Arkansas Medicaid DUR/DRC Board Meeting Minutes

Date / Time:	July 17, 2024 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Jeniffer Martin, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
	X	Geri Bemberg, Pharm.D.	X	Barry Fielder, Pharm.D.	ATC
	X	Clint Boone, Pharm.D.	X	Kyle Stirewalt, Pharm.D.	Empower
	X	Trenton Dunn, Pharm.D.	X	Trinh Mowder, Pharm.D.	Empower
		Lana Gettman, Pharm.D.	X	Lauren Jimerson, Pharm.D.	Summit
	X	Brian King, Pharm.D.	X	Jessica Lawson, Pharm.D.	CareSource
		Michael Mancino, M.D.	X	Jennifer Chapin, Pharm.D.	CareSource
	X	Melissa Max, Pharm.D.		Ifeyinwa Onowu, Pharm.D.	CareSource
	X	Laurence Miller, M.D.		Elizabeth Pitman	DHS Director
	X	Brenna Neumann, Pharm.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
		Daniel Pace, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Paula Podrazik, M.D.	X	William Golden, M.D.	DHS advisor
	X	Chad Rodgers, M.D.	X	Paul Koesy, Pharm.D.	ADH advisor
		Open Pharm.D. position	X	Karen Evans, P.D.	Magellan
		Open M.D. position	X	Jeniffer Martin, Pharm.D.	Magellan
		Open M.D. position	X	Lesley Irons, Pharm.D.	Magellan
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:35am.			
Public comments		1. Derrick Grass, Pharm.D.—NovoNordisk (Wegovy®) 2. Shirley Quach, Pharm.D.—Novartis (Kesimpta®) 3. John Spear, MBA—Kyowa Kirin North America (Crysvita®) 4. Jackie Mills—ALK Abello, Inc. (Grastek®, Ragwitek®, and Odactra®) 5. Tara McKinley, Pharm.D.—Madrigal Pharmaceuticals (Rezdiffra™)			
Announce-ments		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, Dr. Martin or Dr. Evans. 2. Update on Board composition—Resignations include Florin Grigorian, M.D., Charles Marsh, Pharm.D., and Tonya Robertson, Pharm.D. and newly appointed Trenton Dunn, Pharm.D. 3. FFY2023 CMS Annual Survey was submitted. 4. Quarterly provider newsletter-- Arkansas Medicaid Quarterly Newsletter . 5. NADAC Discussion-- NADAC Follow-Up for DUR.docx 6. Bylaws Review-- DUR-DRC Bylaws draft July 2024.docx Suggestions made by Drs. Neumann and Rodgers. With those recommendations, a motion was made by Dr. Podrazik; Seconded by Dr. Miller. All voting members present voted to approve the updated bylaws as amended. Motion passed. 7. SUPPORT Act Discussion—Dr. Pearson gave updates on current benzodiazepine, opioid and naloxone usage.			
Minutes		Motion to approve April 2024 DUR/DRC meeting minutes was made by Dr. Rodgers, seconded by Dr. King. All voting members present voted to approve the minutes as written. Motion passed.			

Reports		• Dr. Martin from Prime Therapeutics/ Magellan gave the fee-for-service RDUR report and presented RDUR criteria for vote for the next quarter. o August 2024—CNS polypharmacy o September 2024—Bipolar disorder with antidepressants and no mood stabilizer o October 2024—Non-compliance with anticonvulsant medications **ACTION:** Motion was made by Dr. Max for the above criteria; seconded by Dr. Bemberg. All other members present voted for the motion. Motion passed. • Dr. Pearson presented the PASSE ProDUR report for January-March 2024 • Dr. Evans from Prime Therapeutics/ Magellan presented the FFS ProDUR report for April-June 2024
PDL Class Review with Criteria		**1) Vaginal Hormones** Chair provided background information on current age limits and off-label usage. Dr. Martin presented a PowerPoint with the following information. a) Overview of medications with information on the various dosage forms b) General information c) Treatment recommendations from North American Menopause Society, American College of Obstetricians and Gynecologists, International Society for the Study of Women's Sexual Health, and American Urological Association d) Claims summary from 7/1/2023-6/30/2024 **DISCUSSION:** Dr. Neumann made the comment that estradiol cream has drastically decreased in price and would recommend making estradiol preferred over Premarin cream. Dr. Pearson noted that currently estradiol and Premarin do not require a PA for adults. Premarin has no age minimum, but estradiol has a minimum of 10 years of age. Dr. Rodgers asked if we should keep the age limit. Dr. Pearson made the recommendation to remove that age on both products for the off-label use of labial adhesions. Dr. Pearson suggested a motion to allow estradiol and possibly Premarin cream to be preferred options without a minimum age. **ACTION:** Motion was made by Dr. Rodgers for PDL placement and criteria; seconded by Dr. King. All other members in attendance voted for the motion. Motion passed. **2) Multiple Sclerosis** Chair provided current preferred drug list and current PA criteria. No criteria changes were recommended unless a non-preferred options is voted to a preferred status. Dr. Martin presented a PowerPoint with the following information. a) Overview of medications by class with documentation of use and efficacy b) Evidence from clinical studies c) Treatment recommendations from American Academy of Neurology d) Treatment algorithm from UpToDate® e) Claims Summary from 7/1/2023-6/30/2024 **DISCUSSION:** Dr. Pearson recommended considering overall net costs with recommendations from the cost committee with at a minimum to add more preferred generics with different mechanisms of action and potentially consider Kesimpta depending on rebate bid language. Dr. Podrazik commented that it seems that requests from neurologists who recommend Kesimpta which is supported in literature for better outcomes are taken into consideration. Dr. Pearson noted that our clinical team reviews requests for Kesimpta and Mavenclad thoroughly together. **ACTION:** Motion was made by Dr. Boone for PDL placement; seconded by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.
Changes to existing criteria or edits		**1) DAW Code Discussion** **DISCUSSION:** Dr. Neumann asked about procedure for contacting the Help Desk on shortages. Dr. Martin answered her questions. Dr. Boone expressed concerns about requiring DAW 9 for plan prefers brands specifically with potential audits and suggested that Magellan make DAW 0 an option for PPB and allow DAW 9 to be optional. Dr. Neuhofel

discussed typical usage of DAW 9 in chain stores. Dr. Pearson stated that we will have discussions with Magellan on possible solutions. Dr. Pearson asked for a motion to be made to limit DAW codes to 0, 1, and 9.

ACTION:
Motion was made by Dr. Neumann to streamline the DAW codes to 0,1, and 9; seconded by Dr. Podrazik. All other members in attendance voted for the motion. Motion passed.

2) Preventive medications for allergen induced rhinitis
PROPOSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis consistent with the FDA approved package insert. Any off-label requests will be reviewed on a case-by-case basis.
    - Grastek®—immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens
    - Odactra™—immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts
    - Oralair®—immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product
    - Ragwitek®—immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
- Beneficiary must have appropriate testing for the specific allergen (e.g., grass, pollens, ragweed, dust mites) for the drug requested. The testing can be either serum testing for the specific IgE antibodies or skin test and must be positive for the specific allergen.
- For Grastek®, Oralair®, and Ragwitek®, the previous allergy season for either ragweed or grass pollen will be reviewed for Medicaid drug claims that are used to treat allergy symptoms. For Odactra®, the Medicaid drug claims for the past 6 months will be reviewed. The beneficiary must have filled drugs to treat allergy symptoms in at least 2 of the following categories during the previous allergy season for Grastek®, Oralair®, and Ragwitek® or in the last 6 months for Odactra® and have at least 2 claims in consecutive months in each category:
    - Nasal inhaled steroid
    - Oral (systemic) antihistamine
    - Leukotriene modifier
    - Ophthalmic allergy drops (topical ocular mas cell stabilizers or antihistamines) for treating allergic conjunctivitis
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Duplication of therapy with allergy shots or other SL allergen extract tablet
    - Has severe, unstable or uncontrolled asthma
    - For continued approval, beneficiary must remain compliant
- Once an approved PA is entered into the system, the continued approval of subsequent claims of the SL allergen extract will require that the beneficiary is adherent to therapy, and the system must find the previous SL allergen extract claim within the previous 37 days of the incoming claim. Incoming claims that are more than 7 days late on a previous 30-day supply will be rejected at point-of-sale and the PA will not be renewed.

QUANTITY:
#31 per 31 days

DISCUSSION:
No comments.

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

New Business

1) Vitiligo

PROPOSED APPROVAL CRITERIA FOR VITILIGO:

- 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 nonsegmental vitiligo
- Beneficiary must meet the following:
  - Body surface area (BSA) involvement must be ≤10%
  - Trial and failure of the following within the last 6 months with 12 weeks trial each
    - Medium to superpotent topical corticosteroid used continuously or intermittently
    - Topical calcineurin inhibitor (i.e., pimecrolimus or tacrolimus)
  - Treatment area includes face, neck, eyelids, or hands
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Baseline description of vitiligo with location
  - BSA of vitiligo
  - Letter of medical necessity over other treatment options
- Initial approval will be 24 weeks

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have documented an at least 50% improvement (Clinical trial measured 75% and 90%)
- Prescriber must submit the following:
  - Current chart notes
  - Current BSA
  - Current description of vitiligo

DISCUSSION:

Dr. Max asked if we would require super potent TSC for children. Dr. Pearson stated we would not and medium strength would be fine especially on the face. Dr. Dunn asked what would happen if a patient had slightly over 10% BSA and what about legs or arms. Dr. Pearson noted that our reviews are not black and white, and we would consider location and higher BSA on a case-by-case basis. Psychosocial issues are a huge factor in reviewing the requests.

ACTION:

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

2) Pustular Psoriasis

PROPOSED APPROVAL CRITERIA:

- Prescribed by or in consultation with a dermatologist
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for the FDA approved indication
- Maximum dose based on support in the manufacturer's package insert or Micromedex®
- Beneficiary must have a diagnosis of generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past 5 years. Those two flares must meet the following criteria from the Effisayil-1 trial to be considered moderate-to-severe. Documentation of those flares must be provided.
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate); and
  - GPPPGA pustulation sub score ≥ 2 (mild); and
  - Presence of fresh pustules (new appearance or worsening of pustules)
  - ≥5% of BSA covered with erythema and the presence of pustules
- Beneficiary must have one of the following treatment options. Please document the correct treatment plan for the beneficiary.
  - Treatment and maintenance following an acute GPP flare

- 900 mg IV infusion loading dose over 90 minutes; may repeat once after one week (requires medical prior authorization request review)
- Followed by 300 mg SQ every 4 weeks
- Any subsequent flares would require a medical prior authorization request review

- Treatment and maintenance when not experiencing a GPP flare
  - 600 mg SQ loading dose
  - Followed by 300 mg SQ every 4 weeks

- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has no history of at least two GPP flares of moderate-to-severe intensity as defined above
  - Active tuberculosis
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous biologics or disease-modifying antirheumatic drugs (DMARDs) that have been tried with response
  - Documentation of other autoimmune diagnoses for the beneficiary and treatment plan
  - Documentation that the beneficiary has been evaluated for tuberculosis
  - Clarification if this will be billed as a medical claim through "buy and bill" or billed as a pharmacy claim through a specialty pharmacy. NOTE: If billing as a medical claim, contact AFMC for PA processing.
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

DISCUSSION:
No comments

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

3) Crysvita®

PROPOSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Must be prescribed by on in consultation with a nephrologist or endocrinologist
- Beneficiary must be diagnosed with either:
  - X-linked hypophosphatemia (XLH); OR
  - FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO); OR
    - Must be a phosphaturic mesenchymal tumor
    - Tumor cannot be curatively resected or localized
  - Diagnosis consistent with any new FDA-approved indications
- Diagnosis must be confirmed by identifying at least one of the following:
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
  - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient
  - Clinical, radiographic, and laboratory findings that support the diagnosis (e.g., evidence of Rickets, evidence of skeletal demineralization, low phosphate and high alkaline phosphatase for age)
- Beneficiary must have a baseline fasting serum phosphorus level with current hypophosphatemia, defined as a phosphate level below the lower limit of normal for patient's age
- Adults must have an inadequate response from oral phosphate and active vitamin D analogs
- Beneficiaries with TIO must have a tumor that cannot be curatively resected or localized
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Continues to take oral phosphate or active vitamin D analogs
  - Severe renal impairment (Glomerular Filtration Rate (GFR) < 30 mL/min)
- Prescriber must submit the following:
  - Current chart notes

- Baseline labs including serum phosphorus, parathyroid hormone, serum total alkaline phosphatase activity, and vitamin D
- Baseline symptoms (e.g., pain, mobility, growth rate, rickets on radiographic evaluation (Rickets Severity Score))
- Medical necessity for patients with closed epiphyses
- Attestation that patient has discontinued oral phosphate supplement and active vitamin D analogs
- Information on tumor resection for TIO patient
- Clarification if this will be billed as a medical claim through "buy and bill" or billed as a pharmacy claim through a specialty pharmacy. NOTE: If billing as a medical claim, contact AFMC for PA processing.

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant with treatment (defined as 75% utilization)
- Beneficiary must not demonstrate unacceptable toxicity (e.g., severe hypersensitivity reactions, hyperphosphatemia or nephrocalcinosis, severe injection site reactions, etc.)
- Beneficiary must demonstrate a positive response with at least ONE (1) of the following:
  - Serum phosphate levels increased compared to baseline
  - Symptom improvement (e.g., pain, mobility, growth)
  - Radiographic imaging indicates improvement in Rickets/osteomalacia
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including serum phosphorus, parathyroid hormone, serum total alkaline phosphatase activity, and vitamin D
  - Current symptoms (e.g., pain, mobility, growth, rickets on radiographic evaluation with RSS)
- Beneficiary with closed epiphyses must have documentation of medical necessity for continuation. Reassessment for efficacy with oral phosphate and active vitamin D analogs may be warranted.

DISCUSSION:
Dr. Rodgers asked if we were communicating with the medical side. Dr. Pearson noted that we are working with AFMC/Steve and will send criteria to Dr. Rodgers.

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

4) Rezdiffra™

PROPOSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Must be prescribed by on in consultation with a gastroenterologist or hepatologist
- Beneficiary must be diagnosed with metabolic-associated steatohepatitis (MASH) [formerly known as noncirrhotic nonalcoholic steatohepatitis (NASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Fibrosis staging documentation requires the following:
  - Liver biopsy results; **OR**
  - Fibrosis score results from 2 testing modalities with at least 1 (one) blood-based non-invasive test (NITs) AND at least 1 (one) imaging test from the lists below:
    - NITs
      - Fibrosis-4 index (FIB-4)
      - AST to platelet ratio index (APRI)
      - NAFLD fibrosis score (NFS)
      - Enhanced liver fibrosis (ELF) or simplified ELF index
      - FibroSure®
    - Imaging tests
      - Vibration-controlled transient elastography (VCTE) (e.g., FibroSCAN®)
      - Two-dimensional shear weave elastography

- Point shear wave elastography
- Magnetic Resonance Elastography (MRE)

- Beneficiary must use this medication in conjunction with appropriate diet and exercise
- Prescriber must rule out any other cause for fibrosis (e.g., alcohol, hepatitis C)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Fibrosis score is not consistent with F2 or F3 fibrosis
  - Concomitant use with a strong CYP2C8 inhibitor is requested (e.g., gemfibrozil)
  - Concomitant use with a moderate CYP2C8 inhibitor (e.g., clopidogrel) requires dosage modification for REZDIFFRA
  - Severe renal impairment
- Prescriber must submit the following:
  - Current chart notes
  - Fibrosis staging documentation as listed above
  - Attestation that the patient has been counseled on an appropriate diet and exercise plan
  - Current labs including comprehensive metabolic panel
  - Documentation of alcohol intake history
  - Current weight for dose verification
    - <100 kg, the recommended dosage is 80 mg orally once daily.
    - ≥100 kg, the recommended dosage is 100 mg orally once daily

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- To continue the medication after 12 months of therapy, the beneficiary should demonstrate a positive response to the medication as defined by:
  - Resolution of MASH/NASH without worsening of fibrosis; OR
  - No worsening of MASH/NASH AND improvement in fibrosis by ≥ 1 stage
- Beneficiary must continue to refrain from excessive alcohol use
- Prescriber must submit the following:
  - Current chart notes
  - Current weight
  - Current labs
  - Attestation that patient continues with diet and exercise plan
  - Current fibrosis staging documentation requires the following:
    - Liver biopsy results; OR
    - Fibrosis score results from 2 testing modalities with at least 1 (one) blood-based non-invasive test (NITs) AND at least 1 (one) imaging test from the lists below:
      - NITs
      - Fibrosis-4 index (FIB-4)
      - AST to platelet ratio index (APRI)
      - NAFLD fibrosis score (NFS)
      - Enhanced liver fibrosis (ELF) or simplified ELF index
      - FibroSure®
    - Imaging results
      - Vibration-controlled transient elastography (VCTE) (e.g., FibroSCAN®)
      - Two-dimensional shear weave elastography
      - Point shear wave elastography
      - Magnetic Resonance Elastography (MRE)

DISCUSSION:
No comments

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

5) **Wegovy®**

PROPROSED 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
- For initial approval, beneficiary must meet all of the following:
  - Diagnosed with established cardiovascular disease with at least **ONE** of the following:
    - History of myocardial infarction **OR** history of stent placement or bypass surgery
    - History of stroke
    - Symptomatic peripheral arterial disease
      - Intermittent claudication with an ABI (ankle brachial index) of less than or equal to 0.9; **OR**
      - Peripheral arterial revascularization procedure or amputation due to atherosclerotic disease
  - Considered either obese or overweight (defined as baseline BMI of ≥ 27 kg/m^2)
  - Considered to be at risk for major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke)
  - Outlined treatment plan includes reduced calorie diet and increased physical activity.
- Beneficiary must not be a current smoker or has started a smoking cessation program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - No documented risk for MACE
  - Not considered overweight or obese (baseline BMI <27 kg/m^2)
  - Personal or family history of medullary thyroid carcinoma (MTC)
  - Diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Requested for weight loss only
  - Current smoker without a cessation plan
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including HbA1c and lipid panel
  - Current and previous therapy for cardiovascular disease
  - Baseline BMI and weight
  - Baseline waist circumference, blood pressure, and heart rate
  - Current treatment plan including medication therapy, reduced calorie diet, and physical activity plan along with attestation that beneficiary has been counseled on lifestyle modifications needed to assist with weight loss

RENEWAL REQUIREMENTS:

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Renewal requires the following:
  - Improvement in cardiometabolic parameters and body measurements
  - Continues with lifestyle modifications
- Prescriber must provide the following:
  - Current chart notes
  - Current BMI and weight
  - Current labs including HbA1c and lipid panel
  - Current waist circumference, blood pressure, and heart rate

QUANTITY EDITS:

- Max of 4 syringes per 28 days (PA required for each strength)

DISCUSSION:

Dr. Neumann asked if there is a maximum treatment duration. Dr. Pearson noted there is no mention in literature. And if the patient continues to be stable on renewals, I don't know that we can deny. Dr. Dunn asked how PAs were done with titrating like this especially with patients needing longer for a step. Dr. Pearson stated we can consider approving for longer than the typical timeframe for the dose change. Dr. Pearson stated that we can consider this. Dr. Podrazik stated that many insurance companies require PA with every dose change and multiple refills are allowed per step. Dr. King asked about shortages that would cause noncompliance. Dr. Pearson stated that we would take that into consideration when reviewing a renewal request. Dr. Neumann asked if we did projections on anticipated utilization. The manufacturer talked to us about the expected population that would meet criteria. This is why we have recommended strict criteria. Dr. Max asked about renewal requirements requiring improvement in cardiometabolic parameters which is different than other scenarios like treating with statins. Dr. Pearson questioned how we would know if there was a reduced risk of MACE. The trial does measure HR, BP, Waist measurement, etc. Dr. Podrazik noted that most patients are going to be most interested in weight loss which will impact these parameters. Dr. Pearson agreed but felt we can't put weight loss as a renewal requirement since we are technically not covering the medication for weight loss. No criteria changes were recommended.

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

6) Tryvio™

PROPROSED 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 is diagnosed with hypertension that is not adequately controlled on at least 3 other antihypertensive drugs **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must continue standard of care antihypertensive medications in combination with TRYVIO
- Prescriber and dispensing pharmacy must be enrolled in the TRYVIO REMS program
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Pregnancy
    - Baseline ALT/AST 3X ULN or moderate to severe hepatic impairment
    - NYHA STAGE III-IV heart failure, unstable cardiac function, or NTproBNP ≥500 pg/mL
    - Noncompliant on standard of care pharmacologic treatment at maximally tolerated doses. Therapies vary by patient, but they typically include ACE inhibitor/ARB, calcium channel blocker, and thiazide diuretic.
- Prescriber must submit the following:
    - Current chart notes
    - Current and previous pharmacologic therapies with pharmacy printouts if new to Medicaid
    - Current blood pressure and blood pressure history if available
    - Current labs including CBC (for hemoglobin), LFTs, pregnancy test if female of reproductive potential
    - Current weight to monitor for fluctuations due to potential edema

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant on therapy as ordered by the prescriber (defined as 75% utilization)
- Beneficiary should demonstrate improvement in blood pressure compared to baseline
- Prescriber should submit the following:
    - Current chart notes
    - Current blood pressure
    - Current labs including CBC and LFTs
    - Current weight

QUANTITY EDITS:

- #31 tablets/31 days

DISCUSSION:
Dr. Golden recommended that we include language about size of blood pressure cuff required for appropriate monitoring. Dr. Golden also recommended adding minoxidil as an option to try prior to this medication. Dr. Podrazik stated that is not something we would typically give. After the meeting, Dr. Max and Dr. Podrazik voiced concerns about the use of minoxidil. We agreed to update the criteria slightly to include other potential classes if can't take the normal standard of care.

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

7) Voydeya™

PROPROSED 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) and require treatment for extravascular hemolysis (EVH) and concomitant therapy with ravulizumab or eculizumab **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 vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* types A, C, W, Y, and B, at least 2 weeks prior to initiation of VOYDEYA, 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 REMS program
- The medication is prescribed by or in consultation with a hematologist
- Beneficiary must have clinically significant EVH defined as anemia with hemoglobin ≤ 9.5 g/dL and absolute reticulocyte count ≥120 X 10^9/L with or without transfusion support
- Beneficiary must have been on a stable dose of either ravulizumab or eculizumab for at least the previous 6 months.
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Severe hepatic impairment (Child-Pugh C)
    - Not on a stable dose of a C5 inhibitor
    - Treatment plan does not include continuation of a C5 inhibitor
    - 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* and *Neisseria meningitidis*) at least 2 weeks prior to initiation of Fabhalta® and no antibiotic drug prophylaxis
    - 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)
    - Recent history of blood transfusions
    - Pregnancy test results (if applicable)
    - Dose requested

RENEWAL REQUIREMENTS:

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary remains on C5 inhibitor
- Beneficiary has an improvement in hemoglobin and/or reticulocyte count 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 and CMP

QUANTITY EDITS:

- 150 mg dose (100 mg + 50 mg taken three times daily)--#180 per 30 days
- 200 mg dose (two 100 mg taken three times daily)--#180 per 30 days

DISCUSSION:
No comments

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

8) Lymepak™

PROPROSED 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 is diagnosed with early Lyme disease (as evidenced by erythema migrans) due to *Borrelia burgdorferi* OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary should not be approved with any of the following:
  - Doesn't meet the minimum age and weight per the package insert
  - Medical necessity over generic doxycycline was not established
- Prescriber must submit the following:
  - Current chart notes with rationale for the Lyme disease diagnosis
  - Medical necessity over generic doxycycline tablets or capsules

QUANTITY EDITS:

- #42 per 21 days

DISCUSSION:
Dr. Golden noted that Lyme Disease is not prevalent in Arkansas, so this drug will not be a go-to agent and should be restricted to an ID specialist. Motin was made to include the requirement of an ID specialist.

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

9) Myhibbin™

PROPROSED APPROVAL CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary has had an allogeneic kidney transplant, heart transplant or liver transplant **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary should not be approved with any of the following:
  - Doesn't meet the minimum age and dose per the package insert
  - Medical necessity over generic mycophenolate was not established
  - ≥7 years of age and no reason why patient could not use a solid oral dosage form
- Prescriber must submit the following:
  - Current chart notes with medical reason for immunosuppressant
  - Current labs to monitor kidney function and watch for neutropenia
  - Medical necessity of Myhibbin™ over generic Cellcept® suspension and solid oral formulations

RENEWAL REQUIREMENTS:

- Beneficiary must remain compliant (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Continued need for suspension dosage form over solid oral form
  - Current labs to monitor kidney function and watch for neutropenia

QUANTITY EDITS:

- 3 bottles per 35 days

DISCUSSION:
Dr. Boone asked if we could re-evaluate Myfortic status. No comments on Myhibbin**.**

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

10) Fluoride toothpaste

PROPROSED 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 have documented tooth sensitivity with necessity of a fluoride toothpaste
		• Prescriber must submit the following:
		  • Current visit notes
		  • Documentation of the medical necessity over generic Denta 5000 Plus Sensitive
		QUANTITY EDITS:
		1 tube per 31 days
		
		DISCUSSION:
		No comments
		
		ACTION:
		The motion was made by Dr. Neumann to accept the criteria as presented; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

		Meeting adjourned at 12:26 pm.