Arkansas Medicaid DUR/DRC Board Meeting Minutes

Date / Time:	January 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**
	X	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.	X	Shannon Burke, Pharm.D.	Empower
		Lana Gettman, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Florin Grigorian, M.D.	X	Jessica Lawson, Pharm.D.	CareSource
	X	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	Shane David, Pharm.D.	ADH advisor
	X	Paula Podrazik, M.D.	X	Karen Evans, P.D.	Magellan
	X	Tonya Robertson, Pharm.D.		Lynn Boudreaux, Pharm.D.	Magellan
		Chad Rodgers, M.D.	X	Lesley Irons, Pharm.D.	Magellan
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. Dominic Marchese, Pharm.D.—Krystal Biotech (Vyjuvek™) 2. Nisreen Shamseddine, Pharm.D.—Ipsen (Sohonos™) 3. Anita Gulmiri, OD—Tarsus Pharmaceuticals (Xdemvy®) 4. Amanda Haikalis, Pharm.D.—Medunik (Pheburane®) 5. Andrea Hawkinson, MS—Recordati Rare Diseases (Carbaglu®) 6. Corey Hicks, PhD—Amgen (Ravicti®) 7. Tony DeFilippo—scPharma (Furoscix®)			
Announce-ments		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Irons. 2. Reimbursement rates are based on WAC, FUL or NADAC. 3. Board member update—New member Charles Marsh, PharmD and resignation James Magee, M.D.  Arkansas Medicaid Quarterly Newsletter . 4. Quarterly provider newsletter-- 5. Diabetic supplies update 6. Hepatitis C criteria update 7. AME cap removal overview			
Minutes		Motion to approve October 2023 DUR/DRC meeting minutes was made by Dr. Mancino, seconded by Dr. King. All voting members present voted to approve the minutes as written. Motion passed.			
PDL Class Review		**1) Ophthalmic Antibiotics** This review is a renewal for the ophthalmic antibiotics drug class. Chair provided the current breakdown of the PDL.			

		Dr. Irons presented a PowerPoint with the following information. a) Overview of medications separated by MOA b) Information on conjunctivitis c) Information on potential infective bacteria d) Treatment guidelines from the American Academy of Ophthalmology e) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** Dr. Pearson suggested that Natacyn remain non-preferred, but we ensure there are preferred options from each mechanism of action except antifungals. There have been drug shortages that have caused the need for non-preferred medication usage. Dr. Neumann noted the shortage of erythromycin ointment, and therefore we need other ointment options like Ciloxan for children and post-surgery. Dr. Max and Dr. Boone have seen the same issue with shortage of erythromycin. The motion was made to consider overall net cost to the state while including each MOA and try to add another ointment. **ACTION:** Motion was made by Dr. Neumamnn for PDL placement; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed. **2) Otic Antibiotics** This review is a renewal for the otic antibiotics drug class. Chair provided the current breakdown of the PDL. Dr. Irons presented a PowerPoint with the following information. a) Overview of medications separated by MOA b) Information on otitis media and otitis externa c) Treatment guidelines from the American Academy of Otolaryngology d) Treatment guidelines from the American Academy of Pediatrics and American Academy of Family Physicians e) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** Dr. Pearson suggested the motion to consider overall net cost to the state while including each MOA. **ACTION:** Motion was made by Dr. Max for PDL placement; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.
PDL Class Review with Criteria		**1) Erythropoiesis Stimulating Agents** This class was reviewed by the Drug Review Committee for PDL placement in May 2018. Point-of-sale criteria was approved by the Drug Utilization Review Board in January 2020. Chair provided a breakdown of the PDL and provided current POS criteria with the recommendation to make no changes to the criteria. Dr. Irons presented a PowerPoint with the following information. a) Overview of medications (brand and generic names) b) Overview of anemia c) Treatment guidelines from the American Society of Clinical Oncology d) Treatment guidelines from the American Society of Hematology e) Treatment guidelines from NCCN and International Kidney Disease: Improving Global Outcomes Group f) Claims summary from 1/1/2023-12/31/2023 **DISCUSSION:** No discussion on criteria. Dr. Pearson asked for a motion for preferred options that are best for the state.

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

The motion was made by Dr. King for PDL placement; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

2) Urea Cycle Disorders
This review is establishing a new PDL class.

Dr. Irons presented a PowerPoint with the following information.

a) Overview of the medications (brand and generic name with strengths and formulations)
b) Information on urea cycle disorders
c) Treatment guidelines from Trans-European Consensus
d) Claims summary from 1/1/2023-12/31/2023

Dr. Pearson provided information on Urea Cycle Disorders (UCD) including disease information and treatment recommendations. Medication doses and approximately gross cost for all products was provided. Dr. Pearson provided updated proposed approval criteria.

PROPOSED 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with:
  - Buphenyl®—urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Carbaglu®—
    - Acute or chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
      - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia OR
      - Maintenance therapy for the treatment of chronic hyperammonemia
    - Acute hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA) as adjunctive therapy (BRAND NAME ONLY)
  - Olpruva™—urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS) and weigh at least 20 kg or have a body surface area of at least $1.2m^2$
  - Pheburane®— urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Ravicti®—urea cycle disorders and cannot be managed by dietary protein restriction and/or amino acid supplementation alone
- Medication must be prescribed by or in consultation with a provider experienced in managing UCDs (e.g., geneticist)
- Beneficiary is unable to maintain a plasma ammonia level within normal range with standard of care treatment (i.e., protein restriction and essential amino acid supplementation when appropriate)
- Beneficiary must continue dietary management with protein restriction with dietary plan provided
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Previous therapies tried with response
  - Current weight and body surface area (BSA)

- Current labs including plasma ammonia and complete metabolic panel
- Dose requested must fall within the parameters from the individual product package insert
  - Pheburane® pellets or Buphenyl® tablets/powder (maximum daily dose of 20 gm)
    - 450 to 600 mg/kg/day orally in patients weighing < 20 kg
    - 9.9 to 13 g/m^2/day orally in patients weighing ≥ 20 kg
  - Carbaglu® tablets
    - Acute treatment for NAGS—100-250 mg/kg
    - Chronic treatment for NAGS—10-100 mg/kg
    - Acute treatment for PA or MMA—150 mg/kg/day for ≤15 kg OR 3.3 g/m^2/day for >15 kg
    - If diagnosed with PA or MMA, provide number days treated while hospitalized. Patient should have a maximum of 7 days total.
  - Olpruva™ pellets (maximum daily dose of 20 gm)
    - 9.9-13 g/m^2/day
  - Ravicti® liquid (maximum daily dose of 17.5 mL (19 gm))
    - 4.5 to 11.2 mL/m^2/day (5 to 12.4 g/m^2/day)

- For non-preferred products, beneficiary must have tried and failed preferred products with documented uncontrolled hyperammonemia despite compliance in the previous year or have documented contraindication/intolerance to all preferred products.

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current plasma ammonia level
  - Current weight and/or BSA and dose requested
- Beneficiary must demonstrate an improvement in clinical presentation and/or decrease in plasma ammonia compared to baseline
- Beneficiary must continue to meet approval criteria

DISCUSSION:

Dr. Pearson recommended making Ravicti non-preferred due to cost per claim. Dr. Pearson suggested that we have preferred with criteria and non-preferred with criteria. Dr. Irons agreed that a step through a sodium phenylbutyrate would be appropriate before Ravicti. Dr. Neumann asked if there were other paid claims for products besides Ravicti. Dr. Pearson discussed grandfathering those already on Ravicti with compliance and medical necessity over sodium product being required. If the Ravicti patient is non-compliant, the medical necessity over a more economical product would be needed. Dr. Podrazik asked if the 3 patients were started on Ravicti because of flavor. Dr. Pearson stated she did not look that deep into the requests, but previous requests there has been mention of bad taste with other products and patient could not handle extra sodium. At the time, we could not question a sodium phenylbutyrate product over Ravicti sone not a PDL class. Dr. Max asked if other products had similar tolerability based on taste as Ravicti. Dr. Irons noted that 3% of patients did not tolerate Pheburane and Olpruva due to taste which is much smaller amount than Buphenyl generic. Dr. Neumann asked about administration in G-tube. The drug reps spoke up and noted that Ravicti, Buphenyl, and Carbaglu can all be administered in G-tube. Dr. Pearson stated that we could update criteria concerning G-tube. Dr. Podrazik asked if we could amend the criteria to include tolerability. Dr. Max asked if we could require a trial and failure of either Olpruva or Pheburane since they are more palatable. Dr. Pearson said that tolerability could be accounted for in the preferred vs. non-preferred agents instead of adding to criteria.

ACTION:

The motion was made by Dr. Bemberg to accept the criteria and PDL placement as amended; seconded by Dr. Marsh. All members in attendance voted for the motion. Motion passed.

New Business

1) Furoscix®

PROPOSED APPROVAL CRITERIA: (Tabled after July 2023 DUR)

- 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed New York Heart Association (NYHA) Class III chronic heart failure and being treated for congestion due to fluid overload **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 cardiologist
- Beneficiary must have tried and failed oral furosemide (160 mg) and one of the following:
    - Torsemide (40 mg)
    - Bumetanide (4 mg)
- Beneficiary must be adherent to CHF therapies (i.e., ACE/ARB, beta blockers, salt restrictions)
- Beneficiary must have documented recent weight gain and increased edema or other symptoms of extracellular volume expansion (e.g., jugular venous distention, pulmonary congestion or rales)
- Beneficiary must have had recent renal lab work done
- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Current and previous therapies for heart failure
    - Medical necessity over oral and IV furosemide and other diuretics class
    - Current and baseline weight
    - Confirmation that beneficiary has a history of at least one prior hospitalization or emergency department visit due to heart failure exacerbations and/or fluid overload, and the beneficiary is stable enough to avoid hospitalization at the time of administration
    - Current labs
    - Attestation that Furoscix will be used short-term then transitioned back to oral diuretics as soon as practical.

RENEWAL REQUIREMENTS:

- Beneficiary continues to have fluid overload
- Prescriber must submit the following:
    - Current chart notes
    - Continued treatment plan for fluid overload
    - Current weight and description of edema

QUANTITY EDITS:

#1 per claim?? Or 7 per 30 days?

DISCUSSION:

Dr. Podrazik stated that we would use this in a subset of truly refractory congestion where we've ruled out all other reasons why they have refractory congestion and tried all standard trials. Multiple diuretics available. Dr. Golden and Dr. Robertson wondered if we have to cover this product. There would be a very tiny patient population that would benefit. Dr. Podrazik stated that there are so many other steps and options to try. Dr. Pearson noted we have to cover as a pharmacy claim since rebate eligible, but we can have very strict criteria. The drug rep noted that this is just another asset for cardiologists before putting a patient into the hospital. This medication would be for acute treatment only and most patients will be on this product 1-2 times per year. Dr. Golden asked if IV furosemide can be done in the home settings. The drug rep confirmed that some people will use IV furosemide with home assistance. Dr. Podrazik continued to try to define the population for needing this med. Dr. Golden suggested that we approve the proposed criteria which is strict and report back utilization to the Board in 6-12 months. Dr. Pearson questioned quantity edits. The Board members were concerned about have no oversight if there were too many doses. Dr. Pace recommended 2-3 doses then he

would want the patient seen by the prescriber. Dr. Podrazik and Dr. Marsh recommended 1-2 doses. So, Dr. Pearson noted the maximum would be 2 doses per claim.

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

2) Imcivree®

PROPOSED 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency or Bardet-Biedl syndrome (BBS) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Confirmation of diagnosis requires:
    - POMC, PCSK1, or LEPR deficiency—genetic testing that confirms variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance
    - BBS—Confirmed by presence of four major features associated with BBS **OR** three major features plus two minor features
        - Major features associated with BBS:
            - Rod-cone dystrophy
            - Polydactyly
            - Obesity
            - Learning disabilities
            - Hypogonadism in males
            - Renal abnormalities
        - Minor features associated with BBS:
            - Speech disorder/delay
            - Strabismus/cataracts/astigmatism
            - Brachydactyly/syndactyly
            - Developmental delay
            - Polyuria/polydipsia (nephrogenic diabetes insipidus)
            - Ataxia/poor coordination/imbalance
            - Mild spasticity (especially lower limbs)
            - Diabetes mellitus
            - Dental crowding/hypodontia/small roots/high arched palate
            - Left ventricular hypertrophy/congenital heart disease
            - Hepatic fibrosis
- Beneficiary must meet the following for obesity diagnosis
    - POMC, PCSK1, or LEPR deficiency must have a baseline body mass index (BMI) ≥30 kg/m^2 or pediatric weight ≥ 95th percentile using growth chart assessment
    - BBS must have a baseline BMI ≥30 kg/m^2 or pediatric weight ≥ 97th percentile using growth chart assessment
- Must be prescribed by or in consultation with a specialist (e.g., endocrinologist, geneticist, obesity specialist)
- Beneficiary should not be approved or continue on this therapy with any of the following:
    - Genetic testing does not confirm POMC, PCSK1, or LEPR deficiency or the variants are classified as benign or likely benign
    - Clinical symptoms do not support the BBS diagnosis

- Doesn't meet obesity requirements
- Obesity is not determined to be related to POMC, PCSK1 or LEPR deficiency or BBS
- End stage renal disease (eGFR < 15 mL/min/1.73m^2)

- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current weight and BMI
  - Genetic testing confirming a diagnosis of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **OR** clinical symptoms suggesting a BBS diagnosis
  - Current estimated glomerular filtration rate (eGFR)
- Initial PA for 4 months

RENEWAL REQUIREMENTS:

- Prescriber must submit the following:
  - Current chart notes
  - Current weight and BMI
- Beneficiary diagnosed with POMC, PCSK1, or LEPR deficiency must have lost at least 5% of baseline body weight or 5% of baseline BMI for patients with continued growth potential after 12-16 weeks
- Beneficiary diagnosed with BBS must have lost at least a 5% of baseline body weight or 5% of baseline BMI for patients <18 years after 1 year with some improvement at 4 month review
- Beneficiary must remain compliant on therapy (defined as at least 75% utilization)
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:

9 vials per month

DISCUSSION:

No comments

ACTION:

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

3) Vyjuvek™

PROPOSED 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene **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 one or more chronic or recurrent open wounds with all of the following:
  - Adequate granulation tissue
  - Excellent vascularization
  - No evidence of active wound infection
  - No evidence or history of squamous cell carcinoma
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB
- Vyjuvek gel must be prepared by a pharmacy and delivered directly to the provider for application in the clinic or home setting by a healthcare professional, and it should be used within 8 hours if left unrefrigerated. If immediate use is not possible, Vyjuvek gel can be refrigerated for up to 48 hours.
- Prescriber must submit **ALL** of the following:

- Current chart notes
- Documentation reporting the presence of the COL7A1 gene mutation
- Plan for acquiring the medication and timeframe for application (application no more than 8 hours after prepared by the pharmacy if left unrefrigerated; administration syringes can be stored for up to 48 hours in the refrigerator)
- Baseline description of wound(s)

- Initial PA will be for a maximum of 6 months

RENEWAL REQUIREMENTS:

- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Response to therapy with description of wound(s)
  - Medical necessity for continued use
- Treated wounds will be evaluated at 6 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 would closure

QUANTITY EDITS:

1 kit per week

DISCUSSION:

Dr. Neumann noted concern about being prepared by the pharmacy and delivered because of waste, and we want to ensure that the patient will not be able to pick up the prescription. The drug rep noted that this is by specialty distribution and not available to direct patient delivery. This could be sent to clinic or home health. Dr. Neumann asked if any pharmacies are signed up in the state. The drug rep noted we have no patients to be treated yet in Arkansas, but the pharmacy/clinic would be within the state. Dr. Marsh asked the manufacturer if they had credentialing requirements for pharmacies, and the rep stated there are no specific credentialing criteria. Dr. Pearson stated that we can amend the criteria to require documentation of plan for acquiring the medication with pharmacy name.

ACTION:

The motion was made by Dr. Neumann to accept the criteria as amended; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

4) Targeted Immunomodulator Criteria for Gout Flares

PROPOSED APPROVAL CRITERIA:

- Prescribed by or in consultation with a rheumatologist or other specialist.
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication.
- Maximum dose based on support in manufacturer's package insert or official Compendia.
- Beneficiary has no therapeutic duplication with any other cytokine & CAM antagonists.
- Beneficiary must be diagnosed with gout flares
- Beneficiary must have tried and failed non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and colchicine (unless contraindicated or not tolerated). (Repeated courses of corticosteroids are not appropriate).
- Beneficiary with frequent gout flares (defined as 3 or more gout flares in the previous year) must be on a urate-lowering medication (e.g., allopurinol, febuxostat, probenecid)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of symptoms

- Current labs including serum urate concentration and documentation of urate crystals in the synovial fluid (if available)
- PA will be approved for 1 dose.
- Renewal requires prescriber to submit updated notes with documentation of continued gout flare. Ilaris® requires at least 12 weeks between doses.

DISCUSSION:
No comments

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

5) Sohonos™

PROPOSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication (As of 1/16/2024, minimum age is 8 years for females and 10 years for males.)
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with fibrodysplasia ossificans progressive (FOP) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with a specialist knowledgeable in FOP
- Growing pediatric patients should have baseline assessment of skeletal maturity via hand/wrist and knee x-rays, standard growth curves and pubertal staging. Continued monitoring is recommended every 6-12 months until skeletal maturity. Palovarotene can cause premature epiphyseal closure and risk vs. benefit may need to be determined.
- Female beneficiaries of reproductive potential should have highly effective contraception.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnancy
  - Moderate to severe hepatic impairment or severe renal impairment
  - Vertebral fractures (consider the benefit vs. risk)
  - Require strong CYP3A inhibitors (e.g., ritonavir, ketoconazole) and moderate or strong CYP3A inducers (e.g., carbamazepine, phenytoin)
  - Requires tetracycline derivatives
  - Requires high dose Vitamin A
- Prescriber must submit **ALL** of the following:
  - Current chart notes with previous therapies tried.
  - Description of this beneficiary's symptoms and disease progression (volume of heterotopic ossification if available as a baseline)
  - Negative pregnancy test within 1 week of initiating therapy
  - Baseline assessment of bone maturity
  - Dose requested (PA is specific to NDC)

RENEWAL REQUIREMENTS:

- Beneficiary continues to meet approval criteria.
- Provider has considered the benefit versus risk on epiphyseal closure.
- Prescriber must submit the following:
  - Current chart notes
  - Negative pregnancy test results
  - Skeletal maturity test results at least once a year
  - Dose requested (PA is specific to NDC)

QUANTITY EDITS:
Nothing specific as multiple doses must be available depending on need of patient.

DISCUSSION:
No comments

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

6) Ojjaara

PROPOSED 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 from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia **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 hemoglobin <10 g/dL
- Beneficiary with severe hepatic impairment (Child-Pugh C) should start with a reduced dose of 150 mg once daily
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Delay starting therapy if beneficiary has active infection
    - Beneficiaries with HBsAg and/or anti-HBc antibody positivity should consult with a hepatologist to monitor for Hep B reactivation
    - Classified as low-risk MF
- Prescriber must submit ALL the following:
    - Current chart notes with documented
    - Previous therapies tried
    - Current labs including CBC with platelets and neutrophils as well as hepatic panel
    - Baseline spleen volume
    - Baseline symptoms attributed to MF
    - Medical necessity over other agents (e.g., ruxolitinib + ESA)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy
- Beneficiary must demonstrate an improvement of documented symptoms compared to baseline
- Prescriber must submit the following:
    - Current chart notes
    - Current labs including CBC with platelets & neutrophils and hepatic panel
    - Updated spleen volume
    - Updated symptoms attributed to MF

QUANTITY EDITS:
#30 per 30 days for each strength

DISCUSSION:
Dr. Marsh asked if the medical necessity refers to the treatment flow chart from the American Journal of Hematology. Dr. Pearson noted that the example from the American Journal of Hematology explained the reason for ruxolitinib. Since this is indicated for anemia, the medical necessity for the combination of ruxolitinib and an erythropoiesis stimulating agent would be needed before moving to Ojjaara.

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.

7) Xdemvy™

PROPOSED 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 has been diagnosed with *Demodex* blepharitis verified by presence of collarettes through a slit lamp exam **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Xdemvy must be prescribed by or in consultation with an optometrist or ophthalmologist
- Prescriber must submit **ALL** the following:
    - Documentation of results seen with slit lamp examination
    - Other therapies tried
    - Medical necessity over topical tea tree oil/shampoo and oral ivermectin

RENEWAL REQUIREMENTS:

- Beneficiary had a previous positive response with a reduction in collarettes and mites.
- Maximum of 2 treatments per year

QUANTITY EDITS:
1 bottle per 6 weeks

DISCUSSION:
No comments

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

8) Opfolda™

PROPOSED 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 an adult diagnosed with late-onset Pompe disease (LOPD) based on documentation of one of the following:
    - Deficiency of GAA enzyme
    - GAA genotyping
- Beneficiary must have tried enzyme replacement therapy (ERT) for at least 24 months without improvement (e.g., improved FVC or 6MWT) with one of the following:
    - Lumizyme (alglucosidase alfa) intravenous infusion; OR
    - Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion
- Must be prescribed by or in consultation with a geneticist, neurologist, or provider that specializes in the treatment of lysosomal storage disorders
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Pregnant

- Not prescribed concomitant Pombiliti infusions (medical billing will be verified)
- End stage renal disease (moderate-severe impairment requires dose decrease)
- <40 kg

- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Generic testing to confirm LOPD
  - Attestation that both female subjects of childbearing potential and male subjects are using contraception
  - Baseline pulmonary function tests (specifically FVC %predicted) and labs for renal function
  - Baseline 6 minute walk test (6MWT)
- Initial PA for 6 months

RENEWAL REQUIREMENTS:

- Beneficiary must continue to receive Pombiliti infusions every 2 weeks and receiving therapy compliantly
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Attestation that both female subjects of childbearing potential and male subjects continue to use contraception
  - Updated PFTs and renal function labs
  - Updated 6MWT

QUANTITY EDITS:

8 capsules/ 28 days

DISCUSSION:

No comments

ACTION:

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

9) Likmez™

PROPOSED 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 trichomoniasis, amebiasis, or anaerobic bacterial infection with one of the following specific bacteria:
  - Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess, caused by *Bacteroides* species including the *B. fragilis* group (*B. fragilis, B. ovatus, B. thetaiotaomicron, B. vulgatus*), *Parabacteroides distasonis, Clostridium* species, *Eubacterium* species, *Peptococcus* species, and *Peptostreptococcus* species.
  - Skin and skin structure infections caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
  - Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.

		○ Bacterial septicemia caused by *Bacteroides* species including the *B. fragilis* group and *Clostridium* species. ○ Bone and joint infections, (as adjunctive therapy), caused by *Bacteroides* species including the *B. fragilis* group. ○ Central nervous system (CNS) infections, including meningitis and brain abscess, caused by *Bacteroides* species including the *B. fragilis* group. ○ Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by *Bacteroides* species including the *B. fragilis* group. ○ Endocarditis caused by *Bacteroides* species including the *B. fragilis* group. • Prescriber must submit **ALL** of the following: ○ Current chart notes ○ Report indicating diagnosis/bacteria requiring treatment ○ Culture and sensitivity if available ○ Medical necessity over other antibiotics available without a PA including metronidazole tablets ○ Dose requested **RENEWAL REQUIREMENTS:** • Continuation requires a report that documents continued bacteria positivity **QUANTITY EDITS:** • No set maximum quantity since based on dose required **DISCUSSION:** No comments **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.
Reports		• FFS claim and eligibility data report • PASSE ProDUR report was not reviewed as there was no significant changes • FFS ProDUR report was not reviewed as there was no significant changes • Dr. Irons from Magellan gave the fee-for-service RDUR report ○ February 2024—7871 Non-adherence to antidepressants ○ March 2024 ○ 7280 Fluoroquinolones boxed warning relating to the increased risk of tendon rupture and tendinitis ○ 7971 Zolpidem or Temazepam > 35 days duration ○ April 2024 ○ 7970 Fluoroquinolones should be used with caution in diabetes ○ 7818 Cyclobenzaprine duration > 6 weeks ○ 15232 Warfarin without a claim for INR testing **ACTION:** Motion was made by Dr. Mancino for the above criteria; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.
Adjourn		Meeting adjourned at 11:55 am.