


## Arkansas Medicaid DUR/DRC Board Meeting Minutes

<b>Date / Time:</b>	July 19, 2023 8:30 AM– 12:30 PM Central		<b>Location:</b>	ZOOM webinar	
<b>Chair:</b>	Cindi Pearson, Pharm.D.		<b>Reports:</b>	Lesley Irons, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		<b>Panelist (voting members)</b>		<b>Panelist (non-voting members)</b>	<b>Organization</b>
		X Geri Bemberg, Pharm.D.		X Barry Fielder, Pharm.D.	ATC
		X Clint Boone, Pharm.D.		X Shannon Burke, Pharm.D.	Empower
		X Lana Gettman, Pharm.D.		X Lauren Jimerson, Pharm.D.	Summit
		X Florin Grigorian, M.D.		X Jessica Lawson, Pharm.D.	CareSource
		Vacant Pharm.D. position		X Jennifer Chapin, Pharm.D.	CareSource
		X Brian King, Pharm.D.		X Ifeyinwa Onowu, Pharm.D.	CareSource
		X James Magee, M.D.			
		Michael Mancino, M.D.		Elizabeth Pitman	DHS Director
		X Melissa Max, Pharm.D.		X Cindi Pearson, Pharm.D.	DHS, DUR Chair
		X Laurence Miller, M.D.		X Cynthia Neuhofel, Pharm.D.	DHS pharmacy
		X Daniel Pace, M.D.		X William Golden, M.D.	DHS advisor
		X Paula Podrazik, M.D.		X Shane David, Pharm.D.	ADH advisor
		Tonya Robertson, Pharm.D.		X Karen Evans, P.D.	Magellan
		X Chad Rodgers, M.D.		X Lynn Boudreaux, Pharm.D.	Magellan
		Vacant Pharm.D. position		X Lesley Irons, Pharm.D.	Magellan
<b>Call to order</b>	Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:50am.				
<b>Public comments</b>	<ol style="list-style-type: none"> <li>1. Dave Miley, PharmD—Teva (Uzedy™)</li> <li>2. Kheelan Gopal, PharmD—LEO Pharma (Adbry™)</li> <li>3. Matt Baker, PharmD—Axsome (Auvelity®)</li> <li>4. Matt Baker, PharmD—Axsome (Sunosi®)</li> <li>5. Lindsay Bebout, PharmD—Indivior (Perseris®)</li> <li>6. Nancy Njuguna, PharmD—Gilead (Biktarvy® and Sunlenca®)</li> <li>7. Allyson Fonte, PharmD—Aimmune (Vowst™)</li> <li>8. Jennifer Shear, PharmD—Jazz Pharmaceuticals (Xywav®)</li> <li>9. Shawn Hayes, PhD—Pharming Healthcare (Joenja®)</li> <li>10. Bill Lester, PhD—Amgen (Tezspire®)</li> <li>11. Benjamin Skoog, PharmD—ACADIA Pharmaceuticals (Daybue™)</li> <li>12. Kenneth Berry, PharmD, RPh—Alkermes (Aristada® and Aristada Initio®)</li> <li>13. Jia Li, RPh, PharmD—Supernus (Qelbree®)</li> <li>14. Jim Musick—GSK (Nucala® and Arexvy)</li> <li>15. Madeline Shurtleff, PharmD—Otsuka (Abilify Asimtufii®)</li> <li>16. Teri Jeffers, MD—Four Season Allergy &amp; Asthma (Dupixent®)</li> </ol>				
<b>Announcements</b>	<ol style="list-style-type: none"> <li>1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Irons.</li> <li>2. Reimbursement rates are based on WAC, FUL or NADAC.</li> <li>3. Welcome new Board members</li> <li>4. Discuss Dr. Johnson's resignation</li> </ol>				

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	 Arkansas Medicaid Quarterly Newsletter
<b>Minutes</b>	5. Quarterly provider newsletter-- Motion to approve April 2023 DUR/DRC meeting minutes was made by Dr. Miller, seconded by Dr. King. All voting members present voted to approve the minutes as written. Motion passed.
<b>PDL Class Review</b>	<ul style="list-style-type: none"> <li>• <b>Short-Acting Beta Agonists</b></li> </ul> This review is a renewal for the SABA drug class. Chair provided the current breakdown of the PDL, and she provided the rationale for reviewing the class at this time. <p>Dr. Irons presented a PowerPoint with the following information.</p> <ol style="list-style-type: none"> <li>a) FDA approved indications</li> <li>b) Comparison of albuterol vs. levalbuterol</li> <li>c) Treatment guidelines</li> <li>d) Guidelines for delivery devices</li> <li>e) Claims summary from 7/1/2022-6/30/2023</li> </ol> <p><b>DISCUSSION:</b></p> Dr. Pearson stated that the cost committee will meet and make their recommendations. Some branded products may be better options for the State than the generic. Dr. Rodgers stated that he hasn't had any problems with current list except for shortages. Dr. Magee stated he doesn't have a problem as long as the generic is available. Dr. Magee asked what kind of recommendation is needed. Dr. Pearson stated that the generics may not be the best option for the State, and the current slide does not include ProAir Respiclick or Digihaler. There is also the levalbuterol products. Dr. Magee stated there is not a preference for levalbuterol as he uses what is covered under the patient's insurance plan. Dr. Rodgers has not much experience in using dry powder products; good results with HFAs. Dr. Rodgers made the motion to use the current preferred list with the potential to add other preferred options if they are economical for the State. Dr. King asked if providers would be notified ahead of time. Dr. Pearson confirmed that the memo would go out in about 30 days with effective date of October 1 <sup>st</sup> . <p><b>ACTION:</b></p> Motion was made by Dr. Rodgers; seconded by Dr. Magee. All members in attendance voted for the motion. Motion passed.
<b>PDL Class Review with Criteria</b>	<p><b>1) Antidepressants</b></p> This review is a renewal for the antidepressant class. Chair provided table with current minimum and maximum doses along with high dose utilization. Also, the Chair provided recommendations for updating those minimum and maximum doses. <p>Dr. Irons presented a PowerPoint with the following information.</p> <ol style="list-style-type: none"> <li>a) FDA approved indications</li> <li>b) Considerations for treatment</li> <li>c) Treatment guidelines</li> <li>d) Claims summary from 7/1/2022-6/30/2023</li> </ol> <p><b>DISCUSSION:</b></p> Dr. Pearson stated that criteria for the class was reviewed and minimum/maximum doses were evaluated. Dr. Pearson recommended to change doses to be consistent with the package insert with the exception of duloxetine since literature supports higher doses. All current high doses will be able to continue. Dr. Pearson consulted with Dr. Miller for the recommendations. Dr. Mancino reviewed prior to the meeting and had no comments on the changes.

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Dr. Pearson stated that the current preferred list works well. If we had to add something, another SNRI like desvenlafaxine would be the recommendation. Dr. Miller agreed with the addition of desvenlafaxine clinically, but we would need to take into account the net cost. Dr. Pearson recommended that the current products like Spravato that have specific criteria remain manual review. Dr. Miller agreed. All non-preferred options would require the medical necessity over preferred.

**ACTION:**

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

Motion was made by Dr. Miller for PDL placement; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.

### 2) Long-Acting Injectable Antipsychotics

This review is a renewal for the LAI antipsychotic class. Chair provided PA approval and denial information and rationale for making this class available with POS edits. Chair also proposed the criteria for the POS edits which would apply to adults only.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Dosing information
- c) Considerations for treatment
- d) Treatment guidelines
- e) Claims summary from 7/1/2022-6/30-2023

**DISCUSSION:**

No comments on criteria.

Dr. Miller commented that it might be helpful to add a longer acting risperidone product in addition to Risperdal Consta that is only available every 2 weeks. Motion was made to review products based on cost but add a longer acting risperidone product.

**ACTION:**

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

Motion was made by Dr. Miller for PDL placement; seconded by Dr. Podrazik. All members in attendance voted for the motion. Motion passed.

### 3) Immunomodulators, Asthma

This review is a renewal for the asthma immunomodulators class. Chair provided current PDL status and recommended no change to current PA criteria that was last approved in October 2022.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Treatment guidelines
- c) Summary of clinical trials
- d) Claims summary from 7/1/2022-6/30-2023

**DISCUSSION:**

No comments on criteria.

Dr. Pearson recommended that we expand and add another preferred option. Dr. Rodgers stated he doesn't prescribe these often as the child will usually get these prescribed by a specialist, but he sees kids on Xolair and Dupixent with good results. With the utilization of Dupixent and the appropriate criteria is used, Dr. Rodgers didn't know why we wouldn't consider it as long as it was good for the State. Dr. Pearson presented a

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motion. The class would continue to be manually reviewed with previously approved criteria and non-preferred would also have to demonstrate the medical necessity over preferred. At least one more medication would be added as a preferred option as long as it has multiple indications and financially be beneficial for the State.

**ACTION:**

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

Motion was made by Dr. Rodgers for PDL placement; seconded by Dr. Bemberg. All members in attendance voted for the motion. Motion passed.

**4) ADHD agents**

This review is a renewal for the ADHD drug class. Chair provided the current PDL status, current POS edits, and recommendation to update the PA form for adults.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Considerations for treatment
- c) Claims summary from 7/1/2022-6/30-2023

**DISCUSSION:**

Dr. Pearson presented the updated ADHD form with the addition of Qelbree and place of employment. No comments on criteria.

Dr. Rodgers commented that he hasn't had a lot of difficulty when everything was available. He does not use atomoxetine often as it doesn't seem to work well for most. If there was something that became available to the State that was a comparable cost to some of the current preferred options, he would be happy to see the addition. Dr. Magee agreed that the list is fine. Dr. Pearson noted that the gross cost presented is well above our net cost due to rebates on the plan prefers brand products. But we monitor those products and would change to generic as preferred if the brand no longer allows a savings. Dr. Boone commented that any time that we choose a brand product over an available generic, we are putting a strain on our pharmacies with increased carrying cost and ordering brand/generic ratios. Any time we can keep a lower cost alternative, they would appreciate it. Dr. Miller stated that he thinks the list looks fine. But clinically, we get a lot of requests for non-stimulants, especially for kids. He would like to consider Qelbree as an alternative to Strattera depending on cost considerations. Dr. Pearson summarized the motion—the current preferred list of chemical entities are fine with the addition of possibly another non-stimulant. When the State reviews this recommendation and that from the cost committee, the overall cost to the state and impact on pharmacies should be taken into consideration.

**ACTION:**

Motion was made by Dr. Miller to accept the criteria on PA form as presented; seconded by Dr. Gettman. All members in attendance voted for the motion. Motion passed.

Motion was made by Dr. Rodgers for PDL placement; seconded by Dr. King. All members in attendance voted for the motion. Motion passed.

**5) Narcolepsy agents**

This review is a renewal for the narcolepsy agent class with the addition of new medications. Chair provided current PDL status, list of new agents, PA approval/denial information, and proposed criteria for narcolepsy, OSA, SWD, and narcolepsy/cataplexy.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Considerations for treatment
- c) Claims summary from 7/1/2022-6/30-2023

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### **DISCUSSION:**

No comments on criteria.

Dr. Pearson made a tentative recommendation to keep at least one CIII stimulant as preferred and based on overall cost, we can add another product indicated for cataplexy. Dr. Golden asked how many patients had the 456 claims, and do we have any records on continuation of these meds. Dr. Golden directed that we take into consideration the products that are consistently taken. Dr. Pearson summarized the motion—there would be at least one preferred CIII stimulant. Products with other indications will be considered on continued utilization and the best options for the State and beneficiaries.

### **ACTION:**

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

Motion was made by Dr. Rodgers for PDL placement; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed.

### **6) Atopic Dermatitis agents**

This review is a new class for atopic dermatitis that includes biologics and topical agents. Chair provided a list of medications to consider, clinical course for AD, NICE guidelines, and proposed criteria for topical calcineurin inhibitors, PDE-4 inhibitors, topical JAK inhibitors, and systemic biologics.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications
- b) Considerations for treatment
- c) Claims summary from 7/1/2022-6/30-2023

### **DISCUSSION:**

Dr. Pearson recommended POS edits for TCIs, POS edits for the PDE-4 inhibitor, manual review on topical JAK inhibitor, and manual review on biologics. Dr. Rodgers asked for clarification of criteria for biologics, but no further discussion.

Dr. Pearson recommended that at least one TCI be preferred, the PDE-4 inhibitor as preferred, the topical JAK inhibitor as non-preferred, and at least one biologic be preferred with manual review criteria that may have to be updated based on supplemental rebate bid language.

### **ACTION:**

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.

Motion was made by Dr. Rodgers for PDL placement; seconded by Dr. Bemberg. All members in attendance voted for the motion. Motion passed.

### **7) HIV agents**

This review is a new class for HIV agents. Chair noted that the AR Department of Health was consulted, provided current PA criteria for 4 medications, and proposed no changes to that criteria.

Dr. Irons presented a PowerPoint with the following information.

- a) FDA approved indications by mechanism of action
- b) Treatment guidelines
- c) Claims summary from 7/1/2022-6/30-2023

### **DISCUSSION:**

No comment on criteria.

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	<p>Dr. Pearson made the recommendation that most products be considered preferred especially the multi-drug combinations. This would exclude the products that are already manually reviewed. Final decision would be based on net cost, and if any products designated non-preferred have utilization, the beneficiaries would be continued on them. Dr. David asked for clarification on Cabenuva and Apretude. Dr. Pearson stated that they would remain manual review.</p> <p><b>ACTION:</b> Motion was made by Dr. Podrazik to accept the criteria as presented; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.</p> <p>Motion was made by Dr. Bemberg for PDL placement; seconded by Dr. Rodgers. All members in attendance voted for the motion. Motion passed.</p>
<p><b>Criteria Update</b></p>	<p><b>1) General medication policy</b> Chair presented a red-lined document for updates to the old “new-to-market” policy. The document outlines general information on new medications, process for label expansions, process for new medications with class on PDL, process for new medications in class not on PDL, process for new medications requiring a PA, and process for non-preferred medications.</p> <p><b>DISCUSSION:</b> Dr. Rodgers asked for clarification of process for new drugs with PDL classes.</p> <p><b>ACTION:</b> Motion was made by Dr. Rodgers to accept the criteria as presented; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed.</p> <p><b>2) RSV</b> Chair presented indication and dosing for new RSV prophylaxis medications along with Synagis. Chair provided positivity information from CDC surveillance data and verbiage from ACIP review.</p> <p><b>DISCUSSION:</b> Discussion was held between Dr. Magee and Dr. Rodgers. Both recommended continuing to follow AAP and ACIP guidance. Dr. Golden also recommended to monitor what ACOG does. No criteria was presented for vote.</p> <p><b>ACTION:</b> No vote. Discussion noted that there is still not information to make a decision. An emergency meeting may need to be called prior to RSV season.</p>
<p><b>New Business</b></p>	<p><b>1) Daybue™</b></p> <p><b>PROPOSED APPROVAL CRITERIA:</b></p> <ul style="list-style-type: none"> <li>• Beneficiary meets the minimum age recommended in the manufacturer’s package insert for this FDA approved indication</li> <li>• Beneficiary is prescribed no more than the maximum dose from the manufacturer’s package insert or based on support from the official Compendia</li> <li>• Beneficiary must be diagnosed with Rett Syndrome <b>OR</b> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.</li> <li>• Provider must submit a detailed baseline clinical presentation of Rett syndrome including, but not limited to the following:             <ul style="list-style-type: none"> <li>○ Abnormal muscle tone/dystonia</li> <li>○ Abnormal respiration pattern</li> <li>○ Feeding difficulties</li> <li>○ Intellectual disability (i.e., I.Q. score &lt; 70)</li> <li>○ Loss of mobility or gait abnormalities</li> <li>○ Partial or complete loss of acquired hand skills</li> <li>○ Partial or complete loss of speech</li> </ul> </li> </ul>

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- Seizures
- Stereotypic hand movement (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatism)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Moderate to severe renal impairment
  - Intolerable diarrhea
  - No improvement in clinical presentation compared to baseline
  - Dose requested is not consistent with weight-based dose recommendation
- Prescriber must submit **ALL** of the following:
  - Current chart notes with description of specific symptoms present in this beneficiary
  - Documentation of the MECP2 mutation (if available)
  - Attestation of a clinical diagnosis of RTT in the absence of a MECP2 mutation
  - Current weight
  - Current dose requested
  - Current labs to determine renal function
  - Treatment plan for severe diarrhea and weight loss
  - Baseline Rett Syndrome Behavior Questionnaire (RSBQ) and the Clinical Global Impression-improvement (CGI-I) score if available
- Initial PA for 3 months

### **RENEWAL REQUIREMENTS:**

- Beneficiary remains compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current RSBQ and/or CGI-I if available
- Beneficiary continues to lack intolerable side effects
- Beneficiary must demonstrate an improvement in clinical presentation compared to baseline

### **QUANTITY EDITS:**

3600 mL per 30 days

### **DISCUSSION:**

Dr. Rodgers recommended to add the requirement of a specialist.

### **ACTION:**

Motion was made by Dr. Rodgers to accept the criteria as amended; seconded by Dr. Magee. All members in attendance voted for the motion. Motion passed.

## **2) Joenja®**

### **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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with activated phosphoinositide 3-kinase delta (PI3K $\delta$ ) syndrome (APDS) with a documented variant in either PIK3CD or PIK3R1 OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a specialist with experience in APDS such as immunology, hematology/oncology, or pulmonology
- In addition to the APDS diagnosis, the beneficiary must demonstrate symptoms consistent with the diagnosis (e.g., sino-pulmonary infection, lymphoproliferation, enteropathy, organ dysfunction, etc.)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Pregnant

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- Weighs less than 45 kg
- Requires concomitant strong CYP3A4 inhibitors (e.g., itraconazole)
- Requires concomitant moderate or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin)
- Moderate to severe hepatic impairment
- Prescriber must submit **ALL** of the following:
  - Current chart notes with documentation of specific symptoms for this beneficiary and documentation of variant
  - Previous therapies including surgery
  - Current negative pregnancy test for females of reproductive potential
  - Current weight
  - MRI or CT imaging results documenting lesions with descriptions
  - Current labs including LFTs
  - Medical necessity over IVIG and sirolimus
  - Baseline % naïve B cell
- Initial PA for 3 months

### **RENEWAL REQUIREMENTS:**

- Prescriber must submit ALL of the following:
  - Prescriber must submit current chart notes
  - Response to therapy
- Beneficiary has a positive response with symptoms with documented decrease in lymph node lesions and/or increase in % naïve B cells

### **QUANTITY EDITS:**

#62/31 days

### **DISCUSSION:**

No comments

### **ACTION:**

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

### **3) Vowst™**

### **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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with *Clostridioides difficile* infection (CDI) following antibacterial treatment for recurrent CDI (rCDI) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have at least 3 separate confirmed C difficile infections within 12 months and given prior therapy with vancomycin and/or fidaxomicin
- Beneficiary must have completed antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with VOWST
- Beneficiary must be prescribed magnesium citrate to take the day prior to beginning VOWST
- Beneficiary should not be approved if any of the following:
  - Prescribed concomitant antibacterial therapy
  - Does not meet the requirements for recurrent CDI
  - Has not been treated with either vancomycin or fidaxomicin
- Prescriber must submit **ALL** of the following:



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- Current chart notes
- Documentation of treatment for previous CDI episodes
- Medical necessity over vancomycin and fidaxomicin if have not been tried and failed
- PA for 1 claim

### **QUANTITY EDITS:**

#12 per claim

### **DISCUSSION:**

Dr. Golden recommended to define a C difficile diagnosis in the criteria based on laboratory assay.

### **ACTION:**

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

### **4) Furoscix®**

### **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 from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed New York Heart Association (NYHA) Class II or Class III chronic heart failure and being treated for congestion due to fluid overload 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 tried and failed oral and IV furosemide
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current and previous therapies for heart failure
  - Medical necessity over oral and IV furosemide
  - Medical necessity over other diuretics classes

### **RENEWAL REQUIREMENTS:**

- Beneficiary continues to have fluid overload
- Oral and IV furosemide have been tried and failed
- Prescriber must submit the following:
  - Current chart notes
  - Continued treatment plan for fluid overload

### **QUANTITY EDITS:**

#1 per claim??

### **DISCUSSION:**

Discussion with Dr. Golden and Dr. Podrazik on the place in therapy for the product. We need to determine what kind of patient population should be considered, how many patients, and when to use it in an outpatient setting.

### **ACTION:**

Discussion was tabled.

### **5) Veozah™**

### **PROPOSED APPROVAL CRITERIA:**

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

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	<ul style="list-style-type: none"> <li>• Beneficiary is prescribed no more than the maximum dose from the manufacturer’s package insert or based on support from the official Compendia</li> <li>• Beneficiary must be diagnosed with menopause and experiencing moderate to severe vasomotor symptoms <u>OR</u> a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.</li> <li>• Beneficiary must be confirmed as menopausal with 1 of the following:             <ul style="list-style-type: none"> <li>• Spontaneous amenorrhea for ≥ 12 consecutive months</li> <li>• Spontaneous amenorrhea for ≥ 6 months with biochemical criteria of menopause (follicle-stimulating hormone [FSH] &gt; 40 IU/L)</li> <li>• Having had bilateral oophorectomy ≥ 6 weeks prior to the screening visit.</li> </ul> </li> <li>• Beneficiary must have tried and failed hormone replacement therapy or have a contraindication to hormone replacement therapy</li> <li>• Beneficiary should not be approved if any of the following:             <ul style="list-style-type: none"> <li>• Has cirrhosis</li> <li>• Has severe renal impairment or end-stage renal disease (eGFR &lt; 30mL/min/1.73m<sup>2</sup>)</li> <li>• Requires concomitant use with CYP1A2 inhibitors</li> </ul> </li> <li>• Prescriber must submit <u>ALL</u> of the following:             <ul style="list-style-type: none"> <li>• Current chart notes</li> <li>• Current labs including FSH level, LFTs, and CMP</li> <li>• Duration of symptoms</li> <li>• Medical necessity over hormone replacement therapy and other options supported in literature (i.e., SSRIs, SNRIs, anti-epileptics, clonidine)</li> </ul> </li> <li>• Initial PA for 3 months</li> </ul> <p><b><u>RENEWAL REQUIREMENTS:</u></b></p> <ul style="list-style-type: none"> <li>• Beneficiary has a documented improvement in symptoms</li> <li>• Beneficiary is compliant on the medication (defined as 75% utilization)</li> <li>• Prescriber must submit current chart notes with documentation of response</li> <li>• Renewal PAs can be approved for 6 months</li> </ul> <p><b><u>QUANTITY EDITS:</u></b> #31/31 days</p> <p><b><u>DISCUSSION:</u></b> Dr. Golden recommended to define moderate symptoms and include verbiage about sleep disturbances and impairment of daily function.</p> <p><b><u>ACTION:</u></b> Motion was made by Dr. Max to accept the criteria as amended; seconded by Dr. Miller. All members in attendance voted for the motion. Motion passed.</p>
<b>Reports</b>	<ul style="list-style-type: none"> <li>• PASSE ProDUR report was sent to Board members</li> <li>• FFS ProDUR report was sent to Board members</li> <li>• Dr. Irons from Magellan gave the fee-for-service RDUR report             <ul style="list-style-type: none"> <li>○ August 2023                 <ul style="list-style-type: none"> <li>○ 7729—Concomitant use of opioid/benzo</li> <li>○ 7983—Antipsychotic in children 0-17</li> </ul> </li> <li>○ September 202: 7848—2 or more SABA in 90 days without controller</li> <li>○ October 2023: 8022—Benzo with 2 or more claims in 90 days without SSRI or SNRI</li> </ul> </li> </ul> <p><b><u>ACTION:</u></b> Motion was made by Dr. Miller for the above criteria; seconded by Dr. Podrazik. All other members present voted for the motion. Motion passed.</p>
<b>Adjourn</b>	Meeting adjourned at 12:40 pm.