Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	January 15, 2025 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Jeniffer Martin, Pharm.D. Prime Therapeutics Karen Evans, P.D. Prime Therapeutics	
Attendance		**Panelist (voting members)**		**Panelist (non-voting members)**	**Organization**
		Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
		Clint Boone, Pharm.D.	X	Kyle Stirewalt, Pharm.D.	Empower
		Ashley Crawley, Pharm.D.	X	Trinh Mowder, Pharm.D.	Empower
	X	Trenton Dunn, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Lana Gettman, Pharm.D.	X	Jessica Lawson, Pharm.D.	CareSource
	X	Michael Mancino, M.D.		Jennifer Chapin, Pharm.D.	CareSource
	X	Melissa Max, Pharm.D.	X	Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Laurence Miller, M.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	Brenna Neumann, Pharm.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Daniel Pace, M.D.	X	Elizabeth Pitman	DHS DMS director
	X	Paula Podrazik, M.D.	X	William Golden, M.D.	DHS advisor
	X	Chad Rodgers, M.D.	X	Christopher Smith, M.D.	DHS advisor
	X	Shailendra Singh, MBBS, FACP	X	Shane David, Pharm.D.	ADH advisor
		Open PharmD position	X	Karen Evans, P.D.	Prime Therapeutics
		Open M.D. position	X	Jeniffer Martin, Pharm.D.	Prime Therapeutics
			X	Lesley Irons, Pharm.D.	Prime Therapeutics
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:34am.			
Public comments		1) Derrick Grass, PharmD, CSP—Novo Nordisk Barry Tedder, MD—cardiologist and lipidologist from Jonesboro, AR Ozempic® and Rybelsus® 2) Beth Zanrucha, PharmD—IntraBio Inc. Aqneursa™ 3) Matt Nguyen, PharmD—AbbVie---gave his time back to the committee Vyalev™ 4) Tracey Maravilla, PharmD—Ascendis Pharma, Inc. Yorvipath™			
Announce-ments		1. There were no conflicts of interest with any voting Board member, Dr. Pearson, Dr. Martin or Dr. Evans. 2. Update on Board composition— a. Resigned—Brian King, PharmD b. Current open positions—1 pharmacist and 1 rare disease physician/APRN 3. Quarterly provider newsletter--  Arkansas Medicaid Quarterly Newslette 4. New medications following the oncology policy a. ITOVEBI b. DANZITEN			
Minutes		Motion to approve October 2024 DUR meeting minutes as presented was made by Dr. Rodgers, second by Dr. Gettman. All voting members present voted for approval of the minutes as written. Motion passed.			
Reports		• Dr. Martin from Prime Therapeutics gave the fee-for-service beneficiary lock-in status, Top 25 reports, slides on net spend, specialty drugs, and state supported brand data. She also presented RDUR criteria for voting for the next quarter. ○ February 2025—Atypical antipsychotics without metabolic testing for adults			

		○ March 2025—Atypical antipsychotics use with caution in patients with diabetes ○ April 2025—Antipsychotics (all types) in children ages 0-17 **ACTION:** Motion was made by Dr. Miller for the above criteria; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed. • Dr. Pearson presented the PASSE ProDUR report for July-September 2024. • Dr. Evans from Prime Therapeutics presented the FFS ProDUR report for October-December 2024
PDL Class Review		**1) Glucagon Agents** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with information on indication, delivery system, and time to recovery b) Visual slide of products c) Guidelines from 2025 American Diabetes Association Standards of Care and 2022 Endocrine Society Clinical Practice d) Claims summary from 1/1/2024-12/31/2024 **DISCUSSION:** Dr. Neumann asked if the traditional Glucagon kit was not rebateable. Dr. Martin stated that there's not a supplemental rebate. Dr. Neumann asked if Gvoke had a rebate that helped with the upfront cost. Dr. Pearson stated that the cost committee would need to review that information and the new supplemental rebate bids are not yet available. Dr. Golden stated that he may have some utilization data to share. Dr. Neumann was wondering if any of them should be non-preferred. As a dispensing pharmacist, she would like them all as preferred. Dr. Pearson stated that as a Medicaid program that is sometimes not ideal. Dr. Pearson asked for a motion. Dr. Max made the motion for an auto injector and nasal powder to be preferred. **ACTION:** Motion was made by Dr. Max for nasal powder and at least one auto injector to be preferred (no criteria to discuss); second by Dr. Rodgers. All other members in attendance voted for the motion. Motion passed. **2) GLP-1 Agonists** Chair provided the background on the last review of the class, list of drugs discontinued, and confirm that this review is for diabetes and major adverse cardiovascular events only and not for weight loss. Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with indications and dosing frequency b) Clinical Outcomes with glycemic efficacy, cardiovascular effects, and microvascular effects c) Guidelines from American Diabetes Association and American Association of Clinical Endocrinologists d) Claims summary from 1/1/2024-12/31/2024 **DISCUSSION:** Dr. Pearson recommended no change to the POS criteria for preferred products, and she recommended at least 2 preferred options with 2 indications for the PDL. Dr. Mancino asked if there was an oral option. Dr. Pearson confirmed there is Rybelsus. Dr. Max commented that Rybelsus doesn't have cardiovascular data like the injection. Dr. Max would like to add semaglutide as preferred. Dr. Max asked about adding CKD to POS edit. Dr. Martin confirmed CKD is not a current indication. Dr. Pace noted that patients with CKD should not take metformin. Dr. Dunn commented about supply issues with these agents, so having 3 preferred would be ideal. Dr. Golden wanted to comment that metformin is safe with GFR >30, and Dr. Podrazik confirmed. Dr. Pearson formulated a motion based on Board comments. Motion was to have 2-3 preferred products with multiple indications with consideration of the cost committee recommendation. **ACTION:** • Motion was made by Dr. Dunn to make 2-3 preferred products with multiple indications preferred with PDL recommendation from cost committee; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed. • POS criteria was not updated.

3) GnRH Receptor Antagonists (uterine disorders)

RECOMMENDED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- 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 prescribed one of the following medications with corresponding indications:
  - Orilissa
    - Moderate to severe pain associated with endometriosis
  - Oriahnn
    - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
  - Myfembree
    - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
    - Moderate to severe pain associated with endometriosis in premenopausal women
- Attestation that beneficiary of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy
- Beneficiary must have tried and failed at least 2 of the following treatment options with at least a 3-month history (unless documentation of contraindication is provided):
  - NSAIDs and/or acetaminophen usage (for endometriosis associated pain)
  - Contraceptives (i.e., combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, and vaginal rings)
  - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
  - Intrauterine device
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Postmenopausal
  - Pregnant
  - Known osteoporosis because of risk for further bone loss (T-score <-1.0 SD)
  - Severe hepatic impairment (Child-Pugh C); dose modifications may be needed for moderate hepatic impairment
  - Requires concomitant organic anion transporting polypeptide (OATP) 1B1 (a hepatic uptake transporter) (e.g., cyclosporine and gemfibrozil)
  - History of major depression or PTSD in the last 2 years OR history of a major psychiatric disorder (i.e., schizophrenia or bipolar) OR history of suicide attempt in the last year
  - Exceeds the following dosing:
    - ORILISSA
      - 150 mg once daily for 24 months-- no hepatic impairment or dyspareunia
      - 200 mg twice daily for 6 months—has dyspareunia
      - 150 mg once daily for 6 months—has moderate hepatic impairment (Child-Pugh B)
    - MYFEMBREE—1 tablet daily for maximum of 24 months
    - ORIAHNN—1 capsule twice daily for maximum of 24 months
  - Request for ORILISSA
    - Chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts)
  - Request for ORIAHNN or MYFEMBREE
    - High risk of arterial, venous thrombotic, or thromboembolic disorders which is defined as having at least one of the following
      - woman over 35 years of age who smoke
      - current or history of deep vein thrombosis or pulmonary embolism
      - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)

- thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
- inherited or acquired hypercoagulopathies
- uncontrolled hypertension
- headaches with focal neurological symptoms or have migraine headaches with aura if over age 35

  - Current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk of hormonally-sensitive malignancies
  - Undiagnosed abnormal uterine bleeding
  - History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL)
  - Concomitant use with oral P-gp inhibitors for MYFEMBREE

- Prescriber must submit the following:
  - Name of the medication being requested
  - Current chart notes with symptom history
  - Documentation of previous therapies tried with duration and response
  - Confirmation of diagnosis with pelvic exam results and imaging/biopsy results (e.g., transvaginal US, MRI, laparoscopy, CT scan)
  - Current labs including CBCs and LFTs
  - Confirmation of negative pregnancy status (i.e., current negative pregnancy test, beginning medication within 7 days of onset of menses, or tubal ligation)
  - Letter of medical necessity outlining the need for one of these medications over other treatment options ((i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery)
  - If requesting a non-preferred medication, provide the necessity of the chosen medication over the preferred option(s).

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate improvement of symptoms (i.e., reduction in endometriosis related pain, decrease in heavy menstrual bleeding and/or improvement in hemoglobin)
- Beneficiary remains free from hepatic impairment, osteoporosis, psychiatric disorders, and pregnancy
- Beneficiary has not surpassed the maximum treatment duration as noted in the package insert
- Beneficiary of reproductive potential remains on non-hormonal contraception
- Prescriber must submit the following:
  - Current chart notes with documentation of current symptoms
  - Current labs including CBCs and LFTs
  - Documentation of negative pregnancy status

Dr. Martin presented a PowerPoint with the following information.

a) Overview of medications with dosing and indications
b) Information on endometriosis and uterine leiomyomata
c) Considerations for treatment
d) Claims summary from 1/1/2024-12/31/2024

DISCUSSION:

Dr. Golden asked about surgical intervention such as myomectomy. Dr. Pearson stated we have the requirement for the medical necessity over surgery. Dr. Golden will get back with Dr. Pearson. Dr. Pearson asked for a motion to accept the criteria as presented and make preferred options based on recommendation from the cost committee.

ACTION:

Motion was made by Dr. Mancino to defer to the cost committee recommendation for PDL placement and to accept the updated criteria as presented; second by Dr. Max. All other members in attendance voted for the motion. Motion passed.

		4) Ulcerative Colitis agents Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with dosage forms b) Information on endometriosis and uterine leiomyomata c) Information on medication dosing and product availability d) Treatment algorithm and AGA guidelines e) Claims summary from 1/1/2024-12/31/2024 **DISCUSSION:** Dr. Neumann asked if the recommendation was for 2 or 3 products in total. Dr. Pearson stated she would like to see at least 2 chemical entities and multiple dosage forms as preferred. Dr. Rodgers made the motion to add 2-3 products to the preferred list with different mechanisms of delivery. **ACTION:** Motion was made by Dr. Rodgers to allow 2-3 products to be preferred with different mechanisms of delivery; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed. **5) Duchenne Muscular Dystrophy** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with mechanism of action and age limitation b) Symptoms of DMD c) Considerations for treatment d) Claims summary from 1/1/2024-12/31/2024 **DISCUSSION:** Dr. Pearson stated that she recommends a steroid product be preferred with criteria and Duvyzat be non-preferred. But all 4 products should still require PA. Dr. Mancino made that motion. **ACTION:** Motion was made by Dr. Mancino to make at least one steroid product preferred with criteria; second by Dr. Gettman. All other members in attendance voted for the motion. Motion passed. **6) Classes without changes** • ALPHA GLUCOSIDASE INHIBITORS • DPP-4 INHIBITORS • MEGLITINIDES • METFORMINS • SGLT-2 INHIBITORS • SULFONYLUREAS • THIAZOLIDINEDIONES • AMYLIN ANALOGUES • ANTIEMETICS • NON-SEDATING ANTIHISTAMINES • INTRANASAL RHINITIS **DISCUSSION:** No comments **ACTION:** Motion was made by Dr. Miller to remove discontinued medications and keep the current preferred options; second by Dr. Rodgers. All other members in attendance voted for the motion. Motion passed.
Changes to existing criteria or edits		**1) FUROSCIX** The chair provided utilization data on FUROSCIX for the last year. **DISCUSSION:** No comments

ACTION:
Motion was made by Dr. Neumann to make no changes to the current prior authorization criteria; seconded by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

2) CRITERIA DOCUMENT UPDATE
The chair shared the drafts for criteria to update the big criteria document. Many of the medications listed in the criteria document had manual review without specific criteria. This proposed update was done to fix that issue.

MRD on document without criteria3.docx

DISCUSSION:
No comment

ACTION:
Motion was made by Dr. Mancino to accept the entire document as presented; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

3) GENERAL MEDICATION POLICY UPDATE
The chair presented updates to the general medication policy to include language about off-label requests and process for updating the criteria document when a new product is on the market.

DISCUSSION:
No comment

ACTION:
Motion was made by Dr. Rodgers to accept the policy updates as presented; second by Dr. Max. All other members in attendance voted for the motion. Motion passed.

New Business

1) NEMLUVIO (nemolizumab-ilto) injection

RECOMMENDED APPROVAL CRITERIA:

Prurigo Nodularis

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease OR has a comorbidity of moderate to severe atopic dermatitis
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis/prurigo nodularis
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- If the request is for a non-preferred medication, the beneficiary must have tried and failed the preferred biologic(s) with this indication before non-preferred options can be approved unless there is a patient specific contraindication to the preferred option(s)
- Beneficiary must have a trial and failure of topical medications and at a minimum must include (unless contraindicated or inappropriate for the patient's age):
    - At least ONE topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) OR superpotent (Class-1) OR medium potency for children; AND
    - At least ONE trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- Prescriber must submit the following:
    - Current chart notes
    - Description of current status for baseline (i.e., BSA of nodules, peak pruritis Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA)
    - Previous therapies tried of no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

DISCUSSION:
No comment

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

2) AQNEURSA (levacetylleucine) granule packet AND MIPLYFFA (arimoclomol citrate) capsule

RECOMMENDED APPROVAL CRITERIA (AQNEURSA):

- 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 have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) 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 geneticist, neurologist, or other specialist with expertise in the treatment of NPD
- Beneficiary should not be approved or continue the medication if meets one of the following:
    - Weighs <15 kg
    - Pregnant
    - Dose requested does not match weight-based dosing found in the package insert
    - Prescribed Miplyffa™ (arimoclomol) to be used concomitantly
- Prescriber must submit the following:
    - Current chart notes
    - Previous therapies tried with response
    - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
    - Current weight and dose requested
    - Neurological symptoms for this specific patient
    - Negative pregnancy test results if applicable
    - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception

RECOMMENDED APPROVAL CRITERIA (MIPLYFFA):

- 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 have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) and prescribed concomitant miglustat 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 geneticist, neurologist, or other specialist with expertise in the treatment of NPC
- Beneficiary with eGFR ≥ 15 to < 50 mL/minute should decrease MIPLYFFA dose frequency
- Beneficiary should not be approved or continue the medication if meets one of the following:
    - Weighs <8 kg
    - Pregnant
    - Dose requested does not match weight-based dosing found in the package insert
    - Prescribed Aqneursa™ (levacetylleucine) to be used concomitantly
    - eGFR < 15 mL/minute
- Prescriber must submit the following:
    - Current chart notes with previous therapies tried with response
    - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
    - Current labs including eGFR
    - Current weight and dose requested

- Neurological symptoms for this specific patient
- Negative pregnancy test results if applicable
- Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
- Letter of medical necessity for the use over Aqneursa™ (levacetylleucine) for this specific patient

RENEWAL REQUIREMENTS: (MIPLYFFA and AQNEURSA)

- Beneficiary remains compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with a decrease or slowed progression in neurological symptoms compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Response to treatment with updated description of symptoms
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of continuing effective contraception and is not currently pregnant

QUANTITY EDITS:

Aqneursa--#120/30 days
Miplyffa--#90/30 days

DISCUSSION:

No comment

ACTION:

Motion was made by Dr. Rodgers to accept the criteria as presented; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

3) HYMPAVZI (marstacimab-hcnq) injection

RECOMMENDED 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 requires routine prophylaxis to prevent or reduce the frequency of bleeding episodes and is diagnosed with one of the following:
  - hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, OR
  - hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
- Beneficiaries must meet ONE of the following for confirming disease severity:
  - Severe disease with <1% of factor VIII or factor IX in blood while on factor products; OR
  - Moderate disease with 1-5% of factor VIII or factor IX in blood while on factor products with ONE of the following (prescriber must submit letter of medical necessity and chart notes to support):
    - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; OR
    - At least two (2) joint bleeds causing hemophilia-related joint damage; OR
    - Poor venous access; OR
    - High Factor VIII or Factor IX dose
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia treatment center
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Continues to receive prophylaxis Factor doses (e.g., FVIII, FIX, or bypassing agents)
  - Hympavzi™ is ordered for breakthrough bleeding
  - Pregnant
- Prescriber must submit the following:
  - Chart notes for the last 24 weeks with summary of bleeding events
  - Previous therapies tried with timeline and response (prophylaxis and acute treatment)
  - Current factor activity and annualized bleeding rate
  - Current labs including CBC
  - Negative pregnancy test results if applicable

- Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
- Attestation that beneficiary has been counseled on proper technique on episodic treatment with factor VIII or factor IX products as needed for breakthrough bleeding episodes
- Medical necessity over prophylaxis factor products and Hemlibra® for hemophilia A

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a decrease in annualized bleeding rate compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC
  - Summary of bleeds since last PA

QUANTITY EDITS:

- #8 /28 days

DISCUSSION:
No comment

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

4) VYALEV (foscarbidopa/foslevodopa) injection

RECOMMENDED 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 advanced Parkinson's disease and experiencing continued motor fluctuations despite compliance on carbidopa/levodopa 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 demonstrated a previous response to levodopa but continue to have motor fluctuations with a minimum of 2.5 hours of "Off" time per day
- Prescriber must attest that patient/caregivers have been counseled on potential adverse effects that require monitoring that could require a dose reduction or discontinuation (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma)
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Requires non-selective monoamine oxidase (MAO) inhibitor
  - Has a major psychiatric disorder
- Prescriber must submit the following:
  - Current chart notes
  - Current symptoms of Parkinson's Disease
  - Average number of "Off" hours per day
  - Medical necessity over increasing the dose on long and short acting oral carbidopa/levodopa products

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary demonstrates a decrease in "Off" hours compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Attestation that patient continues to be monitored for potential adverse reactions (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma)

DISCUSSION:
No comment

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

5) DUVYZAT (givinostat) suspension

RECOMMENDED 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 indication. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders
- Beneficiary must have been stable on prednisone, deflazacort, or vamorolone for at least 6 months unless there is a documented contraindication
- Beneficiary will continue corticosteroid therapy concomitantly unless contraindicated
- Beneficiary should not be approved or continue the medication if meets one of the following:
    - Baseline platelet count less than 150 x 10^9/L
    - Triglycerides remain elevated despite adequate dietary intervention and dosage adjustment
    - Previous gene therapy for the treatment of DMD
    - Currently non-ambulatory
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of the mutation in the dystrophin gene
    - Previous therapies tried with timeframe and response
    - Current labs including platelets and lipids
    - Baseline ECG results if has underlying cardiac disease or taking concomitant medications that cause QT prolongation
    - Current weight
    - Dose requested
    - Baseline assessment of ambulatory function to be used throughout treatment for consistent monitoring (e.g., Time to Stand Test (TTSTAND), 4-stair climb (4SC) time, North Star Ambulatory Assessment (NSAA))
    - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
    - Letter of medical necessity with a significant clinical reason specific to the beneficiary that DUVYZAT is needed over the preferred medications and of medications available as a medical claim (i.e., eteplirsen, golodirsen, casimersen, and viltolarsen)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with either clinical improvement or a decrease in the rate of function decline compared to baseline
- Beneficiary lacks clinically significant or intolerable adverse effects related to treatment (i.e., platelets remain >150 x 10^9/L)
- Prescriber must submit the following:
    - Current chart notes with documentation of response to therapy
    - Current labs including platelets and lipids
    - Attestation that the beneficiary continues physical therapy

QUANTITY EDITS:
420 mL (3 bottles)/35 days

DISCUSSION:
Dr. Pearson read communication from Dr. Veerapandiyan (provider with Arkansas Children's Hospital). Dr. Chris Smith did not have anything to add to the communication read**.**

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

6) LODOCO (colchicine) tablet

RECOMMENDED 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 atherosclerotic disease or have multiple risk factors for cardiovascular disease
- Beneficiary is currently taking standard of care treatment for chronic coronary disease (e.g., antiplatelet, anticoagulant, lipid-lower agent, beta blocker, renin-angiotensin inhibitor)
- Beneficiary should not be approved or continue the medication if meets one of the following:
    - Renal failure (CrCl <15 mL/minute); patients with renal impairment should be monitored
    - Severe hepatic impairment
    - Requires strong CYP3A4 inhibitors or P-gp inhibitors
    - Has pre-existing blood dyscrasias (i.e., myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia)
    - Develops neuromuscular toxicity or rhabdomyolysis
- Prescriber must submit the following:
    - Current chart notes
    - Previous therapies for atherosclerotic disease
    - Letter of medical necessity over the use of colchicine 0.6 mg capsule or tablet (We recommend to remove the POS edit for colchicine tablets and make available without prior authorization).

RENEWAL REQUIREMENTS:

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of any change to cardiovascular status

QUANTITY EDITS:
#30/30 days

DISCUSSION:
Dr. Golden noted cardiology guidelines state that colchicine should not be given with eGFR< 60. Dr. Singh stated there is no contraindication to using colchicine with eGFR< 60. If eGFR is <30, then dose adjustment needs to be made, and people on dialysis can take it with adjustments. Dr. Golden clarified that colchicine was not effective for patients with eGFR <60, and the issue is with effectiveness not toxicity. Dr. Podrazik asked what the limits in the trial were. Dr. Podrazik asked if we would add criteria around eGFR and efficacy. Dr. Mancino recommended that we approve the criteria with changes to be made around efficacy later after research.

ACTION:
Motion was made by Dr. Mancino to accept the criteria as amended; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

7) YORVIPATH (palopegteriparatide) injection

RECOMMENDED 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 hypoparathyroidism
- Must be prescribed by, or in consultation with, an endocrinologist, nephrologist or other specialist knowledgeable in treating hypoparathyroidism

		• Beneficiary must not have adequate control of hypocalcemia with calcium and vitamin D supplements prior to approval • Beneficiary must have a baseline albumin-corrected serum calcium of at least 7.8 mg/dL while using calcium and active vitamin D treatment • Beneficiary should not be approved or continue the medication if meets one of the following: o At increased risk of osteosarcoma o Open epiphyses. YORVIPATH is not approved in pediatric patients o Metabolic bone diseases other than hypoparathyroidism, including Paget's disease of bone. o Unexplained elevations of alkaline phosphatase. o Bone metastases or a history of skeletal malignancies. o History of external beam or implant radiation therapy involving the skeleton. o Hereditary disorders predisposed to osteosarcoma o Has acute post-surgical hypoparathyroidism o Requested dose exceeds 30 mcg per day or dose requested requires more than 1 injection o Prescribed concomitant teriparatide (Forteo®) • Prescriber must submit the following: o Current chart notes o Documentation of previous therapies tried o Dose requested o Current labs including calcium, vitamin D, magnesium o Treatment plan that includes monitoring calcium levels 7-10 days after first dose and after any dose change of YORVIPATH, active vitamin D, or calcium supplements. For maintenance, labs should be checked at a minimum every 4-6 weeks or when patient experiences symptoms of hypocalcemia or hypercalcemia. **RENEWAL REQUIREMENTS:** • Beneficiary must remain compliant with therapy including calcium and vitamin D supplements if prescribed concomitantly (compliance defined as 75% utilization) • Beneficiary has a positive response with albumin-corrected serum calcium within normal limits • If labs are not within desired range and beneficiary takes a 30 mcg daily dose along with calcium and vitamin D supplements, provide medical necessity for continuing the medication. • Prescriber must submit the following: o Current chart notes o Current labs including calcium, vitamin D, magnesium **QUANTITY EDITS:** # 2 pens/28 days **DISCUSSION:** Dr. Golden asked if this medication would cover surgically induced hypoparathyroidism or only metabolic caused hypoparathyroidism. The manufacturer rep confirmed that post-surgical patients were included, but not those acute post-surgical. **ACTION:** Motion was made by Dr. Neumann to accept the criteria as presented; second by Dr. Rodgers. All other members in attendance voted for the motion. Motion passed.
Board comments		No comments
Adjourn		Meeting adjourned 11:40am