Arkansas Medicaid DUR/DRC Board Meeting Minutes

Date / Time:	April 17, 2024 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lesley Irons, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
		Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.	X	Kyle Stirewalt, Pharm.D.	Empower
	X	Lana Gettman, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Florin Grigorian, M.D.		Jessica Lawson, Pharm.D.	CareSource
		Brian King, Pharm.D.		Jennifer Chapin, Pharm.D.	CareSource
		Open M.D. position	X	Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Charles Marsh, Pharm.D.			
	X	Michael Mancino, M.D.		Elizabeth Pitman	DHS Director
	X	Melissa Max, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	Laurence Miller, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Brenna Neumann, Pharm.D.	X	William Golden, M.D.	DHS advisor
	X	Daniel Pace, M.D.	X	Nick Shull, Pharm.D.	ADH advisor
		Paula Podrazik, M.D.	X	Karen Evans, P.D.	Magellan
	X	Tonya Robertson, Pharm.D.	X	Lesley Irons, Pharm.D.	Magellan
	X	Chad Rodgers, M.D.			
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:35am.			
Public comments		1. Kenneth Berry, Pharm.D.—Alkermes (Vivitrol®) 2. Devin Pence, Pharm.D.—Indivior (Sublocade®) 3. Angelia Ting, Pharm.D.—UCB (Zilbrysq®) 4. Shirley Quach, Pharm.D.—Novartis (Fabhalta®) 5. Paul Isikwe, Pharm.D.—Biogen (Zurzuvae™) 6. Joy Sherrick, MS Pharmacy—Chiesi (Filsuvez®) 7. Bryan Wilson, PhD—Genentech (Xolair®)			
Announce-ments		1. Dr. Marsh had a conflict of interest with the product Vivitrol and abstained from voting. There were no other conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Irons. 2. Reimbursement rates are based on WAC, FUL or NADAC. 3. Quarterly provider newsletter-- Arkansas Medicaid Quarterly Newsletter ,			
Minutes		Motion to approve January 2024 DUR/DRC meeting minutes was made by Dr. Mancino, seconded by Dr. Pace. All voting members present voted to approve the minutes as written. Motion passed.			
Reports		• Dr. Irons from Magellan gave the fee-for-service RDUR report and presented RDUR criteria for vote for the next quarter. ○ May 2024—Dental providers with narcotic in last 90 days – American Dental Association updated guidelines ○ June 2024—Concomitant use of opioids and benzodiazepines (SUPPORT Act) ○ July 2024—Concurrent use of opioids and antipsychotics (SUPPORT Act) **ACTION:** Motion was made by Dr. Rodgers for the above criteria; seconded by Dr. Max. All other members present voted for the motion. Motion passed. • Dr. Pearson presented the PASSE ProDUR report for October-December 2023 • Dr. Evans from Magellan presented the FFS ProDUR report for January-March 2024			

PDL Class Review		**1) Injectable Medication Assisted Treatment Agents** Chair provided the history of MAT coverage in Arkansas Medicaid. Dr. Irons presented a PowerPoint with the following information. a) Overview of medications with MOA b) Treatment algorithm from UpToDate® c) ASAM treatment recommendations d) WHO treatment recommendations e) CDC treatment recommendations f) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** Dr. Pearson noted that per legislation, Vivitrol must be classified as preferred and at least 1 of the other 2 products based on what is best for the State. Dr. Rodgers noted that the utilization for Sublocade is higher than Brixadi. Dr. Pearson noted that Brixadi hasn't been on the market long enough to build up utilization. Dr. Mancino noted that patients prefer Brixadi because it has a smaller needle and less problems with nodules at the injection site than Sublocade. Dr. Mancino also stated that Brixadi has the benefit of weekly or monthly dosing which gives flexibility in patient care. Also, Dr. Mancino noted that Brixadi has 3 strengths compared to 2 strengths with Sublocade. Dr. Miller agreed with Dr. Mancino. Dr. Robertson asked if there was a significant difference in cost. Dr. Pearson and Irons noted a slight difference in favor of Brixadi. Dr. Neumann asked if all strengths would be available if preferred. Dr. Irons confirmed. The motion was made to have at least Vivitrol and Brixadi as preferred options. **ACTION:** Motion was made by Dr. Mancino for PDL placement; seconded by Dr. Rodgers. Dr. Marsh abstained from voting due to a conflict. All other members in attendance voted for the motion. Motion passed.
PDL Class Review with Criteria		**1) Triptans** This class was reviewed by the Drug Review Committee for PDL placement in November 2019. Chair provided the current breakdown of the PDL and proposed approval criteria for nasal sprays **PROPOSED APPROVAL CRITERIA:** • Add criteria for nasal spray formulations that requires the trial and failure of the following: o Preferred oral tablets o Preferred oral disintegrating tablets Dr. Irons presented a PowerPoint with the following information. a) Overview of medications with MOA b) Common migraine symptoms c) AHS treatment guidelines d) US Headache consortium guidelines e) AAN and AHS treatment recommendations f) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** Dr. Neumann wanted clarification on what was being voted on. Dr. Pearson confirmed that we are discussing PDL placement for all triptans not just nasal sprays. Dr. Neumann asked if zolmitriptan tablets was non-preferred due to pricing. Dr. Pearson stated that the class was reviewed in 2019, and she wasn't sure the rationale for the vote back then. Dr. Pearson stated that we can consider adding other chemical entities as preferred options if the net cost is comparable, but the current preferred products work well. Dr. Pearson recommended that to get a nasal spray the patient must try and fail the oral options, and the PDL must have at least 1 preferred nasal spray depending on recommendation by the cost committee. Dr. Irons confirmed that zolmitriptan is indicated for 12 years of age and up and rizatriptan is down to 6 years of age. Dr. Neumann stated that the age lower limit would be a factor along with price in determining preferred options. Dr. Rodgers doesn't think there would be a huge barrier if the oral products were required before nasal spray. The motion was to review oral products which are best for the state and require trial of oral before moving to the preferred nasal spray. **ACTION:** Motion was made by Dr. Mancino for PDL placement and criteria approval; seconded by Dr. Rodgers. All members in attendance voted for the motion. Motion passed.

		2) Inhaled corticosteroids (ICS) and inhaled corticosteroids/long-acting beta agonists (ICS/LABA) These classes were last reviewed by the Drug Review Committee in November 2022 with updates effective 1/1/2023. The Drug Utilization Review Board last reviewed these classes for point-of sale edits during the July 2021 meeting to consider SMART guidelines. Chair provided the current breakdown of the PDL, current POS criteria, and discussion questions for ICS agents. **PROPOSED CRITERIA:** **ICS/LABA** No change to ICS/LABA criteria is recommended. ICS • We had multiple conversations with Arkansas Children's Hospital concerning ICS use in asthma and eosinophil esophagitis. Some discussion points: • Maximum age edit for a child with asthma for the preferred ICS HFA formulation of <7 years of age. Once the patient exceeds that age, they would be expected to move to an inhaled powder ICS. Prior authorization can still be approved for HFA on a case-by-case basis. • Fluticasone HFA will have POS criteria like budesonide for EoE looking for a diagnosis in history. Fluticasone and budesonide are the 2 best options for EoE (not mometasone). Dr. Irons presented a PowerPoint with the following information. a) Overview of medications with MOA b) Difference between a metered dose inhaler, breath-activated inhaler, and dry powder inhaler c) GINA treatment guidelines d) NAEPP treatment guidelines e) CHEST guidelines f) GOLD guidelines g) American Thoracic Society guidelines h) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** Dr. Boone asked about a recent issue for many pharmacies with lower WAC prices on many of the brand name products listed as preferred over generic. Pharmacies are losing money on these products as they were purchased prior to the WAC decrease. Examples of drugs with issues included Advair and Focalin XR. Dr. Pearson asked Dr. Boone to delay that discussion until later outside of this Board meeting. Dr. Boone asked us to consider pharmacy reimbursement when we are considering brand name as preferred when a generic is available. Dr. Golden asked what we are doing with leukotriene and asked if they are still being prescribed. Also Dr. Golden wanted to know about monitoring short acting beta agonists without corticosteroids. Dr. Pearson mentioned the potential educational project being established by ACH. Dr. Pearson suggested a motion to include the criteria above with at least one HFA product as preferred along with DPI products. **ACTION:** Motion was made by Dr. Rodgers for PDL placement and criteria; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed**.**
New Business		**1) Eohilia™** **PROPROSED POS APPROVAL CRITERIA:** • Beneficiary must have a billed diagnosis of EoE in the last 2 years • Beneficiary must be ≥11 years of age • Beneficiary must be prescribed no more than 4 mg per day • Beneficiary will be allowed up to 12 weeks of treatment (request for more than 12 weeks will require a prior authorization) **RENEWAL REQUIREMENTS:** • Currently, data for treatment beyond 12 weeks has not been shown to be safe and effective for the treatment of EoE. MicroMedex® and treatment guidelines do support continuation. • If beneficiary is positively responding to EOHILIA, continuation may be considered after EGD at 12 weeks. • Prescriber must submit the following: • Current chart notes • EGD report after 12 weeks of therapy • Medical necessity over fluticasone HFA and budesonide respules

QUANTITY EDITS:
#60 doses (1 carton) per 30 days

DISCUSSION:
Dr. Marsh asked what would be considered a medical necessity over fluticasone and budesonide for continuation of Eohilia. Dr. Pearson noted that age and failure to respond to fluticasone or budesonide respules would be some examples of medical necessity. We would expect a letter outlining a positive response to Eohilia.

ACTION:
The motion was made by Dr. Rodgers to accept the criteria as presented; seconded by Dr. Neumann. All members in attendance voted for the motion. Motion passed.

2) Oncology Policy

This policy will outline the prior authorization review process for oncology drugs covered under the pharmacy benefit for Arkansas Medicaid beneficiaries. This policy does not impact criteria or prior authorization reviews for products covered as a medical benefit.

Cancer treatment options and protocols change so frequently that the published prior authorization criteria is many times outdated. In reviewing oncology drug prior authorization requests, the pharmacy clinical review team considers safety and efficacy for each request that is reviewed on a case-by-case basis.

Policy guidelines

- Prior authorization criteria for oncology drugs covered under this policy will be based on the FDA approved label and support found in the NCCN treatment guidelines with NCCN level of evidence 1 or 2a.
- Requests for an indication, dosage, age, or duration of treatment outside of the FDA approved label and NCCN treatment recommendations are considered off-label.
- Off-label requests will be reviewed for medical necessity on a case-by-case basis while referencing official compendia and peer-reviewed literature along with documentation submitted with the request.
- All prior authorization requests must be submitted by or in consultation with an oncologist or hematologist.
- Documentation supporting the prior authorization request must be submitted at the time of the request.

When submitting an initial prior authorization request for an oncology product, providing all pertinent information with the initial request will expedite reviews. At a minimum, the prescriber must submit:

- Current chart notes
- Type of cancer with documentation of any mutations
- All previous therapies tried with timelines and response (i.e., medications and surgeries)
- Current labs specific to the type of cancer and treatment requesting (e.g., complete blood count, renal function labs, liver function panel, etc.)
- Specific imaging requirements per the package insert (e.g., MRI or CT imaging)
- Letter of medical necessity outlining the rationale for the treatment requested especially if the request is off-label
- Current weight or body surface area
- Dose requested
- Pregnancy test results if recommended in the package insert

For prior authorization renewal requests, the prescriber must submit the following:

- Current chart notes
- Current lab work
- Current weight or body surface area
- Dose requested
- Documentation of current response to treatment
- Attestation that the patient exhibits a positive response from treatment without intolerable side effects

Initial requests may be approved for 3 months, unless otherwise noted, with renewal pending a positive response to treatment without intolerable side effects. Prior authorization renewals may be approved for 3-6 months depending on the level of monitoring required for the treatment.

DISCUSSION:
Dr. Golden asked if we listed functional status as information to be submitted on the initial PA request. He stated that we don't want to necessarily allow chemotherapy for people who are significantly disabled with cancer. Dr. Pearson stated that we stopped looking at ECOG scores a few years ago based on recommendation from this Board. Dr. Golden suggested that we revisit this as there is a whole body of literature about overuse of chemotherapy and cancer use for patients under palliative care. Dr. Golden also asked how this policy relates to the physician administered drugs on the medical side due to potential overlap. Dr. Pearson stated our team tries to ensure that there is no duplicative therapy between pharmacy and medical claims, but the connection between medical and pharmacy is still tough for us. Dr. Pearson amended the criteria to include information on the patient's daily function level.

ACTION:
The motion was made by Dr. Marsh to accept the criteria as amended; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.

3) Xolair®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with one or more IgE-mediated food allergies OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be an Allergy and Immunology specialist
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Prescriber must attest that the beneficiary has been counseled to continue to avoid the foods that cause allergic reactions as this medication is for accidental exposure only
- Beneficiary must continue to have injectable epinephrine on hand with a pharmacy claim within the last year
- Prescriber must submit the following:
  - Current chart notes
  - Baseline serum IgE level
  - Current weight
  - Dose requested (must be supported by the dosing chart in the package insert)
  - Skin prick test results confirming food allergies

RENEWAL REQUIREMENTS:

- Beneficiary remains compliant based on pharmacy claims (defined as 75%). If not compliant, the medical necessity for restarting therapy should be provided.
- Prescriber must submit the following:
  - Current chart notes
  - Serum IgE level is not required for compliant beneficiaries or those with a dose in the last year; dose interruptions lasting one year or more require a new serum IgE level
  - Current weight
  - Dose requested (must be supported by the dosing chart in the package insert)

QUANTITY EDITS:
#4 300 mg prefilled syringe/auto inject per 28 days
#1 150 mg prefilled syringe/auto inject per 28 days
#4 150 mg vial per 28 days
#1 75 mg prefilled syringe/auto inject per 28 days

DISCUSSION:
No comments

ACTION:
The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Rodgers. All members in attendance voted for the motion. Motion passed.

4) Agamree®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Duchenne Muscular Dystrophy (DMD) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary has received all appropriate immunizations according to current ACIP guidelines at least two weeks prior to initiation (at least 4 to 6 weeks prior for live attenuated or live vaccines)
- Dose modifications
  - Mild to moderate hepatic impairment—2 mg/kg once daily with a maximum of 100 mg for beneficiaries more than 50 kg
  - Coadministration with CYP3A4 inhibitors—4 mg/kg once daily with a maximum of 200 mg for beneficiaries more than 50 kg
- Prescriber must specialize in the treatment of DMD and/or neuromuscular disorders
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of the mutation in the dystrophin gene
  - Information on previous glucocorticosteroids tried including explanation of failure or adverse effect caused by the steroid that is not also caused by AGAMREE
  - Letter of medical necessity with a significant reason specific to the beneficiary that AGAMREE is needed over other glucocorticosteroids (e.g., prednisone, prednisolone, deflazacort)
  - Current weight and dose requested
  - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
  - A baseline assessment of ambulatory function using the Time to Stand Test (TTSTAND) has been documented prior to initiating AGAMREE therapy

RENEWAL REQUIREMENTS:

- Beneficiary demonstrates a positive response to vamorolone treatment with clinical improvement in ambulatory function as measured by the Time to Stand Test (TTSTAND) compared to baseline after 24 weeks
- Beneficiary has no clinically significant or intolerable adverse effects related to vamorolone treatment
- Prescriber must submit the following
  - Current chart notes
  - Current weight and dose requested

DISCUSSION:
No comments

ACTION:
The motion was made by Dr. Rodgers to accept the criteria as presented; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.

5) Fabhalta®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) with absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins confirmed by high-sensitivity flow cytometry OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be vaccinated against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B at least 2 weeks prior to initiation of FABHALTA, and recipient must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy

- Prescriber and pharmacy must be enrolled in the REMS program
- Beneficiary currently taking eculizumab (SOLIRIS) or ravulizumab (ULTOMIRIS) must follow the required dose initiation per the package insert
- The medication is prescribed by or in consultation with a hematologist
- Beneficiary must be clinically symptomatic (e.g., fatigue, dyspnea, pain, thrombosis, etc.) and have abnormal labs (e.g., low hemoglobin, high lactate dehydrogenase (LDH), etc.)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment (eGFR < 30 mL/min/1.73 m^2)
  - Severe hepatic impairment (Child-Pugh class C)
  - Active infections caused by an encapsulated bacteria (such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type b)
  - If no vaccinations against encapsulated bacteria (such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type b) at least 2 weeks prior to initiation of Fabhalta and no antibiotic drug prophylaxis
  - Ordered to be used concomitantly with a C5 inhibitor
  - Pregnant or breastfeeding
- Prescriber must submit the following:
  - Current chart notes
  - Documented symptoms as a baseline
  - Documentation of previous therapies
  - Current labs including complete blood count (CBC), comprehensive metabolic panel (CMP), LDH
  - Recent history of blood transfusions
  - Pregnancy test results (if applicable)

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary has an improvement in hemoglobin and/or LDH levels compared to baseline
- Beneficiary has an improvement in overall clinical presentation (e.g., fatigue, dyspnea, reduction in transfusions)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC, CMP, and LDH

QUANTITY EDITS:

#60/ 30 days

DISCUSSION:

No comments

ACTION:

The motion was made by Dr. Pace to accept the criteria as presented; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.

6) Wainua™

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary with multisystem symptoms and/or family history with the diagnosis confirmed with ONE of the following:
  - Confirmation of a transthyretin (TTR) variant by genetic testing
  - Tissue biopsy confirming the presence of amyloid deposits
- This medication must be prescribed by or in consultation with a neurologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- Prescriber must submit the following:

- Current chart notes
- Medical necessity over preferred neuropathic pain agents
- Attestation that Vitamin A is being monitored for possible supplementation
- Baseline modified Neuropathy Impairment Score +7 (mNIS+7) and Norfolk Quality of Life-Diabetic neuropathy (QoL-DN) total score
- Previous therapies tried
- Current labs including liver function tests (LFTs) and basic metabolic panel (BMP)

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75%)
- Beneficiary must demonstrate a positive response with either reduced or stable mNIS+7 and/or QoL-DN scores with improvement in neuropathy
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs and BMP

QUANTITY EDITS:

1/ 30 days

DISCUSSION:

No comments

ACTION:

The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.

7) Zilbrysq®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with generalized myasthenia gravis (gMG) and are anti-acetylcholine receptor (AChR) antibody positive **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a neurologist or other specialist knowledgeable in treating gMG
- Prior to initiating treatment with ZILBRYSQ, the beneficiary must have a baseline Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV and a MG-Activities of Daily Living (MG-ADL) total score ≥6
- Beneficiary must have completed or updated meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to first dose of ZILBRYSQ or the provider must administer the meningococcal vaccine as soon as possible and begin antibacterial drug prophylaxis
- Beneficiary must have tried and failed an acetylcholinesterase (AChE) inhibitor (e.g., pyridostigmine) AND immunosuppressive therapies (e.g., glucocorticoids, azathioprine, or mycophenolate) while on a stable dose **OR** have a documented contraindication or intolerance to those agents
- Prescribers and pharmacies must be certified in the ZILBRYSQ Risk Evaluation Mitigation Strategy (REMS) program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Dose requested is not consistent with weight-based dosing from the package insert
  - Beneficiary is not AChR antibody positive
  - Beneficiary has a current unresolved Neisseria meningitidis infection
  - Beneficiary has suspected or confirmed pancreatitis
  - Baseline MG-ADL total score is <6 or designated as MGFA class I
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with response
  - Serologic test confirming the presence of anti-AChR antibodies
  - Baseline lipase and amylase levels
  - Current body weight
  - Dose requested

- Baseline MG-ADL total score
- Initial PA will be for 3 months

RENEWAL REQUIREMENTS:

- Beneficiary must demonstrate a positive clinical response compared to baseline with an improvement in symptoms and/or improvement in the MG-ADL total score
- Prescriber must submit the following:
  - Current chart notes
  - Current MG-ADL total score
  - Current body weight
  - Dose requested
- Renewal PAs can be approved for 6 months

QUANTITY EDITS:

16.6 mg/0.416 mL—#28 per 28 days
23 mg/0.574 mL—#28 per 28 days
32.4 mg/0.81 mL—#28 per 28 days

DISCUSSION:
No comments

ACTION:
The motion was made by Dr. Miller to accept the criteria as presented; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.

8) Rivfloza™

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary hyperoxaluria type 1 (PH1) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- PH1 must be confirmed by ONE of the following:
  - Molecular genetic testing confirming a mutation in the alanine-glyoxylate aminotransferase (AGXT) gene
  - Liver biopsy results demonstrating reduced alanine-glyoxylate aminotransferase (AGXT) activity
- Beneficiary must have relatively preserved kidney function (≥30 mL/min/1.73 m^2)
- Must be prescribed by or in consultation with a urologist or nephrologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - eGFR < 30 mL/min/1.73 m^2
  - Prescribed concomitant lumasiran (OXLUMO)
  - Does not have genetic testing confirming a mutation in the AGXT gene or liver biopsy confirming reduced AGXT activity
  - Dose is not consistent with weight-based dosing in the package insert
  - Moderate or severe hepatic impairment
  - Diagnosed with any other primary hyperoxaluria type besides PH1
- Beneficiary has tried high dose pyridoxine and did not obtain an adequate response (defined as had < 30% reduction in urinary or plasma oxalate concentration)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Current labs including eGFR, urinary or plasma oxalate levels
  - Genetic testing results confirming a mutation in the AGXT gene or liver biopsy results
  - Current weight and dose requested

RENEWAL REQUIREMENTS:

- Beneficiary must have reduced urinary or plasma oxalate levels
- Beneficiary continues to have stable kidney function (continues to meet approval criteria)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including eGFR, urinary or plasma oxalate levels

- Current weight and dose requested

QUANTITY EDITS:
80 mg (0.5 mL) single-dose vial—2 vials per month (for patients 9-11 years of age weighing less than 50kg)
128 mg (0.8 mL) single-dose Pre-filled Syringe—1 syringe per month
160 mg (1 mL) single-dose Pre-filled Syringe—1 syringe per month

DISCUSSION:
Dr. Golden asked if we considered a response on renewal if a patient falls below eGFR of 30. Dr. Pearson stated that we would be flexible as the cases are not black and white. But since the request would be off-label at that point, we would consult Dr. Golden and peer-reviewed literature.

ACTION:
The motion was made by Dr. Marsh to accept the criteria as presented; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.

9) Zurzuvae™

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with moderate to severe postpartum depression (PPD) no earlier than the third trimester and no later than 4 weeks following delivery OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be ≤12 months postpartum (<365 days)
- Beneficiary should not be approved with any of the following:
  - More than 12 months postpartum
  - Currently pregnant
  - Requesting more than one (1) 14-day course
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Date of delivery
  - Dose requested
    - Typical dose is 50 mg once daily in the evening for 14 days
    - If patient experiences CNS depressant effects within the 14-day period, dose may be decreased to 40 mg once daily in the evening for the remainder of the 14-day period. The prescriber should contact the specialty pharmacy that filled the member's initial ZURZUVAE prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course.
    - Dose should be reduced to 30 mg for the following:
      - Concomitant use with strong CYP3A4 inhibitor (e.g., ketoconazole)
      - Severe hepatic impairment (Child-Pugh C)
      - Moderate or severe renal impairment (eGFR <60 mL/min/1.73 m^2)
  - Attestation that the beneficiary has been counseled on CNS depression risk for infants during breastfeeding. Breastfeeding should be temporarily stopped during the 14-day treatment and for 7 days after if possible.
  - Attestation that the beneficiary is not currently pregnant

QUANTITY EDITS:
One (1) 14-day course

DISCUSSION:
Dr. Mancino asked how we were going to define moderate to severe depression since the study results were based on HAMD which is not typically used by most clinicians. Dr. Miller agreed with Dr. Mancino that the diagnosis would be based on clinical reporting and observations in terms of symptoms. The speaker for Zurzuvae noted differences in diagnosis timeframe in the clinical trial with many diagnosed beyond 6 weeks. A discussion between Dr. Mancino and Dr. Miller about using the DSM-5 diagnosis timeframe and not limiting it to OB or psych providers. Dr. Max asked if we were requiring previous therapy, and Dr. Pearson said that would not be a requirement but we would want to know if there is previous therapy. The Zurzuvae speaker asked about the timeframe for diagnosis

again. Dr. Miller clarified that we will be flexible. Each request will be reviewed individually and timing will be taken into consideration. Once we develop these criteria and review them periodically, we may want to update them to some extent if needed. But we're not going to deny anybody because they didn't make the appointment within the first 4 weeks.

ACTION:
The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.

10) Filsuvez®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB and JEB
- Beneficiary must have wound(s) that are 10-50 cm^2 and lasting 21 days - 9 months
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Ordered concomitant beremagene geperpavec-svdt (Vyjuvek)
  - Diagnosed with EB simplex
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Baseline description of wound(s)
  - Directions on frequency of application
  - Attestation that patient/caregiver has been counseled on proper use
  - Number of tubes expected per month
  - NOTE: For the initial 3 months, the beneficiary may be authorized #30 tubes every 30 days to determine
  - response to treatment. If the beneficiary responds to FILSUVEZ at the 3-month evaluation, more than 1
  - tube per dressing change will be approved, if needed.
- Initial PA for 3 months; if demonstrates efficacy, subsequent PAs can be approved for 6 months

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Response to therapy with description of wound(s)
  - Medical necessity for continued use
- Treated wounds will be evaluated at 3 months for a positive clinical response with request for PA continuation reviewed on a case-by-case basis. Positive response may include:
  - Decrease in wound size
  - Increase in granulation tissue
  - Complete wound closure
- If beneficiary is receiving a positive clinical response at 3 months, the next PA can be approved for 6 months.

QUANTITY EDITS:
#30 per 30 days initially to determine response to treatment. If the beneficiary responds to FILSUVEZ, more than 1 tube per dressing change will be approved, if needed.

DISCUSSION:
No comments

ACTION:
The motion was made by Dr. Pace to accept the criteria as presented; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed.

11) Voquezna®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary prescribed a VOQUEZNA Dual or Triple Pak must be diagnosed with Helicobacter pylori or beneficiary prescribed VOQUEZNA must be diagnosed with ONE (1) of the following:
  - for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults.
  - in combination with amoxicillin for the treatment of H. pylori infection in adults.
- Beneficiary with erosive esophagitis or heartburn must have had previous treatment failure with or a contraindication to all preferred proton pump inhibitors
- Beneficiary with H. pylori must have tried and failed (defined as failure to eradicate H. pylori infection after 14-day course of therapy) ONE (1) of the following:
  - Bismuth quadruple therapy unless contraindicated (e.g., bismuth, metronidazole, tetracycline and proton pump inhibitor); OR
  - Clarithromycin-based therapy unless contraindicated (e.g., clarithromycin, amoxicillin, and proton pump inhibitor)
- Prescribed by or in consultation with a gastroenterologist or infectious disease specialist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Requested duration of treatment for healing erosive esophagitis or relief of heartburn exceeds 8 weeks
  - Requested duration of maintenance therapy for healed erosive esophagitis and relief of heartburn exceeds 6 months
  - Requested duration of treatment for H. pylori exceeds 14 days
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Confirmation of H. pylori if that is the diagnosis
  - Letter of medical necessity requesting VOQUEZNA over guideline-recommended first-line treatment
- Prior authorization duration will be consistent with the documented diagnosis per the package insert
  - VOQUEZNA 20mg—maximum of 8 weeks
  - VOQUEZNA 10mg—maximum of 6 months
  - VOQUEZNA paks—1 short term PA to allow 1 claim

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity outlining the rationale for exceeding FDA approved treatment duration

QUANTITY EDITS:

10 mg--#31/31 days
20 mg--#31/31 days
Dual and Triple Pak--#112/14 days

DISCUSSION:

No comments

ACTION:

The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Boone. All members in attendance voted for the motion. Motion passed.

12) Zoryve® foam

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with seborrheic dermatitis OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Based on the Investigator Global Assessment (IGA), the beneficiary must have moderate to severe seborrheic dermatitis which would be an IGA score of 3-4 with current standard of care treatment (i.e., topical antifungals, topical corticosteroids, topical calcineurin inhibitors)
- Beneficiaries with scalp seborrheic dermatitis must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione)
  - Prescription antifungal shampoo (e.g., ketoconazole)
  - High-potency topical corticosteroids
- Beneficiaries with non-scalp seborrheic dermatitis (body and face) must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Topical antifungal (e.g., ketoconazole, ciclopirox)
  - Low-potency topical corticosteroids
  - Topical calcineurin inhibitor (e.g., tacrolimus)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA impacted
  - Current Investigator's Global Assessment (IGA) score (between 0-4)
  - Current Worst Itch-Numeric Rating Score (WI-NRS) (between 0-10)
  - Medical necessity over all other topical treatment options
- Initial approval will be for 2 months

RENEWAL REQUIREMENTS:

- For continuation, the beneficiary must demonstrate clinical improvement with decreased IGA score and WI-NRS. IGA score must show a 2-grade improvement compared to baseline.
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Medical necessity for continuation of therapy

QUANTITY EDITS:

60 gm (1 container) per 30 days

DISCUSSION:

No comments

ACTION:

The motion was made by Dr. Rodgers to accept the criteria as presented; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.

13) Accrufer®

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with iron deficiency OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a baseline hemoglobin less than 12 mg/dL and baseline ferritin < 30 mcg/L
- Beneficiary must have tried and failed other ferrous products (i.e., sulfate, gluconate, or fumarate) or have a contraindication
- Prescriber must submit the following:

		○ Current chart notes ○ Current labs including CBC and ferritin panel ○ Expected cause of iron deficiency **RENEWAL REQUIREMENTS:** • Beneficiary continues to be at risk for iron deficiency (e.g., chronic kidney disease, inflammatory bowel disease) • Accrufer® was considered effective with increased ferritin and/or hemoglobin • Beneficiary must submit the following: ○ Current chart notes ○ Current labs including CBC and ferritin panel **QUANTITY EDITS:** #60/30 days **DISCUSSION:** No comments **ACTION:** The motion was made by Dr. Pace to accept the criteria as presented; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed. **14) Adthyza Thyroid** **PROPROSED APPROVAL CRITERIA:** • Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication • Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia • Beneficiary must be diagnosed with hypothyroidism OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis. • Beneficiary must have tried and failed levothyroxine • Prescriber must submit the following: ○ Current chart notes ○ Current labs including TSH and serum T4 ○ Medical necessity over levothyroxine and Armour Thyroid ○ Medical necessity for patients who are pregnant or have cardiovascular disease • Initial approval for 6 months **DISCUSSION:** Dr. Golden stated that nobody recommends using animal based thyroid anymore. So why do we even want this product? Dr. Pearson stated that we have to cover it as a prescribed drug since it is rebate eligible. Dr. Golden asked what would justify the use of this product. Dr. Pearson stated they would have to try and fail all other products. **ACTION:** The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.
Adjourn		Meeting adjourned at 12:17 pm.