Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	October 16, 2024 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**
	X	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.		Kyle Stirewalt, Pharm.D.	Empower
	X	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	Brian King, Pharm.D.		Jennifer Chapin, Pharm.D.	CareSource
	X	Michael Mancino, M.D.	X	Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Melissa Max, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
	X	Laurence Miller, M.D.		Cynthia Neuhofel, Pharm.D.	DHS pharmacy
		Brenna Neumann, Pharm.D.		William Golden, M.D.	DHS advisor
		Daniel Pace, M.D.	X	Christopher Smith, M.D.	DHS advisor
	X	Paula Podrazik, M.D.	X	Shane David, Pharm.D.	ADH advisor
	X	Chad Rodgers, M.D.	X	Karen Evans, P.D.	Prime Therapeutics
	X	Shailendra Singh, MBBS, FACP	X	Jeniffer Martin, Pharm.D.	Prime Therapeutics
		Open M.D. position	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 8:35am.			
Public comments		1. David Miley, PharmD (Teva)—Uzedy® & Ajovy® 2. Chad Sanders (Ipsen)—Iqirvo® 3. William Rowe, MSN, RN, ACNP, BC (Intra-Cellular Therapies)—Caplyta® 4. Bryan Wilson, PhD & Kelly Copeland, PharmD (Genentech)—Evrysdi® 5. Nancy Njuguna, BPharm (Gilead Sciences)—Livdelzi® 6. Kenneth Berry, PharmD (Alkermes)—Lybalvi® & Aristada® 7. Matt John, PharmD (Otsuka)—Rexulti® 8. Matt Nguyen, PharmD (AbbVie)—Vraylar®, Ubrelvy® & Qulipta® 9. Erik Schindler, PharmD (Sanofi)—Dupixent® for COPD 10. Jonathan Jones, PharmD (Bristol Myers Squibb)—Cobenfy™ 11. Tyler Gums, PharmD (Pfizer)—Nurtec ODT®			
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—Florin Grigorian, MD & Tonya Robertson, PharmD b. Appointed—Shailendra Singh, MBBS, FACP & Ashley Crawley, PharmD c. Advisor—Christopher Smith, MD 3. Quarterly provider newsletter-- Arkansas Medicaid Quarterly Newsletter (4. New medications following the oncology policy a. Voranigo b. Lazcluze c. Generic Sprycel			
Minutes		Motion to approve July 2024 DUR meeting minutes as presented was made by Dr. Rodgers, seconded by Dr. Miller. 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 RDUR report and presented RDUR criteria for voting for the next quarter. ○ November 2024—			

		• Opioids with MME>50 in the last 6 months and no Naloxone in the last 365 days • Buprenorphine adherences 10 day gap in fill • Narcotic withdrawal treatment (oral) noncompliance 10 day gap in fill o December 2024— • Opioids and gabapentin concurrent use • Triptans are contraindicated with uncontrolled hypertension o January 2025— • Diagnosis of asthma or COPD and claims for oral glucocorticoids **ACTION:** Motion was made by Dr. Miller for the above criteria; seconded by Dr. Mancino. All other members present voted for the motion. Motion passed. • Dr. Pearson presented the PASSE ProDUR report for April-June 2024 as well as slides with overall net expenditures • Dr. Evans from Prime Therapeutics presented the FFS ProDUR report for July-September 2024
PDL Class Review		**1) Overactive Bladder Agents** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with information on the various mechanisms of action b) General information c) Considerations for treatment d) Treatment recommendations from American Urological Association, American Urogynecologic Society, and European Association of Urology e) Claims summary from 7/1/2023-6/30/2024 **DISCUSSION:** The chair made the recommendation to add a product to the preferred list based on the cost committee's recommendation. Dr. Max asked if I meant to add a Beta 3 product. She recommended that we consider adding one of those products with that different MOA. The motion made was to add an additional preferred option with the product being a different MOA if possible with cost committee review. **ACTION:** Motion was made by Dr. Max for PDL placement (no criteria to discuss); second by Dr. King. All other members in attendance voted for the motion. Motion passed. **2) Antipsychotics (oral and injectable)** Chair provided the background on last review of the class, information on Perseris, and notation of update to PA criteria document. Dr. Pearson also presented proposed criteria for Cobenfy. Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with indications and age limits b) Black box warnings c) Considerations for treatment d) Treatment recommendations for Schizophrenia from American Psychiatric Association, World Federation of Societies of Biological Psychiatry, American Academy of Child and Adolescent Psychiatry, and ICER e) Treatment recommendations for Bipolar from VA/DoD, American Psychiatric Association, and FDA indications in pediatrics f) Additional indications g) Claims summary from 7/1/2023-6/30/2024 **DISCUSSION:** Dr. Miller stated that oral antipsychotics should depend on cost committee review. Dr. Miller noted that since Perseris is going away, we will have to look at Uzedy carefully as the only other SQ med. The Chair noted that the recommendation is to have the cost committee consider Uzedy. No discussion on PA criteria. **ACTION:** Motion was made by Dr. Miller for PDL placement; second by Dr. King. All other members in attendance voted for the motion. Motion passed. Motion was made by Dr. Miller for criteria update; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

		3) Antimigraine Agents (excluding triptans) Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with drug classes and indications b) Considerations for treatment c) Treatment recommendations from American Headache Society, European Headache Federation, American Headache Society, and ICER d) Claims summary from 7/1/2023-6/30/2024 **DISCUSSION:** On PDL placement, the chair stated it may benefit our population to add another preferred preventative medication and one acute treatment option as preferred if that update is supported by the cost committee. Dr. Dunn asked if a prescription for these agents would automatically be processed without a PA. The chair stated that a PA would still be required. **ACTION:** Motion was made by Dr. Podrazik for PDL placement; second by Dr. Boone. All other members in attendance voted for the motion. Motion passed. Motion was made by Rodgers for PA criteria update; second by Dr. Dunn. All other members in attendance voted for the motion. Motion passed.
Changes to existing criteria or edits		**1) Voquezna (vonoprazan fumarate)** **PROPOSED APPROVAL CRITERIA:** (red dictates updated criteria language) • Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication • Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia • Beneficiary prescribed a VOQUEZNA Dual or Triple Pak must be diagnosed with *Helicobacter pylori* or beneficiary prescribed VOQUEZNA must be diagnosed with **ONE (1)** of the following: o for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. o to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. o for relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults. o in combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. o in combination with amoxicillin for the treatment of H. pylori infection in adults. • Beneficiary with erosive esophagitis or heartburn must have had previous treatment failure with or a contraindication to all preferred proton pump inhibitors • Beneficiary with *H. pylori* must have tried and failed (defined as failure to eradicate *H. pylori* infection after 14-day course of therapy) **ONE (1)** of the following: o Bismuth quadruple therapy unless contraindicated (e.g., bismuth, metronidazole, tetracycline and proton pump inhibitor); **OR** o Clarithromycin-based therapy unless contraindicated (e.g., clarithromycin, amoxicillin, and proton pump inhibitor) • Prescribed by or in consultation with a gastroenterologist or infectious disease specialist • Beneficiary should not be approved or continue this therapy with any of the following: o Requested duration of treatment for healing erosive esophagitis or relief of heartburn associated with erosive esophagitis exceeds 8 weeks o Requested duration of maintenance therapy for healed erosive esophagitis and relief of heartburn exceeds 6 months o Requested duration of treatment for heartburn associated with non-erosive gastroesophageal reflux disease exceeds 4 weeks o Requested duration of treatment for H. pylori exceeds 14 days • Prescriber must submit the following: o Current chart notes

- Previous therapies tried
- Confirmation of *H. pylori* if that is the diagnosis
- Letter of medical necessity requesting VOQUEZNA over guideline-recommended first-line treatment
- Voquezna requests require an endoscopy report confirming:
  - Current erosive esophagitis with treatment prescribed to heal erosive esophagitis; **OR**
  - Confirmed healed erosive esophagitis with treatment prescribed as maintenance therapy; **OR**
  - Confirmed lack of esophageal erosions but heartburn persists

- PA duration will be consistent with duration per the package insert

RENEWAL REQUIREMENTS:

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

DISCUSSION:
No comments.

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

2) OFEV (nintedanib) capsule & ESBRIET (pirfenidone):

PROPOSED OFEV 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
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with **ONE** of the following:

a. Idiopathic pulmonary fibrosis (IPF)
- Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation of some of the following:
  - Basal and peripheral dominance
  - Honeycombing (usually subpleural)
  - Reticular opacities or ground-glass opacities
  - Traction bronchiectasis
  - Airspace enlargement with fibrosis
- Baseline Pulmonary Function Tests (PFTs)
  - Forced vital capacity (FVC) is ≥50% predicted
  - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-79% of predicted
- Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out

b. Chronic fibrosing interstitial lung diseases with progressive phenotype (also called progressive pulmonary fibrosis) with a high-resolution CT scan indicating pulmonary fibrosis is affecting ≥10% of the lungs with at least two of the following in the last 24 months:
- Worsening respiratory symptoms (e.g., increased dyspnea on exertion)
- Radiological evidence of disease progression with at least one of the following:
  - Increased extent or severity of traction bronchiectasis and bronchiolectasis
  - New ground-glass opacity with traction bronchiectasis
  - New fine reticulation
  - Increased extent or increased coarseness of reticular abnormality
  - New or increased honeycombing
  - Increased lobar volume loss
- PFTs indicate disease progression with at least **ONE** of the following:

- FVC decline ≥10% predicted; OR
- FVC decline ≥5% and <10% predicted with worsening symptoms or imaging; OR
- DLCO decline (corrected for Hb) ≥10% predicted

c. Systemic sclerosis-associated interstitial lung disease (SSC-ILD) requires a diagnosis of systemic sclerosis (SSC) based on rheumatology guidelines and interstitial lung disease with the following:
- High-resolution CT scan indicates pulmonary fibrosis is affecting ≥10% of the lungs
- Baseline PFTs
  - Forced vital capacity (FVC) is ≥40% predicted; AND
  - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-89% of predicted

- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Likely to receive a lung transplant or has had a lung transplant
  - Has relevant airways obstruction (i.e., pre-bronchodilator FEV_1/FVC <0.7)
  - Pregnant or breastfeeding
  - Currently smoking
  - Moderate or severe hepatic impairment (Child Pugh B or C). Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dose of OFEV.
  - Has gastrointestinal perforation
  - Severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease
  - Caution in beneficiaries with known risk of bleeding (benefit outweighing the risk should be provided)
- Prescriber must submit the following:
  - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
  - Dose requested (PA is entered for specific dose)
  - Current labs including liver function tests
  - Baseline pulmonary function tests (PFTs)
  - Baseline 6-minute walk test (6MWT)
  - Letter of medical necessity over immunosuppressant for SSC-ILD patients (i.e., mycophenolate)
  - Documentation verifying the smoking status with **ONE** of the following:
    - exhaled carbon monoxide level (eCO) <6ppm; OR
    - carboxyhemoglobin (COHb) levels of <3%; OR
    - urine cotinine concentration <200 ng/mL

RENEWAL REQUIREMENTS:
- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following
  - Current chart notes
  - Current labs including LFTs
  - Documentation of response to therapy with any of the following:
    - Current pulmonary function tests
    - Current 6MWT
    - Current CT scan results of lungs

QUANTITY EDITS:
100 mg #60/30 days
150 mg #60/30 days

PROPOSED ESBRIET 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
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with idiopathic pulmonary fibrosis (IPF)
    - Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation some of the following:
        - Basal and peripheral dominance
        - Honeycombing (usually subpleural)
        - Reticular opacities or ground-glass opacities
        - Traction bronchiectasis
        - Airspace enlargement with fibrosis
    - Baseline Pulmonary Function Tests (PFTs)
        - Forced vital capacity (FVC) is ≥50% predicted
        - Carbon monoxide diffusing capacity (DLCO) is ≥30% predicted
    - Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out
- Beneficiary should not be approved or continue the medication if meet one of the following:
    - Likely to receive a lung transplant or has had a lung transplant
    - Has relevant airways obstruction (i.e., pre-bronchodilator $FEV_1/FVC < 0.8$)
    - Currently smoking
    - Severe hepatic impairment (Child Pugh C). Patients with mild to moderate hepatic impairment (Child Pugh A or B) should use ESBRIET with caution and consider dose modification or discontinuation if needed.
    - End-stage renal disease requiring dialysis. For patients with mild to severe renal impairment, monitor for adverse events and modify dose or discontinue as needed.
    - Develops Severe Cutaneous Adverse Reactions (SCAR)
- Prescriber must submit the following:
    - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
    - Strength of medication and dosage form requested (PA is entered for specific dose)
    - Current labs including liver function tests
    - Baseline pulmonary function tests (PFTs)
    - Baseline 6-minute walk test (6MWT)
    - Documentation verifying the smoking status with ONE of the following:
        - exhaled carbon monoxide level (eCO) <6ppm; OR
        - carboxyhemoglobin (COHb) levels of <3%; OR
        - urine cotinine concentration <200 ng/mL

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following
    - Current chart notes
    - Current labs including LFTs
    - Documentation of response to therapy with any of the following:
        - Current pulmonary function tests
        - Current 6MWT
        - Current CT scan results of lungs

QUANTITY EDITS:
267 mg tablet or capsule #270/30 days
801 mg tablet #90/30 days

DISCUSSION:
Dr. Podrazik noted in her clinical practice she notices that patients on OFEV tend to be slightly underweight and have a difficult time tolerating the diarrhea associated with this medication. The chair suggested that those patients could change to Esbriet as we don't have these products on the PDL.

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

3) EVRYSDI 0.75 mg/mL (risdiplam) powder for solution

PROPOSED 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 spinal muscular atrophy (SMA) by genetic testing with the following:
  - Documentation of SMN1 gene deletion or mutation; AND
  - Documentation of ≤ 4 copies of SMN2 gene whether a pre-symptomatic infant or symptomatic patient (SMA Type 1, 2, or 3)
- Prescribed by or in consultation with a neurologist experienced in treating SMA
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Dosage requested is not consistent with beneficiary's age and weight
  - Pregnant
  - Requires a Multidrug and Toxin Extrude (MATE1) substrate such as metformin, cimetidine or acyclovir. If concomitant use cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the co-administered drug.
  - Beneficiary had previous administration of gene therapy (i.e., Zolgensma® [onasemnogene abeparvovec-xioi]) either in a clinical study or as part of medical care
  - Provider requests concomitant treatment with a SMN2-targeting antisense oligonucleotide (i.e., Spinraza® [nusinersen])
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies tried
  - Documentation of symptoms and age of onset if not pre-symptomatic
  - Current weight to verify dose requested
  - Genetic testing results
  - Documentation of pulmonary status (e.g., tracheostomy, hours on ventilation, etc.)
  - Negative pregnancy test for a female beneficiary of childbearing potential prior to beginning EVRYSDI therapy and/or has documentation of contraception use
  - Attestation that a female beneficiary of childbearing potential has been counseled about contraception
  - Attestation that a male beneficiary has been counseled about potential infertility with EVRYSDI therapy
  - Documentation that the beneficiary is receiving physical therapy
  - Baseline motor ability assessment results of one of the following:
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **OR**
    - Motor Function Measure Score (MFM-32); **OR**
    - Revised Upper Limb Module (RULM); **OR**
    - Hammersmith Infant Neurological Examination Module 2 (HINE-2); **OR**
    - Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
    - Bayley Scales of Infant and Toddler Development, Third Addition (BSID-III or Bayley-III)

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- A symptomatic beneficiary must demonstrate a positive response in SMA associated signs and symptoms by either an improvement or no significant decline in motor function score compared to baseline assessment by using the same measuring scale as the baseline score **OR** demonstrating improvement or no significant decline in pulmonary function
- A beneficiary starting treatment prior to onset of symptoms must demonstrate a new motor milestone or maintained muscle function compared to pretreatment baseline with better outcomes than would be expected without treatment.
- Beneficiary has not received Zolgensma® since began Evrysdi® and has not been ordered Spinraza® to be given concomitantly
- Prescriber must submit the following:
    - Current chart notes
    - Current weight
    - Female recipients of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage
    - Documentation of continued physical therapy
    - Documentation of response to therapy using the same measuring scale as the baseline score

QUANTITY EDITS:

Based on max dose of 5 mg per day, 3 bottles (240mL total) per 31 days

DISCUSSION:

No comments

ACTION:

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

4) Therapeutic duplication with opioid use disorder medications

a. Maximum allowed daily dose

Based on this recommendation and the fact that patients were getting 2 different dosage forms of OUD medications to increase the daily dose, we recommend increasing the maximum daily dose of buprenorphine from 24 mg to 32 mg per day. For oral buprenorphine products, the quantity should increase to a sufficient quantity per month that allows up to 32 mg/day or equivalent depending on the product. Examples:

- Suboxone 8/2 mg film--#124
- Suboxone 12/3 mg film would stay at #62 (3 per day would be over 32 mg)
- Zubsolv 5.7/1.4--#124 (based on dosing conversion in PI as this strength is equivalent to Suboxone 8/2 mg)

b. The discussion consensus noted there is no medical necessity to take 2 different oral dosage forms (i.e., Suboxone films along with buprenorphine SL tablets). To reach the needed dose, the group would rather see an increase in one formulation than for the patient to use multiple formulations. Therefore, we recommend beginning a therapeutic duplication edit to stop concomitant fills of the oral products.

c. In the report, there were some instances where patients received long-acting injections with oral products as well. Per Dr. Mancino—"patients receiving monthly injections often require supplemental SL buprenorphine until they have had their fourth monthly injection as the monthly injection does not seem to hold off cravings until the fourth injection in many instances." Therefore, the recommendation is to not include the injections in the therapeutic duplication edit.

DISCUSSION:

Dr. Mancino stated that their practice uses Brixadi and found that until they get the 4th injection, patients often require supplementation with smaller doses of oral meds. No other comments.

ACTION:

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

New Business

1) Salicate™ (salicylic acid) 10% gel

PROPOSED APPROVAL CRITERIA:

- 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 excessive keratin in hyperkeratotic skin disorders (e.g., verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis)
- At a minimum, beneficiary must have trial and failure of salicylic acid products over the counter
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Description of beneficiaries' skin disorder as a baseline
  - Letter of medical necessity of this product over other treatment options available including products available over the counter

RENEWAL REQUIREMENTS:

- Beneficiary must demonstrate an improvement of excessive keratin compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

QUANTITY EDITS:

1 bottle every 30 days

DISCUSSION:
No comments

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

2) Alkindi (hydrocortisone) 0.5 mg, 1 mg, 2 mg, and 5 mg sprinkle

PROPOSED APPROVAL CRITERIA:

- Beneficiary does not exceed the maximum age recommended in the manufacturer's package insert (<18 years of age)
- Beneficiary must be diagnosed with adrenocortical insufficiency
- Prescriber must submit the following:
  - Current chart notes
  - Dose requested
  - Medical necessity over hydrocortisone tablets or prednisolone solution which are available without prior authorization

RENEWAL REQUIREMENTS:

- Beneficiary continues to demonstrate the medical necessity of the sprinkle formulation

DISCUSSION:
No comments

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

3) Xolremdi™ (mavorixafor)

PROPOSED 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 WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) that has genotype-confirmed variant of CXC chemokine receptor 4 (CXCR4) with low number of circulating mature neutrophils and lymphocytes **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 an absolute neutrophil count (ANC) ≤400 cells/µL at baseline
- Prescribed by or in consultation with an immunologist, hematologist or dermatologist
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Pregnant
  - Breastfeeding
  - Severe renal impairment (CrCl < 30 mL/min)
  - Moderate to severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including CBC with differential, liver function tests, and basic metabolic panel
  - Current weight
  - Dose requested
  - Pregnancy test for female patient of reproductive potential
  - Attestation that the female patient of reproductive potential has been counseled on the use of an effective method of contraception during treatment for 3 weeks after the final dose.

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a clinical benefit based on any of the following (compared to baseline):
  - Reduced frequency, duration or severity of infections
  - Fewer warts
  - Improved labs (e.g., absolute neutrophil count, white blood cell count, and absolute lymphocyte count)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of clinical response to treatment
  - Current labs including CBC with differential, liver function tests, and basic metabolic panel

QUANTITY EDITS:

#120/ 30 days

DISCUSSION:

No comments

ACTION:

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

4) Iqirvo (elafibranor)

PROPOSED 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 primary biliary cholangitis (PBC) confirmed by TWO of the following:

- An alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal
- Presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher
- Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)

- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take Iqirvo® concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Pregnant
  - Complete biliary obstruction
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Baseline description of muscle pain or myopathy (evaluate periodically for new onset or worsening muscle pain, myopathy, or rhabdomyolysis)
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to Iqirvo® with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid (UDCA) concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase
  - Description of muscle pain or myopathy

QUANTITY EDITS:
#30 per 30 days

DISCUSSION:
No comments

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

5) Livdelzi (seladelpar lysine)

PROPOSED 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 primary biliary cholangitis (PBC) confirmed by TWO of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a tier of 1:40 or higher

- Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take Livdelzi® concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Is pregnant
  - Has complete biliary obstruction
  - Requires OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors
  - Has end-stage renal disease and on dialysis
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to Livdelzi® with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase

QUANTITY EDITS:

#30 per 30 days

DISCUSSION:

No comments

ACTION:

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

6) Winrevair (sotatercept)

PROPOSED 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 pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) Functional Class (FC) II or III
- Initially, must be prescribed by or in consultation with a cardiologist or pulmonologist
- Beneficiary has tried and failed a preferred medication from each of the following categories given as triple therapy for at least 90 days unless contraindicated:
  - Phosphodiesterase Inhibitors
  - Endothelin Receptor Antagonists

- Prostacyclin Analogues
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Beneficiary is diagnosed with pulmonary hypertension WHO groups 2, 3, 4, or 5
  - Baseline platelet count is <50,000/mm^3
  - Experiencing serious bleeding
  - Pregnant
  - Breastfeeding
  - Current smoker without a smoking cessation plan
  - Has restrictive, constrictive, or congestive cardiomyopathy
  - Left ventricular ejection fraction < 45% on an echocardiogram within the previous 6 months
  - Any symptomatic coronary disease events in the previous 6 months
  - Considered Functional Class I or IV
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including hemoglobin (Hgb) and platelets
  - Attestation that Hgb and platelet levels are monitored before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required
  - Attestation that the patient has been counseled on signs and symptoms of blood loss
  - Attestation that a patient of reproductive potential has been counseled that WINREVAIR can impair fertility (male or female)
  - Attestation that a female patient of reproductive potential has been counseled to use contraception due to embryo-fetal toxicity
  - Attestation that a female patient has been counseled that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the final dose.
  - Baseline 6-minute walk distance (6MWD)
  - Baseline echocardiogram

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with stabilization of PAH
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including Hgb and platelets
  - Current 6-minute walk distance
  - Documentation that female of reproductive potential is continuing contraception and is not pregnant

QUANTITY EDITS:
Each strength #4 injections per month (for doses of 90 mg or 120 mg every 3 weeks)

DISCUSSION:
The chair noted that Dr. Golden reviewed the criteria prior to the meeting and did not express any concerns with the criteria. No other comments were made.

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

7) Ohtuvayre (ensifentrine)

PROPOSED APPROVAL CRITERIA:

- Beneficiary must be ≥40 years of age
- Beneficiary must be diagnosed with chronic obstructive pulmonary disease with severity defined by
  - Pre- and Post-bronchodilator FEV1/FVC ratio of <0.70; AND
  - Post-bronchodilator FEV1 ≥30 % and ≤70% of predicted normal; AND
  - History of ≥ 2 moderate or ≥ 1 severe exacerbation(s) requiring hospitalization within the past 12 months

- Beneficiary has exacerbation(s) while compliant for at least 3 months on ONE of the following with continued pulmonary function tests meeting the defined severity listed above:
  - LAMA/LABA combination if blood eosinophil count <300 cells/µL drawn in the last 12 months
  - LAMA/LABA/ICS combination if blood eosinophil count ≥300 cells/µL drawn in the last 12 months
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Current smoker that refuses to start a cessation plan
- Prescriber must submit the following:
  - Current chart notes with previous and current therapies
  - Current pulmonary function tests as baseline
  - Documentation of smoking history
  - If currently smoking, provide smoking cessation plan
  - Medical necessity over Daliresp® (roflumilast) tablet

RENEWAL REQUIREMENTS:

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to therapy as indicated by at least ONE (1) of the following:
  - Decrease in quantity and/or severity of exacerbations; OR
  - Improvement in lung function/FEV1 over baseline; OR
  - Improvement in COPD-related symptoms and/or quality of life
- Beneficiary must remain a non-smoker
- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - Attestation that the beneficiary continues to refrain from smoking

QUANTITY EDITS:

#60 ampules (1 carton)/30 days

DISCUSSION:

No comments

ACTION:

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

8) Dupixent® (dupilumab)

PROPOSED APPROVAL CRITERIA:

(this is subject to change depending on state supplemental rebate language from Sanofi)

- 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
- Prescribed by or in consultation with a pulmonologist
- Beneficiary has been diagnosed with eosinophilic phenotype chronic obstructive pulmonary disease (COPD) that is inadequately controlled on maintenance therapy with moderate to severe airflow limitation defined by the following:
  - Post-bronchodilator FEV1/FVC ratio <0.7; AND
  - Post-bronchodilator FEV1 of 30% to 70% predicted; AND
  - History of ≥ 2 moderate or ≥ 1 severe exacerbation(s) within the past 12 months
- Beneficiary must have a trial and failure of maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (unless contraindicated) with a trial lasting for at least 3 months

		• Beneficiary must have a blood eosinophilic count of at least 300 cells/µL as a baseline drawn in the last 12 months
		• Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
		• Prescriber must submit the following:
		  o Current chart notes with description of COPD symptoms and history of exacerbations for the last 12 months
		  o Documentation of previous therapies tried
		  o Current pulmonary function tests
		  o Baseline labs including CBC with differential
		  o Documentation of smoking history
		
		RENEWAL REQUIREMENTS:
		• Beneficiary remains compliant on COPD maintenance therapy (inhalers and immunomodulator injection)
		• Beneficiary must demonstrate a positive response to therapy as indicated by at least ONE (1) of the following:
		  o Decrease in quantity and/or severity of exacerbations; OR
		  o Improvement in lung function/FEV1 over baseline; OR
		  o Improvement in COPD-related symptoms and/or quality of life
		• Prescriber must submit the following:
		  o Current chart notes
		  o Documentation of response to therapy compared to previous baseline with information on any exacerbations since last PA review
		  o Current PFTs
		
		DISCUSSION:
		No comments
		
		ACTION:
		The motion was made by Dr. Mancino to accept the criteria as presented; second by Dr. King. All members in attendance voted for the motion. Motion passed.

Board comments		Dr. Boone mentioned a Facebook post about the Pharmacy Help Desk. Dr. Pearson stated that help desk representatives were on the call and would do some research.
Adjourn		Meeting adjourned 12:15pm