Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	April 16, 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	Lora Ertmoed, Pharm.D.	Empower
	X	Ashley Crawley, Pharm.D.		Trinh Mowder, Pharm.D.	Empower
		Trenton Dunn, Pharm.D.	X	Jon Delarosa, Pharm.D.	Empower
	X	Lana Gettman, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	John Dawson Irvin, M.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.		Elizabeth Pitman	DHS DMS director
	X	Paula Podrazik, M.D.	X	William Golden, M.D.	DHS advisor
	X	Chad Rodgers, M.D.		Christopher Smith, M.D.	DHS advisor
	X	Shailendra Singh, MBBS, FACP	X	Paul Koesy, Pharm.D.	ADH advisor
		Open Pharm.D. position	X	Karen Evans, P.D.	Prime Therapeutics
			X	Jeniffer Martin, Pharm.D.	Prime Therapeutics
			X	Lesley Irons, Pharm.D.	Prime Therapeutics
			X	Linsey Gillam, 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 8:38am.
Public comments		1) Uche Ndefo, Pharm.D., BCPS—UCB Bimzelx® 2) Tara Koehler, Pharm.D., MPH, BCACP—Pfizer Velsipity® 3) Gabriela Gutierrez, M.D.—Pfizer Litfulo® 4) Marian Gaviola, Pharm.D.—Amgen Otezla® 5) Tyler Lincoln, Pharm.D.—Arcutis Biotherapeutics Zoryve® cream 6) Keith Boesen, Pharm.D.—Rare Disease Therapeutics, Inc. Xromi® 7) Matt Nguyen, Pharm.D.—AbbVie Rinvoq® and Skyrizi® 8) Jeremy Smoldon, PhD—Supernus Onapgo™ 9) Shirley Quach, Pharm.D.—Novartis Cosentyx®
Announce-ments		1. Dr. Singh had a conflict of interest with Bimzelx. We allowed him to vote for the PDL class, as he did not recommend for this product to be preferred. There were no other conflicts of interest with any voting Board member, Dr. Pearson, Dr. Martin or Dr. Evans. 2. Update on Board composition— a. Resigned—Laurence Miller, M.D. b. New member—John Dawson Irvin, M.D. c. Current open positions—1 pharmacist 3. Quarterly provider newsletter--

		 Arkansas Medicaid Quarterly Newsletter , 4. New medications following the oncology policy a. REVUFORJ (revumenib) tablets b. ROMVIMZA (vimseltinib) capsules c. MERCAPTOPURINE (generic for Purixan®) oral suspension 5. ALYFTREK will follow the point-of-sale edits like the other CFTR agents for cystic fibrosis. 6. EVRYSDI tablets will follow the PA criteria currently in place for the EVRYSDI solution. 7. JOURNAVX will not require prior authorization for the medication itself, but it will have a quantity limit of #30/60 days (14 day supply) due to the FDA approved acute pain indication. Pharmacy claims that exceed this limit will require prior authorization.
Minutes		Motion to approve January 2025 DUR meeting minutes as presented was made by Dr. Rodgers, second by Dr. Pace. 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, and Top 25 reports. She also presented RDUR criteria for voting for the next quarter. ○ May 2025—Updated guidelines for treating acute dental pain ○ June 2025—Concomitant use of opioids and benzodiazepines ○ July 2025—Concomitant use of opioids and antipsychotics **ACTION:** Motion was made by Dr. Pace for the above criteria; second by Dr. Podrazik. All other members present voted for the motion. Motion passed. • Dr. Pearson presented the PASSE ProDUR report for October-December 2024. Also, Dr. Pearson gave an update on implementation from the January meeting along with an update on the GLP-1 agonist class. • Dr. Evans from Prime Therapeutics presented the FFS ProDUR report for January-March 2025
PDL Class Review		**1) Insulins** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with information on insulin type, onset of effect, peak time, and duration of effect b) Pharmacokinetic profile of currently available single insulin products c) Information from World Health Organization on biosimilars d) Guidelines from 2025 American Diabetes Association Standards of Care e) Claims summary from 1/1/2024-12/31/2024 **DISCUSSION:** Dr. Neumann noted that Lantus has had some availability issues off and on recently, and she would recommend having a second alternative in the long-acting class. Dr. Pearson is concerned about patients switching back and forth between products and biosimilars might be a way to get around the issue, but we will need to let the cost committee review. Dr. Pearson asked for a motion to allow review with the cost committee for PDL placement. **ACTION:** Motion was made by Dr. Mancino for review by drug cost committee; second by Dr. Max. All other members in attendance voted for the motion. Motion passed. **2) Targeted Immunomodulators** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications by mechanism of action and FDA approved indications b) Treatment guidelines on plaque psoriasis from the American Academy of Dermatology/national Psoriasis Foundation 2019/2020 c) Treatment guidelines on psoriatic arthritis from Group Research and Assessment of Psoriasis/Psoriatic Arthritis (GRAPPA) 2021 and American College of Rheumatology (ACR)/NPF 2018 d) Treatment guidelines on rheumatoid arthritis from ACR 2021 e) Treatment guidelines on juvenile idiopathic arthritis from ACR 2021 and ACR/Arthritis Foundation 2019 f) Treatment guidelines on ankylosing spondylitis from ACR, Spondylitis Association of America (SAA), and Spondylarthritis Research and Treatment Network (SPARTAN) 2019 g) Treatment guidelines on Crohn's Disease from American Gastroenterological Association (AGA) and American College of Gastroenterology (ACG) 2018/2021

h) Treatment guidelines on Ulcerative Colitis from AGA 2020/2021 and ACG 2019
i) Summary of presentation
j) Claims summary from 1/1/2024-12/31/2024

DISCUSSION:
Dr. Singh noted that when it comes to the guidelines sometimes different people interpret them differently. And sometimes most of the organization try not to make it hard, so that it is flexible for interpretation. But when it comes to the different biologics, there is no one better than another and choice should be made on specific patient characteristics. Dr. Singh understands that cost is very important, but we also need to provide some kind of flexibility for the clinical decision making of the physicians who are taking care of these patients. Dr. Pearson noted that our review team does consider the requests on a case-by-case basis and takes into consideration special circumstances. Dr. Singh asked if we have specialists available for peer-to-peer consults. Dr. Pearson noted that we don't typically have peer-to-peer with our medical directors, but we do not have specialists available. Dr. Singh offered to assist us in these situations as his expertise is biologics. Dr. Golden stated there is emerging data about subtypes of these rheumatologic conditions causing the drugs to go through slightly different pathways. So some patients with different subtypes may respond to agents differently than other patients, and we may need to track this later. Dr. Singh agrees and states many of these patients have overlapping diagnoses (e.g., rheumatoid arthritis and lupus) which could impact the best treatment overall. The lupus in these patients could worsen when using TMFs. Guidelines do not cover these types of scenarios. Dr. Pearson noted that the expectation was to add 1-2 more preferred options with different MOAs with multiple indications. Dr. Singh made the motion to allow the cost committee to review products for adding additional preferred products.

ACTION:
- Motion was made by Dr. Singh for review by drug cost committee with at least 1 new preferred medication with different MOA; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.
- Prior approval criteria was not discussed.

3) Long-Acting Opioids

Dr. Martin presented a PowerPoint with the following information.
a) Overview of medications with DEA schedule and FDA approved indications
b) Opioid dispensing rates 2023 from CDC
c) Pharmacology with mechanism of action of the agents
d) Treatment guidelines for cancer pain from American Society of Clinical Oncology (ASCO) 2022 and National Comprehensive Cancer Network (NCCN) 2024
e) Treatment guidelines for non-cancer pain from American Society of Interventional Pain Physicians (ASIPP) 2023 and CDC 2022
f) Treatment guidelines for low back pain from North American Spine Society (NASS) 2020 and American College of Physicians (ACP) 2017
g) Treatment guidelines for neuropathic pain from American Academy of Neurology (AAN) 2021 and ASCO 2020
h) Treatment guidelines for postoperative pain from Institute for Clinical Systems Improvement (ICSI) 2021
i) Summary of presentation
j) Claims summary from 1/1/2024-12/31/2024

DISCUSSION:
Dr. Golden asked if the opioid prescription rates by county were by prescriber or recipient's address. Dr. Martin noted that it is just by prescription location. Dr. Golden mentioned this may skew results as more surgeries would be done in Pulaski County. Dr. Neumann asked where the data came from, and Dr. Martin responded that it came from the CDC. Data presented is all payer rate, not just Medicaid data. Dr. Golden noted that for the last 5-6 years on the National Medicaid report to the Secretary, Arkansas is one of the lower states in terms of high opioid prescribing MMEs for non-cancer patients. Dr. Neumann asked if we reviewed these recently. Dr. Pearson stated that we reviewed fairly recently, and we had added Xtampza at that time. Dr. Crawley noted that due to allergies to morphine, we need to vote for another one to be on there.

ACTION:
Motion was made by Dr. Crawley for review by drug cost committee with adding an additional medication as preferred with different chemical entity; second by Dr. Rodgers. All other members in attendance voted for the motion. Motion passed.

		4) Classes without changes • Antifungals – Topical • Anti-Hyperuricemics • Anti-Inflammatory Agents (NSAIDs) • Corticosteroids – Topical • Glaucoma Agents • Hemorrhoid Preparations • Ophthalmics - Allergic Conjunctivitis • Ophthalmics – Antibiotic-Steroid Combos • Ophthalmics - Anti-Inflammatory • Short-Acting Opioids **DISCUSSION:** No comments **ACTION:** Motion was made by Dr. Podrazik to remove discontinued medications and keep the current preferred options; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed.
Changes to existing criteria or edits		**1) ZORYVE CREAM & VTAMA CREAM** The chair provided an estimated reimbursement rate comparison for all topical atopic dermatitis agents (except for topical steroids). Criteria exists for these products for psoriasis, but the atopic dermatitis indication did not. The chair provided proposed approval criteria for each product based on current criteria for OPZELURA and information from each products' package inserts and recommended placement of these products as non-preferred in the topical atopic dermatitis class. **DISCUSSION:** No comments **ACTION:** Motion was made by Dr. Mancino to approve criteria as presented; second by Dr. Miller. All other members in attendance voted for the motion. Motion passed.
New Business		**1) ATTRUBY (acoramidis hcl) 356 mg tablet** **<u>RECOMMENDED APPROVAL CRITERIA:</u>** • 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 have the diagnosis of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) confirmed with **<u>TWO</u>** of the following: o Echocardiogram; **OR** o Tissue biopsy confirming the presence of transthyretin amyloid deposits; **OR** o Cardiovascular magnetic resonance imaging ▪ If consistent with cardiac amyloidosis, the following should be done to document the presence or absence of monoclonal protein confirmed by **<u>ONE</u>** of the following: • Serum kappa/lambda free light chain ratio analysis • Serum protein immunofixation • Urine protein immunofixation ▪ If monoclonal protein is not found, bone tracer cardiac scintigraphy (pyrophosphate scan) should be performed. Presence of grade 2 or 3 is highly specific for ATTR cardiac disease and tissue biopsy is not needed, but genetic testing is needed to confirm TTR variant. • Must be prescribed by, or in consultation with, a cardiologist • Beneficiary must have New York Heart Association Class (NYHA) I, II, or III heart failure with symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) • Beneficiary must have left ventricular wall (interventricular septum or left ventricular posterior wall) thickness ≥ 12 mm • Beneficiary should not be approved or continue the medication if meets one of the following:

- Impaired renal function (eGFR < 15 mL/min/1.73m^2)
- Baseline NT-proBNP <300 pg/mL or ≥8500 pg/mL
- Goal of treatment is strictly polyneuropathy

- Prescriber must submit the following:
  - Current chart notes
  - Symptoms specific to this patient to support diagnosis
  - Baseline 6-minute walk distance (6MWD)
  - Current labs including baseline eGFR and NT-proBNP level (≥ 300 pg/mL)
  - Baseline echocardiogram with NYHA classification and documentation of tests results to confirm diagnosis
  - Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of patient specific symptoms compared to baseline
  - Updated 6 minute walk distance (6MWD)
  - Current Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score

QUANTITY EDITS:
#120/30 days

DISCUSSION:
No comment

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

2) CRENESSITY (crinecerfont) 25 mg, 50 mg, & 100 mg capsule and 50 mg/mL oral solution

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 diagnosed with classic congenital adrenal hyperplasia with 21-hydroxylase deficiency and meets **ONE** of the following:
  - Requires supraphysiological glucocorticoid doses and has normal androgen levels; **OR**
  - Glucocorticoids provide inadequate androgen control
- Prescribed by, or in consultation with, an endocrinologist
- Beneficiary must remain on glucocorticoid replacement therapy
- Beneficiary requiring concomitant moderate or strong CYP3A4 inducer (e.g., carbamazepine, phenobarbital, bosentan, modafinil) will need dose modification
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Has severe renal impairment or end-stage renal disease
  - Is not prescribed concomitant glucocorticoids
- Prescriber must submit the following:
  - Current chart notes with documentation to support the diagnosis
  - Previous therapies tried with doses
  - Current glucocorticoid dose
  - Current serum androgen levels
  - Current comprehensive lab panel
  - Current weight to confirm proper dosing

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)

- Beneficiary must demonstrate a positive response to treatment with a decrease in required glucocorticoid daily doses compared to baseline and decrease in androgen levels (if elevated at baseline)
- Prescriber must submit the following:
  - Current chart notes
  - Current glucocorticoid dose
  - Current serum androgen levels

QUANTITY EDITS:

- #60/30 days for each capsule strength (PA override for exceeding this quantity if requires a CYP3A4 inducer)
- #120 ml/30 days for oral solution (PA override for exceeding this quantity if requires a CYP3A4 inducer)

DISCUSSION:
Dr. Irvin asked how often the prescriber would need to submit the chart notes. Dr. Pearson noted that typically the initial PA is for 3 months and follow-up PAs can be up to 6 months. The criteria can be updated to reflect this.

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

3) ZEPBOUND (tirzepatide) 10 mg and 15 mg injection—OSA indication only

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 diagnosed with moderate to severe obstructive sleep apnea (OSA) defined as apnea-hypopnea index (AHI) ≥15 respiratory events per hour based on polysomnography (PSG) results.
- Beneficiary must have a baseline diagnosis of obesity defined as body mass index (BMI) ≥ 30 kg/m^2 AND at least one of the following weight-related comorbid conditions:
  - Cardiovascular disease; **OR**
  - Type II diabetes mellitus; **OR**
  - Dyslipidemia; **OR**
  - Hypertension
- Medication must be prescribed by, or in consultation with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
- Beneficiary must have been participating in a comprehensive weight management program for at least 6 months with documented counseling on behavioral modification, reduced-calorie diet, and increased physical activity.
- Beneficiary must have at least a 6 month history of compliant positive airway pressure (CPAP or BiPAP) use without a decrease in AHI below 15 events per hour.
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Has not been on a weight management program for at least 6 months
  - Has not been compliant with nightly CPAP use
  - Prescribed another tirzepatide-containing product or any glucagon-like peptide 1 (GLP-1) receptor agonist to be used concurrently
  - Personal or family history of medullary thyroid carcinoma (MTC)
  - Diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Requested for weight loss only
  - Has been diagnosed with severe gastrointestinal disease including gastroparesis
  - Has a history of pancreatitis
  - Has a history of suicidal attempts or active suicidal ideation
- Prescriber must submit the following:
  - Current chart notes
  - Most recent polysomnography (PSG) results including AHI after CPAP or BiPAP trial
  - Patient specific symptoms attributable to OSA (e.g., self-reported daytime sleepiness, snoring episodes, and AHI events)
  - CPAP/BiPAP usage report
  - Current weight and body mass index (BMI)
- If approved, the PA will be approved for 6 months

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with Zepbound® usage (defined as 75% utilization) and compliant with positive airway pressure (CPAP or BiPAP) usage
- Beneficiary must demonstrate a positive response in OSA self-reported symptoms as compared to baseline (e.g., reduction in daytime sleepiness, reduction in snoring, or reduction in AHI) and decrease in weight/ body mass index (BMI)
- Beneficiary continues with comprehensive weight management program with behavioral modification, reduced-calorie diet, and increased physical activity.
- Prescriber must submit the following:
    - Current chart notes
    - Current weight and body mass index (BMI)
    - Documentation of patient specific symptoms improvement compared to baseline
    - Current CPAP or BiPAP usage report

QUANTITY EDITS:

#4 injections/ 28 days

DISCUSSION:

Dr. Irvin asked if we would need a formal consultation with the pulmonologist, etc. Most of the sleep studies are read by those specialists. He asked if that would be considered a consultation. Dr. Pearson noted that if a specialist read the sleep study and provided a report, then that should be sufficient. Dr. Irvin asked if a patient's BMI falls below 30, would they be required to stop the medication. Dr. Pearson said we don't require that for the other product that is indicated for MACE. Dr. Neumann asked if patient improved and no longer needed a CPAP, would they qualify for a renewal? Dr. Pearson stated that these types of requests would have to be reviewed on a case-by-case basis. Dr. Golden stated there are issues with long-term CPAP adherence requiring us to be flexible and watch how this evolves. Dr. Mancino asked what to do if can't tolerate a CPAP. Dr. Miller stated that is not dissimilar to some of the OSA/stimulant requests, and we look at those as individual considerations. Dr. Max stated that a trial of CPAP sounds reasonable, but there are patients that may truly not be able to tolerate for 6 months. Dr. Neumann asked if this drug would come up for re-evaluation. Dr. Miller suggested to leave the criteria as written and monitor requests for the next 6 months. Then we can bring the medication back to the Board in 6 months.

ACTION:

Motion was made by Dr. Miller to accept the criteria as presented with the request to bring back in 6 months for re-review; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed.

4) SOFDRA (sofpironium bromide) 12.45% gel

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 primary axillary hyperhidrosis with excessive sweating for at least 6 months despite the use of topical antiperspirants
- Beneficiary should not be approved or continue the medication if meets one of the following:
    - Diagnosed with secondary focal hyperhidrosis or Frey's Syndrome
    - Diagnosed with generalized hyperhidrosis, night sweats, or excessive sweating
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of products tried with response
    - Medical necessity over aluminum chloride-containing topical antiperspirants or has documented intolerance
- Initial approval would be for 3 months, subsequent approvals may be up to 6 months.

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with documentation of decreased sweating compared to baseline
- Prescriber must submit the following:

- Current chart notes
- Documentation of response to treatment

QUANTITY EDITS:
1 bottle (50mL)/ 30 days

DISCUSSION:
No comment

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

5) ALHEMO (concizumab-mtci) 60 mg, 150 mg, and 300 mg 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) with factor VIII inhibitors, **OR**
  - hemophilia B (congenital factor IX deficiency) with factor IX inhibitors.
- Beneficiary must meet **ONE** of the following:
  - High factor VIII or IX inhibitor titer (≥5 Bethesda units per mL (BU)); **OR**
  - Factor VIII or IX inhibitor titer <5 BU/mL with inadequate response to high dose factor;
- Beneficiary must have been prescribed, or need, treatment with bypassing agents
- 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 bypassing agents (e.g., rFVIIa or aPCC)
  - Alhemo® 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 episodic or prophylactic bypassing agents (e.g., FEIBA®, NovoSeven RT®, or Sevenfact®)
  - Documentation of **ONE** of the following:
    - Inadequate response to Immune Tolerance Induction (ITI); **OR**
    - Rationale why the beneficiary is not a candidate for ITI;
  - 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 bypassing agents as needed for breakthrough bleeding episodes
- Medical necessity over prophylaxis factor products and Hemlibra® for hemophilia A
- Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months.

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

DISCUSSION:
No comments

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

6) TRYNGOLZA (olezarsen) 80 mg/0.8 mL 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 familial chylomicronemia syndrome (FCS) confirmed by molecular genetic test with fasting triglycerides level ≥ 880 mg/dL and multifactorial (polygenic) chylomicronemia has been ruled out
- Prescribed by, or in consultation with, a cardiologist, endocrinologist, or specialist experienced in treating severe hypertriglyceridemia
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Not on a low-fat diet of ≤20 gm of fat per day
  - Currently smoker
- Prescriber must submit the following:
  - Current chart notes with genetic testing to confirm diagnosis
  - Previous medications tried for lowering triglycerides
  - Current fasting labs including lipid panel
  - Documentation of symptoms associated with FCS (e.g., fatigue, pancreatitis/ abdominal pain, eruptive xanthomas, lipemia retinalis, hepatosplenomegaly)
  - Attestation that beneficiary is on a low-fat diet with ≤20 gm of fat per day
- Initial PA will be for 3 months, renewal PAs may be up to 6 months

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with decrease in fasting triglycerides and decrease in symptoms documented at baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current fasting labs including lipid panel
  - Current documentation of symptoms
  - Attestation that the beneficiary remains on low-fat diet with ≤20 gm of fat per day

QUANTITY EDITS:
1 injection per 30 days

DISCUSSION:
No comments

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

7) ONAPGO (apomorphine) 98 mg/20 ml injection

RECOMMENDED APPROVAL CRITERIA: (red language is different from Vyalev®)

- 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 continue to have motor fluctuations with a minimum of 3 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., hemolytic anemia, reduced resting blood pressure, increase in falls, psychotic-like behavior, etc.)
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Requires the concomitant use of $5HT_3$ antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron)
  - Develops significant daytime sleepiness that interferes with normal daily function (e.g., conversations, eating, driving)
  - Drinks alcohol
  - Has severe renal or severe hepatic impairment
  - Pregnant
- Prescriber must submit the following:
  - Current chart notes
  - Current symptoms of Parkinson's Disease
  - Negative pregnancy test for female patient of reproductive potential
  - 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., excessive daytime sleepiness, increase in falls, hemolytic anemia, psychotic-like behavior, etc.)

QUANTITY EDITS:

No quantity limits due to patient specific dosing.

DISCUSSION:

No comments

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.

8) GOMEKLI (mirdametinib) 1 mg & 2 mg capsules and 1 mg tablet for oral 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 neurofibromatosis type 1 (NF1) and have symptomatic plexiform neurofibromas (PN) not amenable to complete resection **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 at least **ONE** measurable PN **AND** either a positive genetic test for NF1 **OR** have at least **ONE** other diagnostic criteria listed below:
  - 6 or more café'-au-lait macules; **OR**
  - Freckling in axilla or groins; **OR**
  - Optic glioma; **OR**
  - 2 or more Lisch nodules; **OR**
  - Distinctive body lesion; **OR**
  - First-degree relative with NF1
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Diagnosed with retinal vein occlusion (RVO) or retinal pigment epithelium detachment (RPED)
  - Has left ventricular ejection fraction (LVEF) <55% at baseline, or has an absolute decrease in LVEF 20% or greater from baseline after treatment begins
  - Is pregnant
  - Has uncontrolled hypertension
  - History of glaucoma
  - Alanine transaminase (ALT) > 2X ULN
  - Is unable to tolerate GOMEKLI after one dose reduction
- Prescriber must submit the following:
  - Current chart notes with status of plexiform neurofibromas
  - Current baseline left ventricular ejection fraction (LVEF)
  - Previous therapies tried including any surgery
  - Documentation of comprehensive ophthalmic assessment
  - Current body surface area (BSA) for dose determination (Dosed 2mg/m^2 twice daily for 21 days of each 28 day cycle)
  - Current labs including CBC, LFTs and creatine phosphokinase
  - Attestation that female patient of reproductive potential is using contraception
  - Medical necessity over Koselugo® (selumetinib)
- Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months.

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary should have an improvement with size or quantity of plexiform neurofibroma(s) after 9 months of treatment
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy
  - Documentation of left ventricular ejection fraction (LVEF) every 3 months during the first year
  - Current body surface area for dose determination
  - Current labs including CBC, LFTs and creatine phosphokinase
  - Attestation that female patient of reproductive potential is using contraception

QUANTITY EDITS:

1 mg—#84/ 28 days
(capsule available in package size of 42; tablets available in package sizes of 42 and 84)
2 mg—#84/ 28 days (available in package sizes of 42 and 84)
****Each NDC will have max quantity of package size.**

DISCUSSION:

No comments

ACTION:

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

9) INZIRQO (hydrochlorothiazide) 10 mg/mL suspension

RECOMMENDED APPROVAL CRITERIA:

POINT-OF-SALE (POS) EDITS:

- Patients under 7 years of age or have a diagnosis of NPO in the last 365 days; **AND**
- Billed diagnosis of hypertension or edema in the last 2 years

PATIENTS NOT MEETING POS 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 hypertension or edema associated with congestive heart failure, hepatic cirrhosis, or renal disease **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 submit the following:
    - Current chart notes
    - Baseline blood pressure or description of edema
    - Medical necessity over hydrochlorothiazide tablets and capsules

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary should have an improvement with underlying diagnosis
- Prescriber must submit the following:
    - Current chart notes
    - Current blood pressure or description of edema
    - Continued medical necessity of Inzirqo™ suspension over oral solid dosage forms

QUANTITY EDITS:

2 bottles per month (If patient requires a higher dose, a quantity override can be entered.)

DISCUSSION:

Dr. Golden noted that dose range is interesting as typically if a patient doesn't respond to 25 mg or less, they would be changed to another drug. Dr. Pearson noted that there was no clinical trial as this is just a formulation change of a parent drug. Dr. Crawley questioned the diagnosis of NPO within the last 365 days. She felt that treatment of cancer (for example) could cause NPO status to change more quickly than 1 year and leaving the lookback at 1 year could allow patients who can swallow to get this med when not necessary. Dr. Pearson noted that this language is typical for non-solid dosage forms on our POS coding which was verified by Dr. Evans. Dr. Crawley also noted that many meds can be crushed in a g-tube. Dr. Pearson will work with Dr. Evans to update the POS edit to remove the NPO portion.

ACTION:

Motion was made by Dr. Irvin to accept the criteria as amended; second by Dr. Crawley. All other members in attendance voted for the motion. Motion passed.

NOTE: As of 8/1/2025, the program will start electronic PA which can prompt questions about swallowing and ability to crush medication. The following was reviewed with Dr. Crawley, and she was in support of this update instead of removing NPO all together.

New Requirements

- **The beneficiary has history of an NPO procedure code within the past one year (365 days); OR**
- **The prescriber attests that the beneficiary is unable to swallow by mouth due to one of the following:**
    - **enteral feeding**
    - **nasogastric tube,**
    - **peg/pej tube; AND**
    - **The prescriber attests that the above is documented in the beneficiary's medical record (evidence of such is subject to audit); AND**
    - **The prescriber attests that the solid oral formulation cannot be crushed and administered via the feeding tube; OR**
- **The prescriber attests that the beneficiary cannot swallow the solid dosage formulation whole and is not taking any other solid dosage formulation by mouth.**
- **Length of authorization is 6 months.**

		10) XROMI (hydroxyurea) 100 mg/mL solution **<u>RECOMMENDED APPROVAL CRITERIA:</u>** **Point-of-sale (POS) edit** • Patients under 7 years of age or have a diagnosis of NPO in the last 365 days; **AND** • Billed diagnosis of sickle cell disease in the last 2 years **Patients not meeting POS criteria** • Beneficiary must be diagnosed with moderate to severe, painful crises associated with sickle cell anemia • Prescribed by, or in consultation with, a specialist in the treatment of sickle cell. • Prescriber must submit the following: o Current chart notes with documentation of pain crises and blood transfusion frequency o Medical necessity for the use of solution over capsules which are available without prior authorization o Negative pregnancy test if a female of reproductive potential o Attestation that female patients of reproductive potential will be using effective contraception o Attestation that labs will be monitored throughout treatment **<u>RENEWAL REQUIREMENTS:</u>** • Beneficiary is compliant on therapy (defined as 75% utilization) • Beneficiary must demonstrate an improvement in frequency of pain crises and transfusions • Prescriber must submit the following: o Current chart notes o Continued medical necessity for the use of oral solution over capsules o Attestation that female patients of reproductive potential will continue to use effective contraception **<u>QUANTITY EDITS:</u>** None since weight-based dosing **DISCUSSION:** Dr. Crawley noted that she believed hydroxyurea capsules could be opened and put in a G-tube. Dr. Crawley is mainly concerned by the language around NPO in last 365 days. **ACTION:** Motion was made by Dr. Irvin to accept the criteria as amended; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed. **NOTE: As of 8/1/2025, the program will start electronic PA which can prompt questions about swallowing and ability to crush medication. The following was reviewed with Dr. Crawley, and she was in support of this update instead of removing NPO all together.** **New Requirements** • **The beneficiary has history of an NPO procedure code within the past one year (365 days); OR** • **The prescriber attests that the beneficiary is unable to swallow by mouth due to one of the following:** o **enteral feeding** o **nasogastric tube,** o **peg/pej tube; AND** o **The prescriber attests that the above is documented in the beneficiary's medical record (evidence of such is subject to audit); AND** o **The prescriber attests that the solid oral formulation cannot be crushed and administered via the feeding tube; OR** • **The prescriber attests that the beneficiary cannot swallow the solid dosage formulation whole and is not taking any other solid dosage formulation by mouth.** • **Length of authorization is 6 months.**
Board comments		No comments
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