Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	July 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
	X	Clint Boone, Pharm.D.		Lora Ertmoed, Pharm.D.	Empower
	X	Ashley Crawley, Pharm.D.	X	Trinh Mowder, Pharm.D.	Empower
	X	Gabriella Douglass, Pharm.D.		Jon Delarosa, Pharm.D.	Empower
	X	Trenton Dunn, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
		Lana Gettman, Pharm.D.	X	Jessica Lawson, Pharm.D.	CareSource
	X	John Dawson Irvin, M.D.		Jennifer Chapin, Pharm.D.	CareSource
	X	Michael Mancino, M.D.		Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Melissa Max, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
		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.	X	Christopher Smith, M.D.	DHS advisor
	X	Shailendra Singh, MBBS, FACP	X	Shane David, Pharm.D.	ADH advisor
		Open M.D. position	X	Karen Evans, P.D.	Prime Therapeutics
	[redacted]		X	Jeniffer Martin, Pharm.D.	Prime Therapeutics
			X	Lesley Irons, Pharm.D.	Prime Therapeutics
			X	Linsey Gillam, Pharm.D.	Prime Therapeutics
			X	Alyson Greenwood, 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 8:33am.
Public comments		**1) Drew Heiple, MD—Arkansas Medical Group** **Ozempic®** **2) Brock Bumpass, PharmD, MBA, MS—Alnylam Pharmaceuticals** **Amvuttra®** **3) Mary Caroline Carnes, NP Neurology, MSL—Argenx** **Vyvgart Hytrulo®** **4) Kristin Duffey, PharmD, BCPS—Novartis** **Fabhalta® & Vanrafia™** **5) Bashir Kalayeh, PharmD—Bayer Pharmaceuticals** **Kerendia®** **6) Mae Kwong, PharmD—Soleno Therapeutics** **Vykat XR™** **7) Tenicia Talley, PharmD—Sanofi** **Qfitlia™**
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. New member—Gabriella Douglass, Pharm.D. b. Current open positions—1 physician 3. Electronic PA discussion by Dr. Pearson and Dr. Greenwood 4. Physician Administered Drugs discussion by Dr. Pearson 5. Bylaws Update with changes in the committee section  DUR Bylaws draft July 2025.docx

		DISCUSSION: None **ACTION:** Motion was made by Dr. Mancino for approval of bylaws as presented; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed. 6. Rebates on covered outpatient drugs discussion by Dr. Neuhofel 7. Quarterly provider newsletter--  Arkansas Medicaid Quarterly Newsletter . 8. New medications following the oncology policy a. Avmapki™ Fakzynja™ Co-pack 9. System edits updates from previous meeting 10. Update on new dosage forms for Livmarli.
Minutes		Motion to approve April 2025 DUR meeting minutes as presented was made by Dr. Rodgers, second by Dr. Mancino. 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. ○ August 2025—Type 2 diabetes with HF or CAD and no claims for SGLT2 ○ September 2025—Insulin claims in the last 120 days without any claims for blood glucose monitoring supplies ○ October 2025—Diabetes without ACEI or ARB in history last 120 days **ACTION:** Motion was made by Dr. Crawley 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 January to March 2025. • Dr. Evans from Prime Therapeutics presented the FFS ProDUR report for April to June 2025
PDL Class Review		**1) <u>Angiotensin-Converting Enzyme Inhibitors</u>** Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with information on FDA approved indications and age limits b) Overview of guidelines c) Claims summary from 7/1/2024-6/30/2025 **DISCUSSION:** Dr. Pearson noted that this class was brought for full review to move captopril to preferred status. Dr. Golden noted that he would like to see patients on ACE inhibitors moved to ARBs due to lower side effect profile. Dr. Martin responded that we have multiple ARBs available without a PA. Dr. Pearson noted that his proposal may be more of a RDUR review. Dr. Podrazik stated that ACEIs are tier one blood pressure medication, and there is no real difference in terms of potency between the classes. Some patients without side effects stay on low and medium doses of lisinopril as they are sometimes more potent than ARBs. Dr. Pearson stated we would contact specialists before moving forward with any changes. **ACTION:** Motion was made by Dr. Pace to add captopril as a preferred option; second by Dr. Rodgers. All other members in attendance voted for the motion. Motion passed. **2) <u>Antivirals (PAXLOVID)</u>** Dr. Martin presented a PowerPoint with the following information. a) Overview of Paxlovid with indication, dosage, and black box warning. b) Identification of patients that would be considered high-risk if has COVID c) Centers for Disease Control and Prevention 2024 recommendations d) Recommendations in 2024 from American College of Physicians e) Recommendations in 2023 from World Health Organization f) General information on COVID symptoms g) Claims summary from 7/1/2024-6/30/2025

DISCUSSION:
None

ACTION:
Motion was made by Dr. Pace to give PAXLOVID its own PDL class and make it preferred; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed.

3) Oral antivirals

Dr. Martin presented a PowerPoint with the following information.
a) Overview of medications with FDA indications, warnings, dosage, and administration
b) Influenza Clinical Guidelines:
   i. American Academy of Pediatrics: Recommendations for Prevention and Control of Influenza in Children, 2024-2025 Policy Statement
   ii. CDC: Summary of Clinicians on Influenza Antiviral Medications, 2023
c) World Health Organization clinical practice guidelines for influenza 2024
d) Herpes Zoster Clinical Guidelines
   i. CDC Sexually Transmitted Infections Treatment Guidelines, 2021 (Genital Herpes)
   ii. Advisory Committee on Immunization Practices Prevention of Herpes Zoster, 2008
   iii. Department of Health and Human Services Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents, 2024
e) Claims summary from 7/1/2024-6/30/2025

DISCUSSION:
Dr. Rodgers stated if the cost is good, he would give preference to the most commonly used medications. And he stated that Xofluza should be non-preferred. Dr. Rodgers made the motion for 1-2 preferred typical antivirals and at least 1 influenza medication as preferred. No other comments.

ACTION:
Motion was made by Dr. Rodgers for 1-2 preferred typical antivirals and at least 1 influenza meds as preferred determined by cost committee review; second by Dr. Mancino. All other members in attendance voted for the motion. Motion passed.

4) Rosacea Agents

Dr. Martin presented a PowerPoint with the following information.
a) Overview of medications with FDA indications
b) Treatment Guidelines
   i. Pharmacist's Letter—Treatment of Rosacea, 2021
   ii. Global Rosacea Consensus Panel Recommendations, 2019
c) Summary of treatment recommendations and table with rosacea symptoms
d) Claims summary from 7/1/2024-6/30/2025

DISCUSSION:
Dr. Rodgers asked if there was a reason for using metronidazole gel or cream. Dr. Martin noted that the different dosage forms for metronidazole have similar response. Dr. Pearson asked about dosing frequency. Dr. Martin stated that the 0.75% is twice daily and 1% is once daily. Dr. Pearson stated that metronidazole should be a preferred option since it is considered first line. Dr. Rodgers recommended 2 products as preferred if they are cost comparable, otherwise one preferred product would work. Dr. Crawley agreed.

ACTION:
Motion was made by Dr. Rodgers for 1-2 preferred products with decision made based on cost committee recommendation; second by Dr. Crawley. All other members in attendance voted for the motion. Motion passed.

5) Chronic Gastrointestinal Motility

Dr. Martin presented a PowerPoint with the following information.
a) Overview of medications with FDA indications and preferred list status
b) Clinical Guidelines
   i. American Gastroenterological Association (AGA) Guidelines on Pharmacological Management of IBS-C and IBS-D, 2022

		ii. AGA/ American College of Gastroenterology (ACG) Guidelines on Pharmacological Management of CIC, 2023 iii. AGA Guidelines on Medical Management of OIC, 2019 iv. American Society of Clinical Oncology (ASCO) Guidelines for Use of Opioids for Adults with Pain from Cancer or Cancer Treatment, 2022 c) Claims summary from 7/1/2024-6/30/2025 **Dr. Pearson shared the recommended criteria for Viberzi and Lotronex.** **VIBERZI & LOTRONEX (PA Review only, not in POS)** • The beneficiary has diagnosis of irritable bowel syndrome with diarrhea (IBS-D); **AND** • The beneficiary has tried and failed at least three agents from any of the following classes: o Bulk Producing Agents (e.g., Metamucil [psyllium], Citrucel [methylcellulose]) o Antispasmodic Agents (e.g., dicyclomine, hyoscyamine) o Antidiarrheal Agents (e.g., loperamide, diphenoxylate/atropine); **AND** • If Lotronex, the beneficiary is female; **AND** • The beneficiary will not be using the requested agent concomitantly with other chronic GI motility agents in the same class as the requested agent; **AND** • The beneficiary is at least 18 years of age. **DISCUSSION:** Dr. Golden noted that typically these patients are difficult to manage, and we might want to do an analysis on adherence with more targeted clinical management beyond medications used. Dr. Pearson noted that this class was being coded in the ePA system. So, we brought this class for full review to discuss criteria for VIBERZI and LOTRONEX. Dr. Dunn asked if we should add criteria to prevent an IBS-C patient from also being on an IBS-D product and vice versa. Dr. Greenwood commented that we could ask for attestation of this but in the end it may not be necessary as they are manually reviewed. Dr. Dunn was fine with manual review. **ACTION:** Motion was made by Dr. Boone to leave the PDL class as current list and accept the criteria as presented; second by Dr. Irvin. All other members in attendance voted for the motion. Motion passed. **6) <u>Classes without changes</u>** • ANTICOAGULANTS • ANGIOTENSIN RECEPTOR MODULATORS (ARBs, combos, renin inhibitors) • BETA ADRENERGIC BLOCKING AGENTS • BENIGN PROSTATIC HYPERTROPHY AGENTS • CALCIUM CHANNEL BLOCKERS • ESTROGEN REPLACEMENT AGENTS • OSTEOPOROSIS AGENTS • OPHTHALMICS, ANTI-INFLAMMATORY (IMMUNOMODULATORS) • SKELETAL MUSCLE RELAXERS (excluding carisoprodol) • THROMBOPOIESIS STIMULATING PROTEINS **DISCUSSION:** No comments **ACTION:** Motion was made by Dr. Mancino to remove discontinued medications and keep the current preferred options; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.
Changes to existing criteria or edits		**1) <u>CHRONIC SPONTANEOUS URTICARIA</u>** **<u>RECOMMENDED APPROVAL CRITERIA FOR IMMUNOMODULATORS:</u>** • 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 chronic spontaneous urticaria (CSU) with wheals/hives with or without angioedema for >6 consecutive weeks • Must be prescribed by, or in consultation with, a dermatologist, allergist or immunologist

- Beneficiary must minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, and friction from clothing)
- Beneficiary must have at least **ONE** of the following despite treatment listed below:
  - Baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16
  - Baseline Itch Severity Score-7 (ISS7) must be ≥ 8
  - Baseline Urticaria Control Test (UCT) must be < 12
- Beneficiary must have tried and failed the following unless there is a contraindication to their use:
  - Non-sedating H1-antihistamine (nsAH) for a minimum of 2 weeks; **AND**
  - nsAH at 4 times the normal daily dose for a minimum of 4 weeks
- Prescriber must submit the following:
  - Current chart notes
  - Baseline description of urticaria
  - Baseline UAS7 and/or ISS7 and/or UCT scores
  - Previous therapies that were tried with treatment duration
  - Letter of medical necessity over other treatment options

RENEWAL REQUIREMENTS:

- Beneficiary has been compliant with therapy (defined as: 75% utilization)
- Beneficiary must have a positive response with a decrease in urticaria symptoms and an improvement in **ONE** of the following (must use same test as baseline):
  - UAS7
  - ISS7
  - UCT
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of current symptoms
  - Current CSU test with at least **ONE** of the following (must use the same test as baseline):
    - Urticaria Activity Score-7 (UAS7)
    - Itch Severity Score-7 (ISS7) score
    - Urticaria Control Test (UCT)

DISCUSSION:
No comments

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

2) TARGETED IMMUNOMODULATORS

Taltz® (ixekizumab) and Xeljanz®/Xeljanz XR (tofacitinib) moved to a preferred status on 7/1/2025. Before Taltz® or Xeljanz®/Xeljanz® XR can be approved, the beneficiary must have a 3-month trial and failure of a TNF blocker (i.e., Humira® or Enbrel®) unless TNF blockers are contraindicated (i.e., lupus) for the specific patient.

Most non-preferred medications on the AR Medicaid PDL require a trial of 2 preferred medications before moving to a non-preferred option. Prior to 7/1/2025, the TIMs class had Humira® and Enbrel® (both TNF blockers) and Otezla® (PDE4 inhibitor) as preferred options. Otezla has limited indications. Since the other 2 preferred options had the same mechanism of action, we only required a trial and failure of 1 preferred option with the applicable indication. Now that we are adding two (2) additional preferred options with different mechanisms of action, we will be requiring a trial and failure of two (2) preferred options before moving to a non-preferred medication for those indications with more than one (1) preferred option. With this change, the TIMs class will be consistent with other PDL classes.

DISCUSSION:
Dr. Pearson also asked for some grace to update this class as indications change without requiring Board approval.

ACTION:
Motion was made by Dr. Irvin to approve criteria as presented along with permission for agency to update criteria as indications change; second by Dr. Max. All other members in attendance voted for the motion. Motion passed.

3) AMVUTTRA (vutrisiran) 25 mg/0.5 mL injection

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 have the diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) confirmed with **TWO** of the following:
  - Echocardiogram; **OR**
  - Tissue biopsy confirming the presence of transthyretin amyloid deposits; **OR**
  - 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 **ONE** 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
- 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
  - Medical necessity over ATTRUBY and VYNDAQEL/VYNDAMAX

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:

#1 injection per 90 days

DISCUSSION:

Dr. Douglass asked when providing medical necessity, is every 3 months dosing part of that consideration or are we thinking other criteria? Dr. Pearson stated that we have to be cautious with our dollars to ensure there is money to treat everyone, and if that causes a patient to take something every month instead of every 3 months, it is worth a try to see if it's effective. Dr. Neuhofel stated that we do not have to cover medications when ordered for convenience. She noted that we have to be mindful of our state dollars, indications, and treatment guidelines as well. Dr. Irvin asked the cost of the medication. Dr. Pearson stated that it's almost $500,000 a year, which is double the other products. Dr. Crawley asked if we have to cover it at all or have trial and failure of all other products. Dr. Pearson stated that we have to cover it since it is rebate eligible. We do not have this class of drugs on the PDL, but we do have the right to ask why the patient can't use something else. Dr. Irvin asked the cost with rebate. Dr. Pearson stated that all products have the same rebate, 23.1%, and there is no extra supplemental. Dr. Boone asked

if this would affect patients currently on therapy. Dr. Pearson said there are probably no patients on this medication, but if they were we would grandfather them in.

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

4) OZEMPIC (semaglutide) injection and KERENDIA (finerenone) tablet

RECOMMENDED OZEMPIC 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 type 2 diabetes mellitus and chronic kidney disease
- Beneficiary must have urine albumin-creatinine ratio (UACR) of ≥30 mg/g and eGFR <60 mL/min/1.73m^2
- Beneficiary should be taking an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) at maximally tolerated doses or have a contraindication to their use.
- Beneficiary must have a history of a sodium-glucose cotransporter 2 (SGLT-2) inhibitor use prior to beginning this medication or a has a contraindication to their use
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Current labs including urine albumin-creatinine ratio (UACR), eGFR, and HbA1c
  - Current weight

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including urine albumin-creatinine ratio (UACR), eGFR, and HbA1c
  - Current weight
  - Response to therapy

QUANTITY EDITS:
1 pen per month

KERENDIA RECOMMENDED APRPOVAL CRITERIA:

- Beneficiary must be ≥ 18 years of age
- Beneficiary must have a diagnosis of Type 2 diabetes mellitus and chronic kidney disease OR a diagnosis consistent with FDA approved indications
- ~~Beneficiary must have one of the following to confirm the diagnosis of CKD with T2D:~~
  - ~~UACR of 30-300 mg/g, eGFR 25-60 mL/min/1.73m^2 and diabetic retinopathy OR~~
  - ~~UACR of ≥ 300 mg/g and eGFR 25-75 mL/min/1.73m^2~~
- Beneficiary must have UACR of ≥30 mg/g and eGFR ≥25 mL/min/1.73m^2
- Beneficiary should be taking ~~have been treated with~~ an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) unless contraindicated ~~and receiving treatment for diabetes based on treatment guidelines~~
- ~~Beneficiary must have tried and failed an aldosterone inhibitor unless contraindicated~~
- Beneficiary must be a non-smoker or participating in a tobacco cessation program
- ~~Beneficiary must have controlled diabetes (HbA1c <9%) and blood pressure (BP < 130/85)~~
- Beneficiary must have a normal serum potassium level (< 5 mEq/L)
- Beneficiary is not receiving concomitant strong CYP3A4 inhibitors (e.g., fluconazole) and strong or moderate CYP3A4 inducers (e.g., efavirenz, rifampicin)
- Beneficiary has not been diagnosed with adrenal insufficiency (Addison's disease)
- Beneficiary must not have severe hepatic impairment (Child Pugh C)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies

- Current labs including Urinary Albumin-to-Creatinine Ratio (UACR), eGFR, and potassium level
- ~~Medical necessity over other mineralocorticoid receptor antagonists available without a PA~~

- Initial approval for 3 months

Denial Criteria

- ~~Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR~~
- ~~Beneficiary has eGFR < 25 mL/min/1.73m^2; OR~~
- ~~Beneficiary's baseline serum potassium is > 5 mEq/L; OR~~
- ~~Beneficiary is receiving concomitant strong CYP3A4 inhibitors (e.g., fluconazole) and strong or moderate CYP3A4 inducers (e.g., efavirenz, rifampicin); OR~~
- ~~Beneficiary has been diagnosed with adrenal insufficiency (Addison's disease)~~

RENEWAL REQUIREMENTS:

- Beneficiary must demonstrate a decrease in UACR and sustained or improved eGFR after dose titration
- Beneficiary must be a non-smoker
- Beneficiary must have a potassium level that remains < 5.5 mEq/L
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including UACR, eGFR, and potassium
- Approval for 6 months

DISCUSSION:

Dr. Max asked what is our current GLP-1s for type 2 diabetes and heart disease. Dr. Pearson stated our current preferred GLP-1s are VICTOZA and TRULICITY, and neither of these have a CKD indication. Dr. Pearson stated that if we received a request for CKD, we would not require a preferred GLP-1 over OZEMPIC. Dr. Pearson will update the KERENDIA criteria to include the recent updated heart failure indication.

ACTION:

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

5) CARISOPRODOL TABLET (including any carisoprodol containing product)

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 have an acute, painful musculoskeletal condition requiring a muscle relaxer
- Beneficiary must have tried and failed all preferred skeletal muscle relaxers on PDL
- Prescriber must submit the following:
  - Current chart notes
  - Beneficiary's diagnosis that requires a muscle relaxer
  - Letter of medical necessity outlining the rationale for carisoprodol over all other preferred muscle relaxers on the PDL
- If this medication is approved, the beneficiary will only be allowed up to a 3-week supply.

QUANTITY EDITS:

#63/21 days

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.

6) SAVELLA (milnacipran) tablet

RECOMMENDED APPROVAL CRITERIA:

- The request is for SAVELLA (milnacipran); **AND**
  - The beneficiary has a diagnosis of fibromyalgia (ICD-10 M79.7) within the previous 2 years of history, submitted on the incoming pharmacy claim, or documented on the request; **AND**
  - The beneficiary has a history of a 90-day trial of at least 3 of the following within the past 2 years, substantiated by claims history or documented on the request:
    - SSRI or SNRI
    - Gabapentin or pregabalin
    - Tricyclic antidepressant
    - Muscle relaxer; **AND**
- If previous trials cannot be substantiated via claims, the prescriber provides attestation that the beneficiary adhered to previous therapies, and the trial period was sufficient to allow for a positive treatment outcome or that the drug was discontinued due to an adverse event; **AND**
- The prescriber attests that the trial/failure(s) of the preferred medications are documented in the beneficiary's medical record (evidence of such is subject to audit).

DISCUSSION:
Dr. Mancino asked to remove the SSRI requirement and leave SNRI on the list as SSRIs don't really help with chronic pain syndromes. Dr. Douglass agreed with Dr. Mancino.

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

7) LONG-ACTING OPIOIDS

Hydrocodone ER, Hydromorphone ER, Oxymorphone ER, Belbuca, and Tramadol ER (generics for Conzip® and Ryzolt®) will be added to posted criteria. These are currently incorporated in the AutoPA rule for POS edits.

Note: Requests for non-preferred, multi-source brand medications will still need to meet Brand Medically Necessary criteria in addition to the criteria below.

- The beneficiary is established on a long-acting opioid (LAO), defined as use in the last 60 days; **AND**
  - Routine PDL Criteria; **OR**
- The beneficiary is established on chronic, daily use of a short-acting opioid (SAO); **AND**
  - The SAO will be discontinued or decreased upon starting the LAO; AND
  - The total daily MME will be reduced upon starting the LAO to account for incomplete opioid cross-tolerance; **AND**
  - Medical necessity of using a long-acting opiate for chronic, non-cancer pain; **AND**
  - Routine PDL Criteria are met; **OR**
- If the beneficiary is not established on a long-acting or short-acting opioid meeting the criteria above, then one of the following:
  - The beneficiary has diagnosis of malignant cancer in the last 365 days; **OR**
  - **For all except methadone,** the beneficiary currently resides in long-term care; **OR**
  - **For fentanyl patches only**, the beneficiary meets NPO criteria; **AND**
- The beneficiary does not have a history of Suboxone or Subutex in the past 90 days (*State Review Required if not met*); **AND**
- For all other diagnoses other than cancer, none of the following apply:
  - 90 cumulative MME across all opioids filled in the previous 30 days, including the incoming claim
  - Two or more claims for Narcan/naloxone in the past 90 days (*State Review Required if not me*t)
  - A diagnosis for poisoning or overdose for opioids, narcotics, barbiturates, benzodiazepines, or unspecified drug or substance in the last 365 days (*State Review Required if not met).*
- Length of authorization is 6 months.

Methadone oral solution

- The beneficiary is less than or equal to 90 days of age; **AND**
- The beneficiary has a diagnosis of neonatal abstinence syndrome; **AND**
- The quantity of methadone oral solution dispensed is not more than 10mL; **AND**
- The accumulated methadone oral solution quantity between the incoming claim and any other claims within the previous 30 days do not equal more than 10mL total; **OR**
- The prescriber provides medical necessity, quantity requested, dose, and taper plan schedule.
- Length of authorization is 1 month for methadone oral solution.

Note: Routine PDL Criteria do not apply.

Therapeutic Duplication
No therapeutic duplication in drug history between long-acting narcotics

DISCUSSION:
No comment

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

8) FABHALTA (iptacopan) capsule

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 paroxysmal nocturnal hemoglobinuria (PNH) with absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins confirmed by high-sensitivity flow cytometry OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.~~
- Beneficiary must be diagnosed with **ONE** of the following:
  - Paroxysmal nocturnal hemoglobinuria (PNH)
  - Proteinuria with Immunoglobulin A Nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
  - Proteinuria with Complement 3 Glomerulopathy (C3G)
- Beneficiary must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae*~~,~~ and *Neisseria meningitidis* types A, C, W, Y, and B, ~~and *Haemophilus influenzae* type B~~ at least 2 weeks prior to initiation of FABHALTA, and beneficiary must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy
- Prescriber and pharmacy must be enrolled in the FABHALTA REMS program
- This medication must be prescribed by or in consultation with the following:
  - For PNH patients—hematologist or oncologist
  - For IgAN patients—nephrologist
  - For C3G patients—nephrologist
- Beneficiary does not have severe hepatic impairment (Child-Pugh class C)
- Beneficiary does not have an active serious infection caused by encapsulated bacteria, including *Streptococcus pneumonia*, *Niesseria meningtidis*, or *Haemophilus influenzae type b*
- Beneficiary of reproductive potential should not be pregnant or breastfeeding
- Beneficiary with PNH
  - Beneficiary currently taking eculizumab (SOLIRIS) or ravulizumab (ULTOMIRIS) must follow the required dose initiation per the package insert
  - Beneficiary must be clinically symptomatic (e.g., fatigue, dyspnea, pain, thrombosis, etc.) and have abnormal labs (e.g., low hemoglobin (Hgb), high lactate dehydrogenase (LDH), etc.)
  - Beneficiary has baseline Hgb level < 10 g/dL with or without previous C5 inhibitors
  - Beneficiary must not be receiving Fabhalta® in combination with other complement inhibitors used to treat PNH (i.e., Empaveli®, Piasky®, Soliris®, Ultomiris®, Voydeya®)
  - Prescriber must submit the following
    - Current chart notes

- Documented symptoms as a baseline
- Previous therapies
- Current labs including complete blood count (CBD), comprehensive metabolic panel, and lactate dehydrogenase
- Recent history of blood transfusions

- Beneficiary with IgAN
  - Beneficiary must demonstrate continued risk for disease progression with proteinuria ≥ 0.5 g/day, despite at least 3 months of maximally tolerated supportive care (i.e., angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB), immunosuppressive therapy, sodium-glucose co-transporter 2 (SGLT2) inhibitor)
  - Beneficiary must remain on supportive care at maximally tolerated doses unless contraindicated
  - Beneficiary must have had a previous trial and failure of Tarpeyo® (budesonide delayed-release capsule) unless contraindicated for this patient
  - Prescriber must submit the following:
    - Current chart notes
    - Previous therapies
    - Current labs including LFTs, eGFR, lipid panel, and urine protein or UPCR
    - Confirmation of IgAN diagnosis with renal biopsy results and labs
    - Medical necessity over the use of typical supportive care (i.e., ACEi, ARB, SGLT2), Tarpeyo™, Filspari®, and Vanrafia™.
- Beneficiary with C3G
  - Beneficiary must have tried and failed mycophenolate and/or cyclophosphamide and oral glucocorticoids unless there is a contraindication for this specific patient
  - Beneficiary should have tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) at maximally tolerated doses unless contraindicated
  - Prescriber must submit the following:
    - Current chart notes
    - Previous therapies (e.g., RAS inhibitors, corticosteroids, mycophenolate)
    - Documented symptoms
    - Current labs including LFTs, eGFR, lipid panel, and urine protein or UPCR
    - Confirmation of C3G diagnosis with renal biopsy results and labs (protein-to-creatinine ratio (UPCR) ≥ 1 g/g and eGFR ≥ 30 mL/min/1.73 m^2)
    - Medical necessity over immunosuppressants and glucocorticoids
- ~~Beneficiary should not be approved or continue this therapy with any of the following:~~
  - ~~Severe renal impairment (eGFR < 30 mL/min/1.73 m^2)~~
  - ~~Severe hepatic impairment (Child-Pugh class C)~~
  - ~~Active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b)~~
  - ~~If no vaccinations against encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of Fabhalta and no antibiotic drug prophylaxis~~
  - ~~Ordered to be used concomitantly with a C5 inhibitor~~
  - ~~Pregnant or breastfeeding~~
- ~~Prescriber must submit the following:~~
  - ~~Current chart notes~~
  - ~~Documented symptoms as a baseline~~
  - ~~Documentation of previous therapies~~
  - ~~Current labs including complete blood count (CBC), comprehensive metabolic panel (CMP), LDH, and lipid panel~~
  - ~~Recent history of blood transfusions~~
  - ~~Pregnancy test results (if applicable)~~

RENEWAL REQUIREMENTS:

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

		▪ Current labs including CBC, CMP, and LDH • Beneficiary with IgAN o Beneficiary has documented improvement in proteinuria with a reduction in UPCR or urine protein compared to baseline o Prescriber must submit the following: ▪ Current chart notes ▪ Current labs including LFTs, eGFR, lipid panel, and urine protein or UPCR ▪ Attestation that patient has tested negative for pregnancy if of reproductive potential • Beneficiary with C3G o Beneficiary has documented improvement of proteinuria with a reduction in UPCR or urine protein o Prescriber must submit the following: ▪ Current chart notes ▪ Current labs including LFTs, eGFR, lipid panel, and urine protein or UPCR ▪ Attestation that patient has tested negative for pregnancy if of reproductive potential **QUANTITY EDITS:** • 200 mg - #31/31 days • 400 mg - #31/31 days **DISCUSSION:** Dr. Golden commented that IgA nephropathy can wax and wane. We will need to discuss later about possible tapering with reconsideration requests to see if can be taken off the medication. **ACTION:** Motion was made by Dr. Pace to accept the criteria as presented; second by Dr. Irvin. All other members in attendance voted for the motion. Motion passed.
New Business		**1) VANRAFIA (atrasentan) 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 from the manufacturer's package insert or based on support from the official Compendia • Beneficiary is diagnosed with primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy and at risk for rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g • Medication must be prescribed by, or in consultation with, a nephrologist • Beneficiary must demonstrate continued risk for disease progression with proteinuria ≥ 0.5 g/day, despite at least 3 months of maximally tolerated supportive care (i.e., angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB), immunosuppressive therapy, sodium-glucose co-transporter 2 (SGLT2) inhibitor) • Beneficiary must remain on supportive care at maximally tolerated doses unless contraindicated • Beneficiary of reproductive potential should have a negative pregnancy test prior to beginning this medication and use effective contraception throughout the use of this medication • Beneficiary does not have severe hepatic impairment • Prescriber must submit the following: o Current chart notes o Previous therapies o Current labs including LFTs, eGFR (≥ 30 mL/min/1.73m^2), lipid panel, and urine protein or UPCR o Confirmation of the IgAN diagnosis with renal biopsy results and labs o Attestation that patient has tested negative for pregnancy if of reproductive potential **RENEWAL REQUIREMENTS:** • Beneficiary has been compliant with therapy (defined as: 75% utilization) • Beneficiary has documented improvement in proteinuria with a reduction in urine protein-to-creatinine ratio (UPCR) or urine protein from baseline • Prescriber must submit the following: o Current chart notes o Current labs including LFTs, eGFR, lipid panel, and urine protein or UPCR o Attestation that the patient of reproductive potential has tested negative for pregnancy and beneficiary remains on contraception

QUANTITY EDITS:
#31/ 31 days

DISCUSSION:
No comment

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

2) VYKAT XR (diazoxide choline) tablet

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 hyperphagia associated with Prader-Willi syndrome (PWS)
- Beneficiary must not be pregnant or breastfeeding
- Beneficiary should not exceed a dose of 5.8 mg/kg/day or 525 mg per day
- Beneficiary must exhibit hyperphagia with food seeking behavior with patient specific behaviors to include some of the following:
  - Frequency of foraging through trash for food
  - Frequency of sneaking or stealing food
  - Frequency of continued asking for food despite being told "no"
  - Becomes upset or distressed when denied food
  - Seems to constantly think about food
- Prescriber must submit the following:
  - Current chart notes
  - Genetic testing results confirming diagnosis of PWS
  - Patient specific clinical manifestations with examples of food seeking behavior
  - Current weight and BMI as baseline and dose verification
  - Current labs including fasting blood glucose (FBG) and HbA1c as a baseline (FBG should be monitored at least once every week for the first 2 weeks, then at least once every 4 weeks, and as clinically indicated.)
  - Specific plan to ensure that the patient is in a food-secure environment with strict limitation of food intake
- Initial PA for 4 months

RENEWAL REQUIREMENTS:
- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with a decrease in caregiver identified hyperphagia events compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current food seeking behavior update
  - Current weight and BMI
  - Current fasting blood glucose and HbA1c
  - Documentation of signs of fluid overload

QUANTITY EDITS:
- 25mg #120/30 days
- 75 mg #90/30 days
- 150 mg #90/30 days

DISCUSSION:
Dr. Irvin asked if the price is $1 million per patient per year. Dr. Pearson clarified that cost is for the maximum dose for patients at least 135 kg. So far we have had requests for children, so the cost would not be that high. Dr. Irvin stated he has an adult patient with Prader-Willi but justifying the cost is going to be difficult.

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

3) QFITLIA (fitusiran sodium) pen and vial

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 hemophilia A or B with or without factor VIII or 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
- Beneficiary with inhibitors 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 an antithrombin (AT) activity ≥ 60% prior to beginning QFITLIA
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia treatment center
- Beneficiary should not be prescribed prophylaxis Factor doses (e.g., FVIII, FIX, or bypassing agents)
- Beneficiary should not be prescribed QFITLIA for breakthrough bleeding
- For a beneficiary with history of symptomatic gallbladder disease, the prescriber should consider an alternative treatment and consider interruption or discontinuation if gallbladder disease occurs after beginning treatment
- Beneficiary should not have hepatic impairment (Child-Pugh A, B, or C)
- 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, antithrombin activity, and annualized bleeding rate
  - Current labs including CBC and LFTs
  - Documentation of ONE of the following for beneficiaries with inhibitors:
    - Inadequate response to Immune Tolerance Induction (ITI); **OR**
    - Rationale why the beneficiary is not a candidate for ITI;
  - 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

- 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 and antithrombin (AT) activity compared to baseline
- Beneficiary with antithrombin activity outside of the desired range of 15-35% will require dose modification
  - AT activity <15% will require a dose decrease
  - AT activity >35% after 6 months will require a dose increase
- Beneficiary should discontinue the medication if the AT level remains <15% despite a 10 mg dose every 2 months

- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and antithrombin activity
  - Current requested dose
  - Summary of bleeds since last PA

QUANTITY EDITS:
- 20 mg vial—1 every 2 months
- 50mg pen—1 every 2 months
- *Dose modification to monthly dosing will require an additional override

DISCUSSION:
No comments

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.

4) VYVGART HYTRULO (efgartigimod-hyaluronidase) syringe

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 **ONE** of the following:
  - Generalized myasthenia gravis (gMG) and is anti-acetylcholine receptor (AChR) antibody positive; **OR**
  - Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Must be prescribed by, or in consultation with, a neurologist or a specialist in treating gMG or CIDP
- Beneficiary must not be prescribed concomitant treatment with a complement inhibitor (e.g., Soliris®, Ultomiris®, Zilbrysq®) or another neonatal Fc receptor blocker (e.g., Rystiggo®)
- Beneficiary with gMG
  - Must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
  - Must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification II to IV
  - Must have MG-Activities of Daily Living (MGADL) total score ≥5
  - Must have tried and failed while on stable doses either an acetylcholinesterase (AChE) inhibitor (e.g., pyridostigmine) or immunosuppressive therapy (e.g., glucocorticoids, azathioprine, or mycophenolate) or the beneficiary has a documented contraindication or intolerance to those agents
  - Should not receive the first dose in a new cycle sooner than 50 days from beginning of previous cycle
- Beneficiary with CIDP
  - Must have other possible disease states (such as Guillain–Barré syndrome) ruled out
  - Must have previously been treated with intravenous immunoglobin (IVIG) and glucocorticoids unless there is a contraindication to their use
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Attestation that patient is up to date on required vaccines prior to beginning therapy
  - Documentation of patient's clinical presentation with specific symptoms
  - For gMG patients, test results documenting presence of AChR antibodies, baseline MGFA classification, and baseline MGADL total score
  - For CIDP patients, baseline disability score (e.g., Inflammatory Neuropathy Cause and Treatment (INCAT) disability score, Rasch-built overall disability scale (RODS), Modified Rankin Score (mRS), Grip strength with Martin Vigorimeter, or Medical Research Council (MRC) scale, etc.)

RENEWAL REQUIREMENTS:
- Beneficiary has been compliant with therapy (defined as: 75% utilization)
- Beneficiary has documented improvement of patient's specific symptoms
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of patient's current clinical presentation after starting the requested medication

- For gMG patients, provide current baseline MGFA classification, current MGADL total score, and documentation of continued need for treatment of gMG
- For CIDP patients, current disability test scores with the same test used for baseline (e.g., Inflammatory Neuropathy Cause and Treatment (INCAT) disability score, Rasch-built overall disability scale (RODS), Modified Rankin Score (mRS), Grip strength with Martin Vigorimeter, or Medical Research Council (MRC) scale, etc.)

QUANTITY EDITS:
- 4 injections per 28 days

DISCUSSION:
No comment

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

5) CTEXLI (chenodiol) 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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with cerebrotendinous xanthomatosis (CTX) confirmed by genetic testing and elevated serum cholestanol and bile alcohols (23S-pentol)
- Prescriber must submit the following:
  - Current chart notes
  - Clinical presentation specific to this patient
  - Genetic testing results confirming a CYP27A1 variant is present
  - Baseline labs including LFTs, serum cholestanol and serum/urine bile alcohols levels

RENEWAL REQUIREMENTS:
- Beneficiary has been compliant with therapy (defined as: 75% utilization)
- Beneficiary has documented improvement of patient's specific symptoms and serum cholestanol and serum/urine bile alcohols levels (23S-pentol)
- Prescriber must submit the following:
  - Current chart notes
  - Clinical presentation specific to this patient after starting CTEXLI
  - Current labs including LFTs, serum cholestanol and serum/urine bile alcohols levels

QUANTITY EDITS:
- #93/ 31 days

DISCUSSION:
No comments

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

6) BUCAPSOL (buspirone) capsule

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 anxiety disorders

		• Beneficiary must have tried and failed first-line maintenance medication for the treatment of anxiety (e.g., SSRI, SNRI) unless there is a contraindication
		• Beneficiary must have a history of buspirone generic tablet use
		• Prescriber must submit the following:
		  ○ Current chart notes
		  ○ Long-term treatment plan (buspirone is not typically used long-term)
		  ○ Medical necessity over buspirone generic tablets
		
		QUANTITY EDITS:
		• 7.5 mg #62/ 31 days
		• 10 mg #124/ 31 days
		• 15 mg #124/ 31 days
		
		DISCUSSION:
		No comments
		
		ACTION:
		Motion was made by Dr. Irvin to accept the criteria as presented; second by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

Board comments		No comments
Adjourn		Meeting adjourned 12:00pm