Arkansas Medicaid DUR Board Meeting Minutes

Date / Time:	July 20, 2022 8:30 AM– 12:30 PM Central		**Location:**	ZOOM webinar	
Chair:	Cindi Pearson, Pharm.D.		**Reports:**	Lynn Boudreaux, 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	Phuong Luu, Pharm.D.	Empower
		Florin Grigorian, M.D.		Lauren Jimerson, Pharm.D.	Summit
	X	Jill Johnson, Pharm.D.		Turkesia Robertson-Jones, Pharm.D.	CareSource
		Brian King, Pharm.D.	X	Jennifer Chapin, Pharm.D.	CareSource
	X	James Magee, M.D.		Elizabeth Pitman	DHS Director
	X	Michael Mancino, M.D.	X	Cindi Pearson, Pharm.D.	DHS, DUR Chair
		Laurence Miller, M.D.	X	Cynthia Neuhofel, Pharm.D.	DHS pharmacy
	X	Paula Podrazik, M.D.	X	William Golden, M.D.	DHS advisor
	X	Tonya Robertson, Pharm.D.	X	Shane David, Pharm.D.	ADH advisor
		Vacant M.D. position	X	Karen Evans, P.D.	Magellan
		Vacant M.D. position	X	Lynn Boudreaux, Pharm.D.	Magellan
		Vacant Pharm.D. position	X	Lesley Irons, Pharm.D.	Magellan
		Vacant Pharm.D. position			
Call to order		Meeting held virtually by ZOOM webinar. A quorum was present, and the chair called the meeting to order at 8:36am.			
Public comments		1) Dave Miley, Pharm.D.—Teva Ajovy® 2) Andrew Howe, Pharm.D.—Novartis Vijoice® 3) Jenna McGowan, Pharm.D.—AbbVie Ubrelvy® 4) Jenna McGowan, Pharm.D.—AbbVie Qulipta® 5) Paul Saskin, Ph.D., FAASM—Idorsia Quviviq® 6) Eardie Curry, Pharm.D.—Genentech Hemlibra® 7) Andrew Delgado, Pharm.D., Ph.D.—Bristol Myers Squibb Camzyos® 8) Gia McLean, Pharm.D.—Amgen Aimovig®			
Announcements		1. There were no conflicts of interest by any voting Board member, Dr. Pearson, or Dr. Boudreaux. 2. Reimbursement rates are based on WAC, FUL or NADAC. Arkansas Medicaid Quarterly Newsletter 3. Quarterly provider newsletter-- 4. Board was notified that the bylaws will be reviewed during the October DUR meeting.			

Minutes		Motion to approve April 2022 meeting minutes was made by Dr. Mancino, seconded by Dr. Gettman. All voting members present voted to approve the minutes as written. Motion passed.

Criteria change review		**1. Acute and prophylaxis migraine treatment**
		ACUTE MIGRAINE TREATMENT
		(MIGRANAL/TRUDHESA, ELYXYB, NURTEC ODT, REYVOW, UBRELVY)
		PROPOSED APPROVAL CRITERIA:
		• Any new medications for acute migraine treatment released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.
		• Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
		• Recipient must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) OR a diagnosis consistent with FDA indication; AND
		• Recipient must have a failure of at least TWO (2) preferred 5HT1B/1D receptor agonists (triptans) using two (2) different chemical agents not just different dosage forms at maximally tolerated doses AND one of those trials should include a non-steroidal anti-inflammatory steroid (NSAID) unless recipient has one of the following contraindications:
		  • For triptans
		  • Ischemic coronary artery disease; OR
		  • Arrhythmias; OR
		  • History of stroke or transient ischemic attack (TIA); OR
		  • Peripheral vascular disease; OR
		  • Ischemic bowel disease; OR
		  • Uncontrolled hypertension
		  • NSAID allergy
		• Prescriber must submit the following:
		  • Current chart notes; AND
		  • Documentation of migraine frequency and severity/duration; AND
		  • List of all therapies trialed with timeframes; AND
		  • Attestation that medication overuse headaches have been ruled out.
		DENIAL CRITERIA:
		• Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
		• Recipient has any of the following:
		  • Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – UBRELVY and NURTEC ODT
		  • Requires continued use of a strong CYP3A inducer (rifampin) – UBRELVY and NURTEC ODT
		  • Requires continued use of P-gp or BCRP substrates – REYVOW
		  • End stage renal disease (CrCl <15 mL/min) – UBRELVY, NURTEC ODT, and ELYXYB
		  • Severe hepatic impairment (Child-Pugh Class C) – REYVOW, NURTEC ODT, and ELYXYB
		  • NSAID allergy or recent coronary artery bypass graft (CABG) surgery -- ELYXYB
		• UBRELVY recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CrCl 15-29 mL/min)
		CONTINUATION CRITERIA:
		• Recipient demonstrates a positive response with a decrease in the severity/duration of migraines; AND
		• Prescriber must submit the following:
		  • Current chart notes; AND
		  • Documentation of current migraine frequency and severity/duration.
		
		MIGRAINE PROPHYLAXIS
		(NURTEC ODT, QULIPTA, AIMOVIG, EMGALITY, AJOVY)
		PROPOSED APPROVAL CRITERIA:

- Any new medications for migraine prevention released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.
- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
- Recipient must have a diagnosis of either:
    - Chronic migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) with ≥15 headache days per month with ≥8 migraine days per month (EMGALITY, AJOVY, or AIMOVIG); OR
    - Episodic migraine or episodic cluster headache (EMGALITY, NURTEC ODT, or QULIPTA); OR
    - Diagnosis consistent with FDA indication; AND
- Recipient has documented failure of a 3-month trial of at least ONE agent from TWO of the following preventative classes:
    - Anticonvulsants (e.g., valproate, topiramate)
    - Antidepressants (e.g., amitriptyline, venlafaxine)
    - Beta blockers (e.g., propranolol, metoprolol, atenolol)
- Prescriber must submit the following:
    - Current chart notes; AND
    - Documentation of migraine frequency and severity/duration; AND
    - List of all therapies trialed with timeframes; AND
    - Attestation that medication overuse headaches have been ruled out.

DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- If approved, recipient does not have a reduction from baseline in monthly migraine days or migraine severity; OR
- Recipient is not adherent to prescribed dose; OR
- Recipient has medication overuse headache caused by opiate overuse or other headache medication overuse; OR
- Beneficiary is <18 years of age or >65 years of age; OR
- Recipient has any of the following:
    - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
    - Requires continued use of a strong CYP3A inducer (rifampin) – NURTEC ODT
    - End stage renal disease (CrCl <15 mL/min) – NURTEC ODT
    - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA

CONTINUATION CRITERIA:

- Recipient must have a reduction from baseline in monthly migraine days and migraine severity after 3rd month of treatment; AND
- Prescriber must submit the following:
    - Chart notes since previous PA approval; AND
    - Documentation of current migraine frequency and severity; AND
- Recipient is adherent to therapy; AND
- Recipient has decreased claims of acute migraine treatment

DISCUSSION:

Dr. Johnson asked if Nurtec ODT would be allowed first before an injectable CGRP for prevention. Dr. Pearson stated that the upcoming PDL review will dictate that placement. Dr. Golden asked if any of these agents document a reduction of Botox usage as we needed to coordinate the totality of care and where Botox should be placed in terms of prior authorizations. Dr. Pearson stated that upon research, there is not a contraindication with the use of Botox and these agents, so the denial criteria of concurrent Botox was removed. Since Botox is a medical claim only, it makes coordination of care with pharmacy claims a little more difficult. Dr. Golden stated he wasn't looking at contraindications but if these medications would preclude the use of Botox and vice versa. Dr. Pearson stated she

would do more research on the use of Botox with these preventative agents with the assistance of the medical review team. No changes to proposed criteria were recommended.

ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Podrazik. Dr. Gettman's audio prevented a vote, but all other members present voted for the motion. Motion passed.

2. Hemophilia A review

PROPOSED APPROVAL CRITERIA FOR HEMLIBRA:
(highlighted has been added/changed from original)
APPROVAL CRITERIA for Hemophilia A WITH Inhibitors:

- Recipient must have a diagnosis of congenital hemophilia A with inhibitors AND ONE (1) of the following:
    - High factor VIII inhibitor titer (≥5 Bethesda units per mL (BU)); OR
    - Factor VIII inhibitor titer <5 BU/mL with inadequate response to high dose factor
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; AND
- Prescriber must submit the following:
    - Chart notes for the last 24 weeks; AND
    - Current labs including CBCs and LFTs; AND
    - Documentation that Hemlibra® is prescribed for the prevention of bleeding episodes (not acute treatment); AND
    - Documentation of any previous treatment with episodic and prophylactic bypassing agents (FEIBA®, NovoSeven RT®, or Sevenfact®); AND
    - Documentation of one of the following:
        - Inadequate response to Immune Tolerance Induction (ITI); OR
        - Rationale why the recipient is not a candidate for ITI; OR
    - Attestation that recipient will NOT be receiving concurrent prophylactic treatment with bypassing agents or has possibility of receiving ITI while taking Hemlibra®; AND
    - Attestation that the recipient has been counseled on proper technique on episodic treatment with bypassing agents as needed for breakthrough bleeding episodes; AND
    - Current weight; AND
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

APPROVAL CRITERIA for Hemophilia A WITHOUT Inhibitors:

- Recipient must have a diagnosis of congenital hemophilia A without inhibitors with ONE (1) of the following:
    - Severe disease with <1% of factor VIII in blood while on factor VIII products; OR
    - Moderate disease with 1-5% of factor VIII in blood while on factor VIII products with ONE (1) 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
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; AND
- Prescriber must submit the following:
    - Chart notes for the last 24 weeks; AND
    - Current labs including CBCs and LFTs; AND
    - Documentation that Hemlibra® is prescribed for the prevention of bleeding episodes (not acute treatment); AND

- Documentation of any previous prophylactic and/or episodic FVIII infusions; AND
- Attestation that recipient will NOT be receiving concurrent prophylaxis factor VIII; AND
- Attestation that recipient has been counseled on proper technique on episodic treatment with factor VIII products as needed for breakthrough bleeding episodes; AND
- Current weight; AND

- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

No change to denial criteria

PROPOSED APPROVAL CRITERIA FOR NOVOSEVEN RT and SEVENFACT

(Reworded old criteria but no recommended changes)

- Recipient must have a diagnosis of congenital or acquired hemophilia A or B with inhibitors confirmed by blood coagulation testing requiring treatment of bleeding episodes or peri-operative management; AND
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; AND
- Recipient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (Hemlibra®) (NovoSeven® or Sevenfact® may be taken as breakthrough for patients taking emicizumab) – Hemophilia A only
- Recipient has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – Hemophilia B only
- Prescriber must submit the following:
  - Chart notes with history of bleeds and treatment for the last 24 weeks; AND
  - Current labs; AND
  - Current weight for dosing; AND
  - Provide requested dose as PA will be entered for specific dosing requirements Hemophilia A or B with Inhibitors

NO change in criteria for Factor VII Deficiency, Glanzmann's Thrombasthenia or Acquired Hemophilia.

PROPOSED APPROVAL CRITERIA FOR FEIBA

(Reworded old criteria but no recommended changes)

- Recipient must have a diagnosis of hemophilia A or B with high factor VIII or factor IX titer inhibitors (≥ 5 Bethesda Units) requiring treatment for ONE of the following:
  - Control and prevention of bleeding episodes; OR
  - Peri-operative management; OR
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; AND
- Recipient has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (Hemlibra®) (FEIBA® may be taken as breakthrough for patients taking emicizumab) – Hemophilia A only
- Recipient has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – Hemophilia B only
- Prescriber must submit the following:
  - If doses above 100 units/kg or daily doses of 200 units/kg are required, provide the treatment plan to monitor for Disseminated Intravascular Coagulation (DIC) or signs of ischemia and thromboembolic events; AND
  - Chart notes with history of bleeds and treatment for the last 24 weeks; AND
  - Current labs; AND
  - Current weight for dosing; AND
  - Provide requested dose as PA will be entered for specific dosing requirements

DISCUSSION:

Hemlibra discussion:

Dr. Johnson stated that ICERs report on Hemlibra without inhibitors made the point that when quantifying the cost effectiveness, Hemlibra's cost can offset the consumption of another expensive drug like high dose factor VIII. And the ICER report found Hemlibra may not be cost effective for patients on lower doses of factor VIII. So, it might be worth looking at or inserting criteria around patients that are high consumers of factor VIII. Dr. Pearson asked where the breaking point is between high and low users. Dr. Johnson state that the ICER report noted factor VIII doses taken from the trials. Dr. Pearson asked if adding a fourth bullet under moderate disease defining high doses would fix these concerns, and Dr. Johnson agreed.

Bypassing agent discussion:

No discussion—motion made for presented criteria

ACTION:

Motion made to approve the criteria as amended for Hemlibra was made by Dr. Mancino; seconded by Dr. Podrazik. Motion made to approve the criteria as presented for the bypassing agents was made by Dr. Johnson; seconded by Dr. Boone. All members present voted for the motion. Motion passed.

3. SGLT-2 Inhibitors for Heart Failure

PROPOSED POS APPROVAL CRITERIA:

Criteria 1:

- Billed diagnosis of heart failure in the last 2 years; AND
- Medicaid pharmacy profile indicates paid claims for a beta blocker or ACEI/ARB/ARNi in the last 60 days

Criteria 2:

Medicaid pharmacy profile indicates a paid claim in the last 60 days for either:

- Jardiance (empagliflozin); OR
- Farxiga (dapagliflozin)

If doesn't meet POS criteria, a prior authorization will be required.

PROPOSED MANUAL REVIEW APPROVAL CRITERIA:

- Based on current treatment guidelines for treating heart failure without a diabetes diagnosis (includes empagliflozin and dapagliflozin); AND
- Recipient must have New York Heart Association (NYHA) class II-IV heart failure with low left ventricular ejection fraction (LVEF) ≤ 40% and elevated NT-proBNP or BNP; AND
- Recipient must be prescribed the following therapy titrated to the maximum tolerated or target doses:
    - Angiotensin Receptor-Neprilysin Inhibitor (ARNI)/ Angiotensin-Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB); OR
    - Beta blocker;
    - Diuretic (as needed);
    - If not on standard of care therapy listed above, explain the reason; AND
- Prescriber must submit the following:
    - Current chart notes with documentation of previous therapy; AND
    - Baseline LVEF; AND
    - Baseline N-terminal pro–B-type natriuretic peptide (NT-proBNP) or BNP

DISCUSSION:

Dr. Johnson commented that the presented criteria is correct when discussing HFrEF. There is new data for empagliflozin with patients who have HFpEF and acute decompensated heart failure. Empagliflozin can be effective for patients with EF <40% and those with EF greater than 40%. The guidelines in HFrEF patients give SGLT-2 inhibitors a rating of 1 and a rating of 2a for HFpEF patients.

		The recommendation is not as strong but should still be considered because it does show a reduction in heart failure hospitalizations. Dr. Johnson stated that we do want people to get evidence based therapy. Dr. Pearson asked if HFpEF patients have elevated BNP. Dr. Johnson stated that these patients may have cardiac stretch and fluid retention causing heart failure, but she wasn't sure about BNP. Dr. Pearson stated that the POS criteria does not look for a specific ejection fraction, just a diagnosis of heart failure. But the manual review criteria may need to be changed. Dr. Johnson stated that the recommendations of typical standard of care therapies in HFpEF patients is weaker than that of SGLT-2 inhibitors. Per guidelines, we may consider SGLT-2 inhibitors after diuretics in HFpEF. Dr. Pearson stated that she would research more and incorporate Dr. Johnson's proposal. Dr. Robertson asked if we were going to totally change our criteria on a 2a recommendation. Dr. Johnson noted that the data came from large, randomized control trials, and it would be hard to deny a request. Dr. Pearson asked if Dr. Robertson was okay with that addition. She suggests waiting for more data, but she is fine with the addition. Dr. Podrazik noted from a Lancet article asymptomatic and symptomatic patients with LV systolic dysfunction can have elevated BNP. Dr. Pearson will review the treatment guidelines pertaining to HFpEF. **ACTION:** Motion made to approve the criteria as amended was made by Dr. Johnson; seconded by Dr. Podrazik. Dr. Gettman's audio prevented a vote, but all other members present voted for the motion. Motion passed.

New Business		**1. CAMZYOS™ (mavacamten)**
		PROPOSED APPROVAL CRITERIA:
		• Recipient must be at least 18 years of age; AND
		• Recipient must have a diagnosis of NYHA Class II-III obstructive hypertrophic cardiomyopathy OR a diagnosis consistent with any updated FDA indications; AND
		• Prescribers, patients, and pharmacies must be enrolled in the Camzyos™ REMS program due to risk of heart failure due to systolic dysfunction; AND
		• Recipient must have tried and failed beta blockers and calcium channel blockers unless contraindicated; AND
		• Prescriber must submit the following:
		  • Current chart notes; AND
		  • Previous treatment; AND
		  • Confirmation for absence of pregnancy and attestation that females of reproductive potential will use effective contraception; AND
		  • Baseline LVEF, Valsalva LVOT peak gradient, and mixed peak oxygen consumption
		DENIAL CRITERIA:
		• Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
		• Recipient has a baseline LVEF <55% or Valsalva LVOT peak gradient < 50 mmHg; OR
		• Recipient requires moderate to strong CYP2C19 inhibitors or inducers, OR strong CYP3A4 inhibitors, OR moderate to strong CYP3A4 inducers; OR
		• Recipient is pregnant
		CONTINUATION CRITERIA:
		• Recipient must have LVEF ≥50% to continue; AND
		• After 30 weeks, the recipient must have at a minimum an improvement of mixed peak oxygen consumption and no worsening in NYHA class; AND
		• Prescriber must submit the following:
		  • Current chart notes; AND
		  • Echocardiogram reports at weeks 4,8,12 and every 12 weeks; AND
		  • Documentation of response to treatment
		QUANTITY EDITS:
		#31/ 31 days

DISCUSSION:
None

ACTION:
Motion made to approve the criteria as presented was made by Dr. Mancino; seconded by Dr. Gettman. All members present voted for the motion. Motion passed.

2. VIJOICE® (alpelisib)

PROPOSED APPROVAL CRITERIA:

- Recipient must be ≥2 years of age; AND
- Recipient must have a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) requiring systemic therapy OR a diagnosis consistent with any updated FDA approved indications; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Genetic testing results identifying a PIK3CA mutation and/or the clinical presentation confirming the diagnosis; AND
    - Identify which PROS disease has been confirmed; AND
    - Current labs including fasting plasma glucose and HbA1c; AND
    - Previous treatment including surgery (provide explanation if surgery is not an option); AND
    - Baseline size/volume of target lesion(s); AND
    - Attestation that both males and females of reproductive potential have been counseled on the importance of contraception; AND
    - Current dose requested (Patients unable to swallow tablets can use any dose to make a suspension based on preparation guidance from the packet insert.)
        - Recipient <6 years—max of 50 mg daily
        - Recipient 6-17 years of age—50 mg daily for at least 24 weeks before increasing to 125 mg daily
        - Recipient ≥18 years of age—max of 250 mg daily

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient has been diagnosed with severe cutaneous adverse reactions (SCARs) including Stevens-Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis or pneumonitis; OR
- Recipient cannot tolerate the minimum dose of 50 mg daily; OR
- Recipient requires a concomitant strong CYP3A4 inducer or BCRP inhibitor; OR
- Recipient has Type 1 or uncontrolled Type 2 diabetes

CONTINUATION CRITERIA:

- Recipient does not demonstrate disease progression, had at least at 20% reduction in lesion volume by week 24, and has no unacceptable toxicity; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Documentation of response to therapy; AND
    - Current dose requested

QUANTITY EDITS:
50 mg--#31/ month
125 mg--#31/ month
250 mg pack--#62/ month

AGE EDITS:
50 mg—2-17 years
125 mg—18+ (if child needs this dose, another PA can be entered)
250 mg pack—18+

DISCUSSION:
Dr. Johnson noted that this drug was FDA approved as an accelerated approval, and the packet insert states that a confirmatory trial is recommended. Dr. Johnson requested that we review this product in a year or so to ensure that the confirmatory trial has not be terminated. Dr. Pearson agreed. Dr. Robertson asked how reduction in lesion volume will be measured. Dr. Pearson stated that a radiological review will compare baseline and current. It will be difficult to determine actual size of "lesion" if whole limb, but we will do the best we can.

ACTION:
Motion made to approve the criteria as presented was made by Dr. Johnson; seconded by Dr. Mancino. All members present voted for the motion. Motion passed.

3. RADICAVA ORS® (edaravone)

PROPOSED APPROVAL CRITERIA:

- Recipient must be ≥18 years of age; AND
- Recipient must have a diagnosis of amyotrophic lateral sclerosis (ALS) OR a diagnosis consistent with any updated FDA approved indications; AND
- Recipient must have disease duration ≤ 2 years; AND
- Recipient must have FVC ≥80% at baseline; AND
- Recipient must have a baseline ALS Functional Rating Scale score (ALSFRS-R) ≥ 24; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Baseline ALSFRS-R score; AND
    - Duration since first symptoms; AND
    - Pulmonary Function Test

CONTINUATION CRITERIA:

- Recipient remains compliant on therapy; AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Current Pulmonary Function Test; AND
    - Updated ALSFRS-R score

QUANTITY EDITS:
50 mL bottle--#1 per 28 days
70 mL bottle--#1 per 28 days

DISCUSSION:
Dr. Johnson notes that ICER is reviewing this medication, and the evidence report is questioning the drug's efficacy. Most of the trials showed no significant difference with the use of Radicava, and one of the trials showed a small benefit giving a C+ recommendation. The cost effectiveness is outrageous at like $12 million per QALY. It really doesn't look very effective and with continuation criteria without benefit is very concerning. Dr. Pearson asked how you would define response and when to stop coverage especially for a disease that continually progresses. Dr. Golden stated that situations like this are a problem with other neuromuscular degenerative diseases that demonstrate progressive injury. Dr. Golden stated we need to look at how to determine whether any of these drugs used for neuromuscular degenerative diseases are really achieving anything. Dr. Pearson asked if we should require a trial of Riluzole first. Dr. Johnson noted that ICER is comparing Radicava against standard of care which includes Riluzole. Dr. Johnson stated that it's important to be aware of where the evidence lies and where there's insufficient evidence as treating with this product can cost AR Medicaid lots of money with no benefit for the patient. Dr. Pearson stated we can add the requirement for Riluzole but how do we know it fails as every patient progresses at a different rate. Dr. Johnson stated that thought provoking points not reflected in the direct ICER report will be available possibly in August, and she suggested we table this drug until the next meeting. Dr. Robertson agreed with tabling the discussion.

ACTION:
This medication was tabled until the October DUR meeting pending more study data.

4. TREATMENT OF EOSINOPHILIC ESOPHAGITIS (Budesonide respules and dupilumab)
PROPOSED APPROVAL CRITERIA:
Pulmicort respules (budesonide) (No change in other inhaled corticosteroids)
- Criteria 1: Recipient < 4 years of age; OR
- Criteria 2: Regardless of age, recipient has a billed diagnosis of EoE

Dupixent (dupilumab)
- Recipient must be ≥ 12 years of age and at least 40 kg; AND
- Recipient must have a confirmed diagnosis of eosinophilic esophagitis (EoE) with at least 2 of the following:
    - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain)
    - Esophageal biopsy indicates ≥15 eosinophils per high-power field (eos/hpf)
    - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows)
- Recipient must have at least a 12-week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide) and proton pump inhibitors (e.g., pantoprazole or omeprazole); AND
- Prescriber must submit the following:
    - Current chart notes; AND
    - Previous therapies including dietary restrictions, procedures, or pharmacological treatment; AND
    - Baseline eos/hpf; AND
    - Baseline recipient determined Dysphagia Symptom Questionnaire (DSQ) score

CONTINUATION CRITERIA:
- Recipient demonstrates a positive response with one of the following after 6 months of treatment:
    - Achieved remission with ≤ 6 eos/hpf; OR
    - Decrease in DSQ score from baseline by at least 20 points
- Prescriber must submit the following:
    - Current chart notes; AND
    - Current recipient determined DSQ score; AND
    - Current eos/hpf

DISCUSSION:
Dr. Magee asked how many Flovent inhalers a patient could get per month. Dr. Pearson confirmed that we had increased the maximum to 2 ICS inhalers per month. No other comments.

ACTION:
Motion made to approve the criteria as presented was made by Dr. Magee; seconded by Dr. Podrazik. Dr. Johnson was absent from the vote, but all other members present voted for the motion. Motion passed.

5. MAXIMUM DOSE FOR TARGETED IMMUNOMODULATORS
DISCUSSION:
Dr. Mancino asked about the significance of antibodies in the labs drawn. Dr. Pearson stated that data indicates patients with antibodies have lower detectable drug levels. Dr. Golden suggested that we save this discussion for later after more research by our staff and Board members. Dr. Mancino stated when he treats patients with bipolar and their Depakote level is subtherapeutic but patient is stable, he doesn't change therapy based on that lab but on the patient themselves. Dr. Mancino stated that for doses above FDA approved for any indication with support on MicroMedex and clinically it makes sense to increase their dose, then he would support that. If a medication is safe for

		a 6 year old for another condition, it depends on what the interaction between the medication and the condition are in terms of safety and tolerability. Dr. Mancino stated he would rely on the clinical judgment of the person requesting the higher dose and hope that the prescriber had a discussion with the patient about this dose exceeding the FDA approved dosing. Dr. Golden commented on the case study about the notion that lower drug levels will allow inflammatory disease to predominate causing long term complications. Dr. Robertson asked if there is evidence that TDM is supposed to occur. Dr. Pearson shared 1 article but recommended that we can have a separate meeting on this topic at a later time. Dr. Robertson is not comfortable exceeding FDA approved or literature supported doses. **ACTION:** This discussion was tabled for a future meeting later this month. **6. AGE EDITS FOR SEDATIVE HYPNOTICS** **PROPOSED LIMITATIONS:** Limit the minimum age on the non-benzo sedative hypnotics to match the FDA approved information. What about triazolam, temazepam, estazolam, and flurazepam? **DISCUSSION:** Dr. Mancino consulted with his childhood adolescent psychiatry colleagues, and they were not aware of any good data around use of benzos for sleep disorders in children as defined by less than the FDA approved ages. They felt like those should be reserved for very short term use. There is potential for substance use disorder development if they're used this early on. Dr. Golden noted that using pharmacologic products for sleep disorders are generally discouraged long-term. Dr. Golden suggested that if they are used for sleep, that we limit the number of pills per month to be used episodically or periodically. Dr. Podrazik discussed retrospective literature on adults with benzos as amnestic agents which shorten the time to dementia. Dr. Pearson stated that we may look at this issue with RDUR. Dr. Golden stated we should look at behavioral health and development disability patients separately. **ACTION:** Motion to change the minimum age for all sedative hypnotics for benzos and non-benzos to be consistent with the manufacturer's package insert was made by Dr. Mancino; seconded by Dr. Magee. Dr. Gettman and Dr. Johnson were absent from the vote, but all other members present voted for the motion. Motion passed.
Reports		• Dr. Pearson gave the ProDUR report for the PASSEs • Dr. Evans from Magellan gave the fee-for-service ProDUR report • Dr. Boudreaux from Magellan gave the fee-for-service RDUR report
Adjourn		Meeting adjourned at 12:07pm.