Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	April 20, 2022 8:43 – 11:46 AM 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.		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	X	Nick Shull, Pharm.D.	ADH
		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 8:43am.			
Public comments		1. Tom DeAngelis, Pharm.D.—Xeris Pharmaceuticals Recorlev® 2. Doug McCann, Pharm.D.—Takeda Livtencity™ 3. Rowland Elwell, Pharm.D.—Calliditas Tarpeyo™ 4. Keanna Dandridge, MSN—Novartis Leqvio® 5. Samantha Sam, Pharm.D.—ViiV Healthcare Apretude			
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. Quarterly provider newsletter-- Arkansas Medicaid Quarterly Newsletter			
Minutes		Motion to approve January 2022 meeting minutes was made by Dr. Podrazik, seconded by Dr. Miller. All voting members present voted to approve the minutes as written. Motion passed.			

Criteria change review		**1. Antiemetics During Pregnancy** Dr. Pearson provided a summary of treatment options with guidelines from UpToDate, indications for multiple medications, coverage summary from other Medicaid programs, and pregnancy concerns. Dr. Pearson provided the following as proposed criteria: **Two point-of-sale options for Diclegis®** 1) Recipient has a billed diagnosis of pregnancy and no documentation of delivery or pregnancy termination within the last 9 months; **OR** 2) Recipient has a billed diagnosis of pregnancy and no documentation of delivery or pregnancy termination within the last 9 months **AND** a pharmacy claim for ondansetron or promethazine in the last 90 days **Bonjesta® criteria:** • Manual review on a case-by-case basis • Confirmation of pregnancy • Medical necessity over Diclegis® **Promethazine, 5HT-3 antagonist, and NK-1 antagonists** • No change—promethazine does not require a PA, 5HT-3 antagonists and NK-1 antagonists will remain on the preferred drug list with ondansetron as preferred option • Quantity limits still apply **DISCUSSION:** Dr. Bemberg asked if we were voting brand/generic on Diclegis®. Dr. Pearson stated it is currently not on our PDL, but we may review for Plan Prefers Brand status. The POS edits decided today would apply to the preferred option. Dr. Bemberg recommended option 1 that did not include pharmacy claim for other antiemetics in history. Dr. Evans asked if lab values would be included. Dr. Bemberg agreed to include both diagnosis and labs. Bonjesta® will remain manual review. **ACTION:** Motion made to approve the criteria as amended was made by Dr. Bemberg; seconded by Dr. Johnson. All members present voted for the motion. Motion passed.
New Business		**1. Livarli™ (maralixibat chloride)** Dr. Pearson provided the estimated reimbursement rate, information on Alagille Syndrome, and drug information. LIvamarli™ was tabled during the January 2022 DUR Board meeting for further research. Dr. Pearson provided the following as proposed criteria: **APPROVAL CRITERIA:** • Recipient must be ≥1 year of age; AND • Recipient must have a confirmed diagnosis of Alagille syndrome with a baseline presence of cholestatic pruritis OR a diagnosis consistent with FDA indication; AND • Recipient has elevated serum bile acid concentration; AND • Recipient has documented failure of ursodeoxycholic acid (Ursodiol®) AND a bile acid sequestrant unless there is a documented contraindication; AND • Recipient should continue ursodeoxycholic acid concomitantly; AND • Prescriber must submit the following: o Current chart notes; AND

- Current labs including serum bile acid level, LFTs, and fat-soluble vitamins (A,D,E, and INR); AND
- Current weight for dose determination; AND

- 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 documented hepatic decompensation; OR
- Prescriber orders a daily dose >28.5 mg; OR
- Recipient is not concurrently ordered ursodeoxycholic acid; OR
- Recipient should discontinue LIVMARLI if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 380 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 fat-soluble vitamins, and LFTs; AND
  - Dose required

QUANTITY EDITS:
3 bottles (90 mL)/ 30 days

DISCUSSION:
No comments

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

2. Livtencity™ (maribavir)

Dr. Pearson provided the estimated reimbursement rate, information on cytomegalovirus, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 12 years of age and weigh at least 35 kg; AND
- Recipient must have received either a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) with diagnosed CMV that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet OR a diagnosis consistent with the FDA approved indication; AND
- Recipient must not exceed the following dosages:
- 800 mg per day
- If co-administered with carbamazepine: 1600 mg per day
- If co-administered with phenytoin or phenobarbital: 2400 mg per day
- Prescriber must submit the following:

- Current chart notes; AND
- Labs confirming active CMV infection with CMV DNA level and CBC; AND
- Negative pregnancy test if of reproductive potential; AND
- Documentation of previous therapies; AND
- Current weight; AND

- Initial PA request approved for maximum of 2 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient's treatment plan includes concomitant use with valganciclovir or ganciclovir; OR
- Recipient has end stage renal disease or severe hepatic impairment; OR
- Prescriber ordered as prophylaxis therapy; OR
- Recipient has been diagnosed with central nervous system CMV disease including CMS retinitis; OR
- Prescriber orders for dose outside of recommendation by the manufacturer

CONTINUATION CRITERIA:

- Recipient has documented plasma CMV DNA level above the lower limit of quantification (>137 IU/mL) which confirms CMV viremia clearance has not occurred; AND
- Prescriber must submit the following:
  - Chart notes; AND
  - Response to therapy; AND
  - Treatment plan if needed beyond 8 weeks

QUANTITY EDITS:
#124/31 days

DISCUSSION:
No comments

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

3. Tarpeyo™ (budesonide)

Dr. Pearson provided the estimated reimbursement rate, information on Immunoglobulin A Nephropathy, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; AND
- Must be prescribed by or in consultation with a nephrologist; AND
- Recipient must have a diagnosis of immunoglobulin A nephropathy (IgAN) with proteinuria OR a diagnosis consistent with the FDA approved indication; AND

- Recipient must have eGFR ≥35 mL/min/1.73 m2 and proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g) at baseline despite ACEi or ARB therapy; AND
- Recipient must be on a stable dose of maximally tolerated RAS inhibitor unless contraindicated for at least 90 days; AND
- Recipient must be prescribed in combination with an ACEi or ARB; AND
- Recipient must have trialed and failed corticosteroids; AND
- Recipient will take a maximum of 9 months of therapy at the maximum dose of 16 mg per day followed by 2 weeks of tapered dose at a maximum dose of 8 mg per day (unless new data supports continued use); AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Previous treatment; AND
  - Confirmation for the diagnosis of IgAN with renal biopsy for patients with severe disease; AND
  - Current labs including eGFR, urine protein or UPCR; AND
  - Medical necessity over corticosteroids and immunosuppressants available without a PA; AND
- Initial PA for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has severe hepatic impairment; OR
- Prescriber orders for >9 months of therapy (unless new data supports continued use)

CONTINUATION CRITERIA:

- Recipient has been compliant with therapy; AND
- Recipient has documented improvement in proteinuria with a reduction in UPCR from baseline; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs

QUANTITY EDITS:
#124/31 days

DISCUSSION:
Dr. Podrazik stated that the fairly high side effect profile of budesonide suggests more systemic absorption than theoretically thought there would be, and there is no comparison to glucocorticoids. If the patient fails a different glucocorticoid, how do we know that putting them on this medication that has systemic side effects is going to be any more effective? Dr. Pearson stated that we don't know that because there really are no studies to that effect. Dr. Johnson stated that budesonide has been shown to reduce the surrogate marker of urine protein to creatinine ratio, but there's a meta-analysis with different trials of steroids that show steroids reduced end stage renal disease not just a surrogate marker. We really would need to see both in the budesonide trials. Based on this information, Dr. Johnson supports requiring a trial of other glucocorticoids for now.

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

4. Apretude (cabotegravir)
Dr. Pearson provided the estimated reimbursement rate, information on HIV and PrEP, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:
- Recipient must be ≥12 years of age weighing at least 35 kg; AND
- Recipient must be at-risk for sexually acquired HIV-1 infections; AND
- Recipient must have a current negative HIV-1 test; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current HIV test results; AND
  - Medical necessity over oral PrEP options (e.g., generic Truvada®); AND
  - Document if recipient will have the 28-day oral lead-in therapy or begin with APRETUDE; AND
  - Attestation that the prescriber has counseled the patient about the importance of compliance; AND
- Prior authorization will be approved for 12 months.

DENIAL CRITERIA:
- Recipient has a positive HIV test either prior to initiating APRETUDE or during treatment; OR
- Medical necessity over oral PrEP options was not provided

CONTINUATION CRITERIA:
- Recipient remains compliant on every other month injections. Recipient would be considered noncompliant if they missed more than 2 injections in a year; AND
- Recipient remains HIV negative; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current HIV test results

QUANTITY EDITS:
1 injection every 2 months (quantity override will be needed for first 2 months during loading doses)

DISCUSSION:
Dr. Bemberg agrees with the comment on noncompliance. Dr. Johnson asked if Medicaid is able to consider cost effectiveness. There was an article in the Annals of Internal Medicine in February that says for Apretude to be cost effective over oral generics like generic Truvada, the commonly acceptable willingness to pay threshold of $100,000 per QALY would require Apretude to cost no more than $3700 per year. Dr. Johnson stated that if we cannot consider cost effectiveness, then there is no doubt Apretude is superior based on clinical trials. There is some question surrounding the patients that dropped from the trials on their HIV status and the fact that nonadherent patients were allowed to stay in the trial

and randomized into the trial. Dr. Pearson stated her opinion that based on overall cost, the necessity over generic Truvada must be provided. Dr. Johnson feels that the modified intention to treat is a problem. Dr. Johnson made the motion to accept the proposal as written.

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

5. Leqvio® (inclisiran)

Dr. Pearson provided the estimated reimbursement rate for Leqvio®, Repatha® and Praluent®, information on HeFH and ASDVD, mechanism of action for Leqvio® and the PCSK9 inhibitors, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) OR a diagnosis consistent with the FDA approved indication; AND
- Recipient must be compliant on maximally tolerated statin doses AND ezetimibe use concomitantly; AND
- Recipient should have an LDL-C ≥ 70 mg/dL and/or non-HDL-C ≥ 100 mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the recipient has a contraindication; AND
- If approved, recipient must continue statin at maximally tolerated dose; 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
- Prescriber must submit the following:
  - Current chart notes; AND
  - Chart notes during trials of statins and ezetimibe; AND
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly; AND
  - Treatment goals with goal LDL-C; AND
- Initial approval for 3 months

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient does not have baseline lipids meeting approval criteria; OR
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe.

CONTINUATION CRITERIA:

- Recipient is compliant on statin therapy in addition to LEQVIO; AND
- Recipient has an improvement in LDL-C since beginning LEQVIO; AND
- Prescriber must submit the following:
  - Current chart notes; AND

- Current labs including lipids

QUANTITY EDITS:
#1 dose per 6 months (except for the extra dose needed at 3 months)

DISCUSSION:
Dr. Johnson asked if the PCSK9 inhibitors were on the PDL. Dr. Pearson confirmed that we have the products on the PDL but both are non-preferred. Dr. Johnson stated that both PCSK9 inhibitors have been shown to reduce in clinical endpoints. Inclisiran has uncertainty as it does not have the data yet and is still enrolling and will not be done until June 2026. ICER's report for inclisiran was put into a model that translated LDL reduction into the assumption that it will reduce major cardiovascular events. Without the full data, it is uncertain whether cardiovascular events will be impacted. At this time, Dr. Johnson would recommend requiring the medical necessity of inclisiran over the PCSK9 inhibitors. Dr. Robertson and Dr. Podrazik agreed with Dr. Johnson's assessment.

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

6. Recorlev® (levoketoconazole)
Dr. Pearson provided the estimated reimbursement rate, information on hypercortisolemia and Cushing's Syndrome, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of Cushing's syndrome with hypercortisolemia, and surgery is not an option or has not been curative OR a diagnosis consistent with the FDA approved indication; AND
- Prescriber must be an endocrinologist; AND
- Recipients with hypokalemia or hypomagnesemia will need to delay initiation until resolved; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of surgery status; AND
  - Current labs including:
    - Urine free cortisol levels (normal is <150 nmol/24 hours OR 3.5-45 mcg/24 hours); AND
    - Liver function tests; AND
    - Comprehensive metabolic panel; AND
    - Baseline electrocardiogram; AND
- Recipient should have a trial and failure of ketoconazole and mitotane unless contraindicated or recipient cannot tolerate both medications

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR

- Recipient has cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic cholelithiasis, or history of drug induced liver injury due to ketoconazole; OR
- Recipients that develop hypocortisolemia should decrease the dose or discontinue the medication; OR
- Recipient continues to have hypercortisolemia despite maximum recommended dosage of 1200 mg per day; OR
- Recipient takes other medications that cause QT prolongation or has any of the following:
  - Prolonged QTcF interval >470 msec at baseline
  - History of torsades de pointes
  - Ventricular tachycardia
  - Ventricular fibrillation
  - Long QT syndrome

CONTINUATION CRITERIA:

- Recipient has a positive response with a decrease in urine free cortisol levels and decrease in symptoms; AND
- Prescriber must submit the following:
  - Current chart notes with response to therapy; AND
  - Current labs including cortisol, LFTs and CMP; AND
  - Any new ECG reports since last PA

QUANTITY EDITS:
#248/31 days

DISCUSSION:
No comments

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

7. Besremi® (ropeginterferon alfa-2b)

Dr. Pearson provided the estimated reimbursement rate (for Besremi®, Jakafi®, Inrebic®, Vonjo®), information on polycythemia vera, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; AND
- Recipient must have a diagnosis of polycythemia vera OR a diagnosis consistent with the FDA approved indication; AND
- Recipient meets one of the following:
  - Males: Hemoglobin > 16.5 g/dL or hematocrit ≥ 49% or increased red cell mass; OR
  - Females: Hemoglobin > 16 g/dL or hematocrit ≥ 48% or increased red cell mass;
- Hemoglobin/hematocrit requirements must be accompanied by one or more the following: (per UpToDate)
  - Splanchnic vein thrombosis

- Unusual thrombosis
- Aquagenic pruritus
- Splenomegaly
- Leukocytosis
- Thrombocytosis
- Microvascular symptoms
- Documentation of JAK2 V617F mutation (per clinical trial)

- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history in previous 3 months. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant of hydroxyurea; AND
- Recipient must take aspirin unless contraindicated; AND
- Recipient of reproductive potential must have a negative pregnancy test; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current negative pregnancy test results if of reproductive potential; AND
  - If recipient takes hydroxyurea, provide the discontinuation taper schedule and initial BESREMi dose must be 50 mcg every 2 weeks; AND
  - Current labs including CBC, LFTs; AND
  - Monitoring plan for patients with underlying depression diagnosis

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); OR
- Recipient has a history or active serious or untreated autoimmune disease; OR
- Recipient is an immunosuppressed transplant patient; OR
- Recipient has a diagnosis of severe psychiatric disorder (i.e., severe depression, suicidal ideation, or suicide attempt)

CONTINUATION CRITERIA:

- Recipient has seen a positive response to therapy after 6 months with an improvement in one of the following:
  - Hematocrit
  - Platelets
  - Leukocytes
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current negative pregnancy test results if of reproductive potential; AND
  - Current labs

QUANTITY EDITS:

#2 injections per month

DISCUSSION:

Dr. Johnson asked why we would not require the medical necessity over Pegasys which had a complete hematological response of 94% compared to 61% for Besremi. The indirect comparison data looks as good or even possibly better with Pegasys and NCCN

recommends all interferon products as preferred treatment options. Dr. Johnson recommends requiring the medical necessity over Pegasys be added to the criteria.

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

8. Vonjo™ (pacritinib)

Dr. Pearson provided the estimated reimbursement rate (for Besremi®, Jakafi®, Inrebic®, Vonjo®), information on primary and secondary myelofibrosis, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must be diagnosed with intermediate or high-risk primary or secondary myelofibrosis with platelets <50 × 109/L OR a diagnosis consistent with FDA approved indication or Compendia support; AND
- Recipient should have a treatment plan for diarrhea; AND
- Recipient has palpable splenomegaly ≥5 cm; AND
- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant to hydroxyurea; AND
- Recipient must taper off other kinase inhibitors; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including CBCs with differential and coagulation testing; AND
  - Baseline electrocardiogram

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient requires concomitant use of strong CYP3A4 inhibitors or inducers; OR
- Recipient has active bleeding; OR
- Recipient has a baseline QTc >480 msec; OR
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); OR
- Recipient has an eGFR <30 mL/min; OR
- Recipient has had a splenectomy; OR
- If approved, the recipient may be denied renewal if does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; OR
- Recipient is unable to tolerate the minimum dose of 100 mg once daily

CONTINUATION CRITERIA:

- Recipient must remain compliant on therapy; AND
- Recipient must show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; AND
- Prescriber must submit the following:
  - Current chart notes; AND

- Current labs including CBCs with differential and coagulation testing

QUANTITY EDITS:
#124/31 days

DISCUSSION:
Dr. Johnson commented that 99% of the people in the trial discontinued and there is confusion on how to accurately measure spleen volume. Is spleen volume a marker for symptom reduction which may be related to quality of life? Dr. Pearson stated that this criteria is consistent with the other drugs having similar indications. Motion made to approve as presented.

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

9. Pyrukynd® (mitapivat)
Dr. Pearson provided the estimated reimbursement rate, information on pyruvate kinase deficiency, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a confirmed diagnosis of pyruvate kinase (PK) deficiency with hemolytic anemia OR a diagnosis consistent with FDA approved indication or Compendia support; AND
- Recipient's baseline hemoglobin should be ≤ 10 g/dL; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including baseline hemoglobin, LFTs; AND
  - Dose requested (initial dose should be 5 mg twice daily); AND
  - Test results for variants of the PKLR gene; AND
  - Previous treatment including transfusion frequency and RBC units required for baseline; AND
  - Medical necessity over other treatment options; AND
  - Attestation that prescriber has counseled the patient on compliance importance and the requirement to taper if discontinuing

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Prescriber is requesting a dose > 50 mg twice daily; OR
- Recipient has moderate or severe hepatic impairment; OR
- Recipient requires either a strong CYP3A inhibitor or strong CYP3A inducer and a dose modification may be needed for use with a moderate CYP3A inhibitor or moderate CYP3A inducer; OR
- Recipient has 2 non-missense mutations in the PKLR gene; OR
- Recipient has seen no benefit by 24 weeks of therapy based on hemoglobin level or transfusion frequency

CONTINUATION CRITERIA:

- Recipient has seen a positive response from the maximum dose with either a ≥1.5 g/dL increase in hemoglobin or a at least a 33% reduction in number of RBC units transfused compared to baseline; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs; AND
  - Dose requested

QUANTITY EDITS:
#62 per month of each strength

DISCUSSION:
No comments

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

10. **Oxervate™ (cenegermin-bkbj)**
Dr. Pearson provided the estimated reimbursement rate, information on Neurotrophic Keratitis, clinical trial information, and drug information. Dr. Pearson provided the following as proposed criteria:

APPROVAL CRITERIA:

- Recipient must be ≥ 2 years of age; AND
- Recipient must have a diagnosis of neurotrophic keratitis OR a diagnosis consistent with FDA approved indication or Compendia support; AND
- Recipient must have stage 2 or stage 3 neurotrophic keratitis; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Stage of neurotrophic keratitis; AND
  - Documented trials of the following; AND
    - Stage 2: Artificial tears, lubricant ointments, prophylactic antibiotic eye drops, and topical corticosteroids (if inflammation)
    - Stage 3: All products for stage 2 plus N-acetylcysteine, tetracycline, OR medroxyprogesterone
  - Medical necessity if requesting for > 8 weeks of therapy

QUANTITY EDITS:
1 vial per day per affected eye

DISCUSSION:
Dr. Grigorian suggested to require surgery with amniotic membrane which is very effective. Dr. Grigorian agreed that this product should only been used in stage 2 or 3 disease. Dr. Johnson asked if amniotic membrane was a one-time treatment or required multiple treatments. Dr. Grigorian stated that it can be multiple but is usually a long time in between. Dr. Pearson stated that the amniotic membrane surgery would be billed as a

		medical claim making the requirement of use difficult to force on the pharmacy claim of this product. But we can ask the medical necessity of Oxervate over this procedure. **ACTION:** Motion to approve criteria as amended was made by Dr. Grigorian; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed.
Reports		**1. ProDUR Report** a. The combined PASSE ProDUR report for the 2nd quarter of SFY 2022 (October-December 2021) was given by Dr. Pearson. The PASSEs had a combined 276,119 paid claims with 47,278 ProDUR alerts resulting in 24,889 cancelled claims or 52.6% of alerts cancelled at POS. Top 10 drugs by amount paid and claim count for each PASSE was also provided. b. Dr. Karen Evans from Magellan gave the FFS quarterly ProDUR reports. The average number of paid claims per month was 396,839 with 69% of those claims screened by DUR. Of the claims screened by DUR, pharmacies received 394,164 alert messages. Approximately 75.3% 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 with dose adjustments on antidiabetic medications based on eGFR, Top 25 drug report by claims, Top 25 products by reimbursement, Top 25 products by net net expenditures, Top 10 prescribers by total volume, Top 10 pharmacies by total volume, correction for report given last quarter, Top 10 prescribers of opioids, and Top 10 pharmacies filling opioid claims. Dr. Robertson asked for a comparison with surrounding states on prescription count/1000 patients. Dr. Golden asked for a PDMP comparison between Medicaid and commercial insurance. The Board made the following recommendations: **May 2022**—New criteria for CKD in diabetes **June 2022**—7529 FDA Box warning: chronic use of metoclopramide has been linked to tardive dyskinesia **July 2022**—New criteria for NSAIDs in patients with CKD Motion was made by Dr. Bemberg to accept the recommended criteria and seconded by Dr. Mancino. All other members present voted to accept the motion. Motion passed.
Adjourn		Meeting adjourned at 11:46am.