Arkansas Medicaid DUR/DRC Board Meeting Minutes

Date / Time:	October 18, 2023 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lesley Irons, Pharm.D. Magellan Karen Evans, P.D. Magellan	
		Panelist (voting members)		**Panelist (non-voting members)**	**Organization**
		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
		Florin Grigorian, M.D.	X	Jessica Lawson, Pharm.D.	CareSource
	X	Brian King, Pharm.D.	X	Jennifer Chapin, Pharm.D.	CareSource
	X	James Magee, M.D.	X	Ifeyinwa Onowu, Pharm.D.	CareSource
		Charles Marsh, Pharm.D.			
	X	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	Brenna Neumann, Pharm.D.		William Golden, M.D.	DHS advisor
	X	Daniel Pace, M.D.	X	Shane David, Pharm.D.	ADH advisor
		Paula Podrazik, M.D.	X	Karen Evans, P.D.	Magellan
		Tonya Robertson, Pharm.D.		Lynn Boudreaux, Pharm.D.	Magellan
	X	Chad Rodgers, M.D.	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 8:39am.			
Public comments		1. Dave Miley, PharmD—Teva (Austedo®/Austedo XR®) 2. John Deason, PharmD—Neurocrine (Ingrezza®) 3. Cherin Hall, PhD—Novartis (Leqvio®) 4. Dominic Marchese, PharmD—Krystal Biotech (Vyjuvek™) 5. Erin Conley, PharmD—Amgen (Repatha®) 6. Jennifer Farmer—FARA and Darla Sparacino—patient advocate (Skyclarys™) NOTE: Industry requested to speak on Sohonos™ and Imcivree®, but they were not on the call.			
Announce-ments		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Irons. 2. Reimbursement rates are based on WAC, FUL or NADAC. 3. Welcome new Board members  Arkansas Medicaid Quarterly Newsletter (4. Quarterly provider newsletter--  RSV policy.docx 5. RSV policy--  Provider memo preferred diabetic su 6. Diabetes supplies update--			

		7. AME cap removal overview
Minutes		Motion to approve July 2023 DUR/DRC meeting minutes was made by Dr. King, seconded by Dr. Miller. All voting members present voted to approve the minutes as written. Motion passed.
PDL Class Review		**1) Colony Stimulating Factors** This review is a renewal for the CSF drug class. Chair provided the current breakdown of the PDL. Dr. Irons presented a PowerPoint with the following information. a) Overview of neutropenia b) FDA approved indications c) Pharmacology d) Dosages e) Treatment guidelines f) Summary g) Claims summary from 7/1/2022-6/30/2023 **DISCUSSION:** Dr. Max asked if Neulasta Onpro was covered. Dr. Pearson confirmed that it is covered as a non-preferred option. Dr. Max agreed that we should have at least 1 pegfilgrastim and 1 filgrastim formulation, and there is concern about patients that live in rural areas that have difficulty traveling the day after chemo. Dr. Pearson made the recommendation to have at least 1 pegfilgrastim and 1 filgrastim product as preferred, and the final decision would be the best for the state. Neulasta Onpro would be considered if financially makes sense for the state, but if non-preferred it could still be available through the PA process. **ACTION:** Motion was made by Dr. Max for PDL placement; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.
PDL Class Review with Criteria		**1) Movement Disorders** This review will be adding a new class to the PDL. Chair provided current criteria for all three products. The only recommended change to the current criteria was to update the indications for Ingrezza. Dr. Irons presented a PowerPoint with the following information. a) Overview of Huntington's Disease and Tardive Dyskinesia b) FDA approved indications c) Pharmacology d) Dosages and pharmacokinetics e) Treatment guidelines for Huntington's Disease f) Treatment guidelines for Tardive Dyskinesia] g) Summary h) Claims summary from 7/1/2022-6/30/2023 **DISCUSSION:** Dr. Mancino stated that tetrabenazine appears to be the lower cost, but it may not be the best option for someone with suicidal ideation. Dr. Miller stated that we (Medicaid pharmacy program) get some requests for tetrabenazine from children's hospital, but most requests are for Ingrezza and Austedo. Dr. Pearson stated that these products have basically the same side effects and effectiveness. So, does it come down to what is best for the state? Dr. Miller stated that would be a consideration. Dr. Pearson asked for that motion. No comments on criteria. **ACTION:** The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed. The motion was made by Dr. Miller for PDL placement; seconded by Dr. Mancino. All members in attendance voted for the motion. Motion passed.

2) Long-Acting Opioids

This review is a renewal for the LAO class. Chair provided current PDL and current PA criteria for non-preferred products and general denial criteria. The chair made the recommendation to keep the current criteria.

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:

Dr. Pearson stated we may need to consider asking for an abuse deterrent option as preferred if the cost is not prohibitive. Dr. Neumann asked if an abuse deterrent would need a previous incident like an ER visit or code for overdose. Dr. Pearson stated that we have not discussed that previously. Dr. Pearson explained our typical criteria for long-acting opioids including a 60 day lookback. If opioid treatment naïve, a PA would be required. Dr. Pearson asked for a motion for multiple different chemical entities as preferred with an abuse deterrent if financially feasible. And preferred products will be decided on what is best for the state.

Dr. Evans confirmed that the criteria provided is accurate. No other comments on criteria.

ACTION:

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

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

3) Lipotropins (excluding statins)

This review is a renewal for some of the lipotropics class and an addition of products to the PDL. The chair provided current PDL status and recommended criteria changes on some of the products.

Dr. Irons presented a PowerPoint with the following information.

a) Overview of cholesterol
b) FDA approved indications
c) Pharmacology
d) Dosages
e) Treatment guidelines
f) Effects on lipids
g) Summary
h) Claims summary from 7/1/2022-6/30/2023

DISCUSSION:

Dr. Pearson said we should consider making some PCSK9 inhibitor(s) as preferred. Dr. Max asked if they would be preferred with criteria. Dr. Pearson confirmed that they would be manually reviewed. Dr. Max questioned having fenofibrate as preferred but commented those drugs may be recommended for some patients. Dr. Pearson stated that currently Lovaza was not preferred but has POS edits. Dr. Pearson recommended Zetia be preferred without criteria. Dr. Neumann agreed with that but suggested that Lovaza be made non-preferred due to Omega-3 being over the counter and much cheaper. Dr. Pearson summarized a motion—continue to have multiple classes with preferred agents, add ezetimibe as a preferred product as well as a PCSK9.

No comments on criteria.

ACTION:

		The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed. The motion was made by Dr. Mancino for PDL placement; seconded by Dr. Pace. All members in attendance voted for the motion. Motion passed.
New Business		**1) Vanflyta®** **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 Acute Myeloid Leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis. • Beneficiaries of reproductive potential (male or female) must use effective contraception • Beneficiary should take VANFLYTA with standard chemotherapy during the induction (cytarabine and anthracycline) and consolidation (cytarabine) phase and as monotherapy during maintenance phase. • Prescriber and pharmacy must be VANFLYTA REMS certified • Beneficiary should not be approved or continue this therapy with any of the following: o Severe hypokalemia or hypomagnesemia o Long QT syndrome (QTcF interval > 450 ms at baseline), history of ventricular arrhythmias or history of torsades de pointes o Ordered as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT)—not indicated for this population • Prescriber must submit ALL the following: o Current chart notes o Documentation of previous failed therapies and current therapies o Current labs including potassium and magnesium o Current ECG report (also once weekly during induction and during early maintenance phase) o Test results confirming FLT3-ITD mutation positivity o Dose requested **RENEWAL REQUIREMENTS:** • Prescriber must submit the following: o Current chart notes o Current labs including potassium and magnesium o Current ECG report o Dose requested • Beneficiary must continue to meet approval criteria **QUANTITY EDITS:** 2 tablets per day **DISCUSSION:** No comment **ACTION:** The motion was made by Dr. Mancino to accept the criteria as presented; seconded by Dr. Max. All members in attendance voted for the motion. Motion passed. **2) Akeega™** **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 deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer 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 either receive gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy
- Beneficiary must be prescribed prednisone concomitantly
- Beneficiaries with female partners of reproductive potential should use effective contraception
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Develops hypertensive crisis or severe cardiovascular adverse reactions
    - Moderate to severe hepatic impairment
    - Develop symptoms of posterior reversible encephalopathy syndrome (PRES)
    - Confirmed myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML)
    - Not prescribed concomitant GnRH analog or have a bilateral orchiectomy
- Prescriber must submit ALL the following:
    - Current chart notes
    - Documentation of previous therapies tried
    - Genetic report documenting presence of BRCA mutation
    - Current labs including CBC, CMP, and LFTs

RENEWAL REQUIREMENTS:

- Prescriber must submit
    - Current chart notes with response to therapy
    - Current labs including CBC, CMP and LFTs
- Beneficiary does not develop denial criteria

QUANTITY EDITS:

#62/ 31 days

DISCUSSION:

No comments

ACTION:

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

3) Skyclarys™

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 Friedreich's ataxia confirmed by detection of a mutation of the FXN gene 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 exhibit clinical symptoms consistent with Friedreich's ataxia (e.g., muscle weakness, decline in coordination, frequent falling)
- Skyclarys™ is prescribed by or in consultation with a physician who specializes in the treatment of Friedreich's ataxia

- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe hepatic impairment (Child-Pugh C); dosage adjustment for moderate hepatic impairment (Child-Pugh B)
  - Require treatment with a strong or moderate CYP3A4 inducer
  - Require treatment with a strong or moderate CYP3A4 inhibitor (may use concomitantly with a dose adjustment)
  - Consider discontinuation with signs and symptoms of fluid overload and/or heart failure
  - Left ventricular ejection fraction (LVEF) <40%
  - B-type Natriuretic Peptide (BNP) >200 pg/mL
- **Prescriber must submit ALL the following:**
  - Current chart notes
  - Current labs including ALT, AST, bilirubin, B-type Natriuretic Peptide (BNP), and lipid parameters prior to initiating therapy (ALT, AST, bilirubin monthly for the first 3 months)
  - Baseline modified Friedreich's Ataxia Rating Scale (mFARS) score (must be between 20-80)
  - Specific symptoms associated with Friedreich's ataxia for this beneficiary
  - Genetic test results confirming the diagnosis

RENEWAL REQUIREMENTS:
- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current mFARS score
  - Current labs (monitor every 3 months) including ALT, AST, and bilirubin
- Beneficiary must demonstrate an improvement or stabilization in clinical presentation compared to baseline
- Beneficiary must continue to meet approval criteria

QUANTITY EDITS:
90/ 30 days

DISCUSSION:
Dr. Mancino asked if there are any FA specialists in Arkansas? Dr. Pearson noted that according to the FA alliance there is not. Dr. Mancino noted that may be why nobody in Arkansas uses the mFARS score. Dr. Mancino asked if this was a multi-site trial. Jen Farmer from FARA clarified information on the trial. Dr. Mancino asked to move the requirement for an FA specialist but require a neurologist. Dr. Mancino also recommended to remove the LVEF requirement since we asked to monitor BNP, and he asked to remove the mFARS requirement. Dr. Mancino did add that we should include a description of impact for the 4 areas involved (bulbar function, upper limb coordination, lower limb coordination, and upright stability). For renewal, "the beneficiary must demonstrate an improvement or stabilization in clinical presentation compared to baseline on the 4 areas."

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

NOTE: Due to technical difficulties, multiple medications could not be reviewed. The following medications will be added to the January 2024 agenda.
- Olpruva™
- Imcivree®
- Vyjuvek™
- TIMs gout flare indication
- Sohonos™

Reports

- PASSE ProDUR report was not reviewed as there was no significant changes
- FFS ProDUR report was not reviewed as there was no significant changes

		• Dr. Irons from Magellan gave the fee-for-service RDUR report o November 2023 ▪ 7771—CNS Polypharmacy—chronic use 3/90 days ▪ 7948—Gabapentin use and no FDA approved indication o December 2023: 15203—Member with stimulant type ADHD drugs, under 18 and no diagnosis in last year for FDA approved indication o January 2024: 7930—Statin use in persons with cardiovascular disease—HEDIS **ACTION:** Motion was made by Dr. Mancino for the above criteria; seconded by Dr. King. All other members present voted for the motion. Motion passed.
Adjourn		Meeting adjourned at 11:55 am. After a break due to technical difficulties