  - Requested dose

QUANTITY EDITS:

20 mg--#60/ 30 days
40 mg--#60/ 30 days

PA required for quantity override on patients with T315I mutation

DISCUSSION:
Dr. Johnson stated that the indication for patients with the T315I mutation should have to fail ponatinib as it is not contraindicated and has data that shows a 58% molecular response rate compared to 24-49% with asciminib, and the ponatinib is cheaper. If ponatinib was one of the TKIs tried prior to development of the mutation, they can bypass it when diagnosed with the mutation.

ACTION:
Motion to approve the amended criteria was made by Dr. Johnson; seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

7. Vuity™ (pilocarpine hydrochloride)
Dr. Pearson provided the estimated reimbursement rate, indication, drug information, and information on presbyopia. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:
- Recipient must be ≥18 years of age; **AND**
- Recipient must have a diagnosis of presbyopia **OR** a diagnosis consistent with FDA approved indication; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Medical necessity over other treatment options for presbyopia

DENIAL CRITERIA:
- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has a history of glaucoma or ocular hypertension; **OR**
- Recipient has a history of cataract surgery, phakic intraocular lens surgery, corneal inlay surgery, radial keratotomy, or any intraocular surgery

CONTINUATION CRITERIA:
- Recipient has documented improvement in presbyopia defined as the patients gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA)

QUANTITY EDITS:
2 bottles per 25 days

DISCUSSION:
Dr. Grigorian stated that the total addressable market is huge as at least half of the adults after 65 will have this condition. Dr. Grigorian feels that the criteria is stringent enough, but we should allow only one bottle per 25 days.

ACTION:
Motion to approve the amended criteria was made by Dr. Grigorian; seconded by Dr. King. All members present voted for the motion. Motion passed.

8. Voxzogo™ (vosoritide)
Dr. Pearson provided the estimated reimbursement rate, indication, drug information, information on achondroplasia and clinical trial results. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be 5-17 years of age; **AND**
- Recipient must have a diagnosis of achondroplasia (ACH) **OR** a diagnosis consistent with FDA approved indications; **AND**
- Recipient must have open epiphyses; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Genetic test results and radiologic findings confirming the diagnosis of achondroplasia; **AND**
  - Baseline standing height; **AND**
  - Current weight; **AND**
  - Requested dose; **AND**
  - X-ray demonstrating epiphyses status for patients nearing puberty

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Recipient has closed epiphyses; **OR**
- Recipient has a diagnosis of hypochondroplasia or short stature condition other than ACH; **OR**
- Recipient has been treated with growth hormone in the previous 6 months

CONTINUATION CRITERIA:

- Recipient demonstrated a positive response with linear growth velocity after 1 year; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current standing height; **AND**
  - Current weight; **AND**
  - Requested dose; **AND**
  - X-ray demonstrating epiphyses status for patients nearing puberty

QUANTITY EDITS:

Each strength--#30 vials/30 days (packaged in 10 vials per kit)

DISCUSSION:

Dr. Mancino commented that nearing puberty is a huge variation and wonders if we should pick an age to require x-rays. Dr. Magee stated that he would expect the prescriber to be getting x-rays frequently. Dr. Magee asked what specialist would be ordering this medication—genetics? Dr. Magee asked how a provider submitted an x-ray for review. Dr. Pearson stated we would expect the radiologist report not actual x-rays. Dr. Robertson asked the Board to define a positive response with linear growth velocity after 1 year. Dr. Johnson stated that we are assuming they continue to grow with the same velocity, but we don't have the data beyond 52 weeks. Dr. Johnson noted that these are kids which will be growing without the medication, so we don't know if growth continues at the same rate or not. Dr. Johnson asked how many years we would approve this for. Dr. Pearson stated that per the FDA indication, approval could be up to 12 years. Dr. Robertson asked if this is a medication we have to cover. Dr. Pearson stated this is a rebateable drug for a documented genetic illness, so we would be required to cover it. Dr. Golden stated that this medication would probably fall under EPSDT. Dr. Grigorian stated that this is not a cosmetic treatment. Dr. Mancino asked to review the growth charts again…growth in these patients would have a mean of about 4cm per year. Dr. Miller commented that it will be manually reviewed

which allows the clinical team to ask questions, and we should not box ourselves in with specific numbers. Dr. Pearson stated that we can ask for the x-ray reports yearly to monitor epiphyses status. Dr. Magee noted that a new clinic has been started at ACH for skeletal dysplasia with specialists including ortho/genetics/endo.

ACTION:
Motion to approved as amended was made by Dr. Mancino; seconded by Dr. Miller. All members present voted for the motion. Motion passed.

9. Carbaglu® (carglumic acid)

Dr. Pearson provided the estimated reimbursement rate, indications, information on the urea cycle and information on the disease states (NAGS deficiency, PA, and MMA). Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must have a diagnosis of hyperammonemia due to N-acetylglutamate Synthase (NAGS) deficiency, Propionic Acidemia (PA), or Methylmalonic Acidemia (MMA) **OR** a diagnosis consistent with FDA approved indication; **AND**
- Recipient must remain on standard of care therapy for acute, severe hyperammonemia, and CARBAGLU can be used alone in chronic NAGS; **AND**
- Prescriber must order a dose consistent with diagnosis and kidney function; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including plasma ammonia levels and eGFR; **AND**
  - Current weight; **AND**
  - Current BMI for recipients with PA or MMA weighing more than 15 kg; **AND**
  - Daily dose requested; **AND**
  - Number of days treated while hospitalized for PA or MMA (max of 7 days total)

DENIAL CRITERIA:

- Recipient does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber requests therapy for PA or MMA for longer than 7 days total which includes doses received during hospitalization; **OR**
- Prescriber requests dose outside of guidance from package insert

CONTINUATION CRITERIA:

- Recipient with chronic NAGS has a positive response with plasma ammonia levels maintained in the normal range; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including plasma ammonia levels and eGFR; **AND**
  - Current weight; **AND**
  - Daily dose requested

DISCUSSION:
Dr. Miller stated that since this should be used as adjunctive treatment in acute NAGS, we need to add the requirement of continued standard treatment for acute NAGS with

		prescriber submitting that documentation. **ACTION:** Motion made to approve as amended by Dr. Miller; seconded by Dr. Podrazik. Dr. Gettman did not vote. All other members voted for the motion. Motion passed.
Reports		**1. ProDUR Report** a. The combined PASSE ProDUR report for the 1st quarter of SFY 2022 (July-September 2021) was given by Dr. Pearson. The PASSEs had a combined 282,469 paid claims with 45,618 ProDUR alerts resulting in 24,395 cancelled claims or 53.5% of alerts cancelled at POS. b. Dr. Karen Evans from Magellan gave the FFS quarterly ProDUR reports. The average number of paid claims per month was 364,875 with 71% of those claims screened by DUR. Of the claims screened by DUR, pharmacies received 350,542 alert messages. Approximately 74.5% of those alerts were not overridden by the reviewing pharmacist. **2. RDUR Report** Dr. Lynn Boudreaux from Magellan presented the quarterly RDUR report which included the following: lock-in report, potential intervention criteria, Top 25 drug report by claims, Top 25 products by reimbursement, Top 25 products by net net expenditures, Top 10 prescribers by total amount paid, Top 10 pharmacies by total amount paid, Top 10 prescribers of opioids, and Top 10 pharmacies filling opioid claims. The Board made the following recommendations: **February 2022**—7827 Bipolar Disorder with antidepressants and no mood stabilizers **March 2022**—7942 Members with 6 or more narcotic claims with no naloxone in 180 days AND 7982 concurrent use of opioids and antipsychotics **April 2022**—7742 CNS polypharmacy Motion was made by Dr. Mancino to accept the recommended criteria and seconded by Dr. Robertson. All other members present voted by roll call to accept the motion. Motion passed.
Adjourn		Meeting adjourned at 12:17pm.