DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES

Hybrid: Brown Auditorium & Zoom Conference

December 2, 2021

Members Present: Pamela Beahm, MD; Susan DeLeo, RPh (virtual); William McCormick, PharmD; Melissa Myers, MD; Kaitlyn Simoneau, PharmD; Keith Stahl, MD

Members Absent: none

Presenters and Professional Staff: Margaret Clifford, RPh; Lise Farrand, RPh; Honesty Peltier, PharmD, Clinical Manager, Magellan RX Management; Gita Rana, Analyst, Magellan RX Management

Agenda: Attached

2:02 PM, Ms. Clifford opened the public comment and presented the DUR policy for the public hearing.

Speaker	Company	Topic
Chuck Berds, PharmD, MBA	Novo Nordisk	Wegovy™
Paul Isikwe, PharmD	Teva	Ajovy [®]
Tamela Martin, MS	Biohaven	Nurtec™ ODT
Amy Tomasello, PharmD, MS	AbbVie	Qulipta [®]
Patrick Lewis, PharmD	Amryt Pharma	Juxtapid [®]
Rae Ann Maxwell, RPh, PhD	Biogen	Aduhelm™, Spinraza™

Meeting called to order at 2:29 PM

I. INTRODUCTIONS AND WELCOME TO BOARD MEMBERS

II. OLD BUSINESS

- a. Dr. McCormick presented the committee with the draft minutes from the June 8, 2021 meeting.
- b. Board Discussion
 - i. No comments.

MOTION	To accept the proposed draft minutes from the June 8, 2021 DUR meeting with the amended language.		
MOTION PASSED	In favor	Opposed	Abstained
MICTION PASSED	6	0	0

III. NEW BUSINESS

A. DUR Business Operations

- 1. Overview of Drug Utilization Patterns for the New Hampshire Medicaid Fee-for Service Program
 - a. Overview of Drug Utilization Program and Patterns for New Hampshire Medicaid was presented.

2. Prospective DUR Reports

- a. Approximately 600 to 850 claims each month generated ProDUR messages from February 2021 to October 2021.
- b. The prospective DUR report for February 2021 to October 2021 was presented and reviewed. The top 5 encounters of the ProDUR modules were reviewed for each category:
 - i. Drug-Drug Interactions
 - 1. Quetiapine with Bupropion
 - 2. Clozapine with Oxcarbazepine
 - 3. Lamotrigine with Lacosamide
 - 4. Clozapine with Lorazepam
 - 5. Trazodone with Sertraline
 - ii. Duplicate Ingredient
 - 1. Combinations of mixed amphetamine products
 - 2. Lamotrigine
 - 3. Dexmethylphenidate
 - 4. Methylphenidate
 - 5. Olanzapine
 - iii. Duplicate Therapy
 - 1. Bupropion Bupropion
 - 2. Sertraline Sertraline
 - 3. Levetiracetam Lamotrigine
 - 4. Lamotrigine Lamotrigine
 - 5. Dexmethylphenidate Dexmethylphenidate
 - iv. Early Refill
 - 1. Gabapentin
 - 2. Buprenorphine/Naloxone
 - 3. Lamotrigine
 - 4. Bupropion
 - 5. Trazodone
- c. The Early Refill (ER) report from February 2021 to October 2021 was reviewed with the report broken down by reason for request. COVID was added as a reason for early refill requests beginning in March 2020 due to the pandemic. There have been no early refill requests due to COVID since March 2020. The most consistent reasons for requesting early refills were Increased/Variable Dose followed by Lost or Stolen and Vacation.

3. Utilization Reports

a. The utilization analysis report on data from February 2021 to October 2021 for single source, multi-source and generic drug utilization was reviewed. The total claims for All Drugs during the period was 40,112. All measures for this report were impacted by the claim volume for COVID vaccines adjudicated through the POS system and reported as single source brand volume. This impacted the average generic drug rate as 35.9% over the 9-month period.

4. Retrospective DUR Reports

a. RetroDUR quarterly review for February 2021 to October 2021 was presented showing a total of 9 topics which had been completed. The report showed a breakdown of each topic by # of letters mailed to prescribers, # of affected members, # of responses to letters received and the % of responses received. It was noted that some activities are for the purpose of education and do not request feedback from the prescriber which impacts the response rate for these activities. The board requested a summary of changes to prescribing patterns related to the selected DUR activities during future presentations to assess the impact on members.

5. RetroDUR Interventions

 a. The board reviewed the list of possible RetroDUR intervention topics for implementation beginning December 2021. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
15008	Polypharmacy	116
7741	Leukotriene inhibitor without asthma diagnosis	21
7734	Diabetics without an ACEI or ARB in history; modify and add statins	14
8022	Benzodiazepines - 2 or more claims in recent 90 days without a SSRI or SNRI in the last 6 months	8
7280	Fluoroquinolones Boxed Warning relating to the increased risk of tendon rupture and tendinitis.	7
7848	SABA_ 2 or more in 90 days without a controller medication	5
	Clozapine use with concurrent benzodiazepines	unknown

B. COVID-19 Status Update

 COVID vaccines have been available for adjudication through the pharmacy claims system since mid-December 2020. All Medicaid recipient's vaccine claims are covered through the Fee-for-Service Program if the claim is billed through POS. There were 25,942 paid claims for COVID vaccines for Medicaid recipients through October 31, 2021. There were 16,137 unique Medicaid IDs with claims for at least 1 vaccine dose. This does not account for all vaccine administration for Medicaid recipients, as the state sites did not bill insurances. Dual-eligible recipients are also not reflected in these counts as Medicare would have provided full coverage.

C. Review of Current Clinical Prior Authorization Criteria with Proposed Changes

1. Anti-Obesity

- a. Change the criteria name to Weight Management.
- b. Remove discontinued phentermine doses and add new strengths of Qsymia[®].
- c. Addition of Wegovy® for chronic weight management in adults.
- d. Addition of Imcivree™ for chronic weight management in pediatric patients ≥ 6 years of age and adults with obesity due to genetic variants with specific approval and renewal criteria.
- e. Update the FDA-approved indication for Saxenda® to include patients ≥ 12 years of age.
- f. Board Discussion
 - i. Remove duplicate language criteria 5 "At least two other risk factors (see Table 1)."

	MOTION	To accept the Anti-Obesity Criteria as presented with amendment.		
	MOTION PASSED	In favor	Opposed	Abstained
		6	0	0

2. Calcitonin Gene-Related Peptide (CGRP) Inhibitor – Migraine and Cluster Headache

- a. Update FDA-approved indication for Nurtec™ ODT for the preventative treatment of episodic migraine in adults. Add this to the Migraine Headache Prevention criteria when requested for prevention.
- b. Add Qulipta™ to the criteria specific to Migraine Headache Prevention aligned with the FDA-approved indication for the preventative treatment of episodic migraine in adults.
- c. Board Discussion
 - i. No comments

MOTION	To accept the Calcitonin Gene-Related Peptide (CGRP) Inhibitor – Migraine and Cluster Headache Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

3. CNS Stimulant and ADHD/ADD Medications

- a. Reorganize the medication table to alphabetize by generic name.
- b. Add Adzenys ER, Jornay PM®, Azstarys®, Sunosi®, and Qelbree® to the medication table with the indication and dosage forms.
- c. Board Discussion
 - i. No comments

MOTION	To accept the CNS Stimulant and ADHD/ADD Medications as presented with no amendments.		
NAOTIONI DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

4. Dupixent® (dupilumab)

- a. Update the available dosage forms of Dupixent®.
- b. Update the minimum age for Dupixent® use in patients with asthma to 6 years of age.
- c. Board Discussion
 - For the atopic dermatitis criteria, include allergist and immunologist to dermatologist as the physician specialty.
 - ii. For the atopic dermatitis criteria, extend the initial length of approval to four months.

MOTION	To accept the Dupixent® (dupilumab) Criteria as presented with amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

5. **Hepatitis C**

- a. Remove the need for prior authorization in treatment naïve patients for preferred products.
- b. Board Discussion
 - i. No comments

MOTION	To accept the Hepatitis C Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

6. **Hyaluronic Acid Derivatives – Injection**

- a. Addition of Durolane®, a one-time 3 mL injection of sodium hyaluronate for osteoarthritis of the knee.
- b. Board Discussion
 - i. No comments

MOTION	To accept the Hyaluronic Acid Derivatives – Injection		
MOTION	Criteria as presented with no amendments.		
MOTION DASSED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

7. Spinraza® (nusinersen)

- a. Add that the patient has not received previous treatment of Zolgensma® or concurrent treatment with Evrysdi™.
- b. Board Discussion
 - i. No comments

MOTION	To accept the Spinraza® (nusinersen) as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

D. Review of Current Clinical Prior Authorization Criteria with No Proposed Changes

1. Pulmonary Arterial Hypertension (Phosphodiesterase Type 5) Inhibitors

- a. Board Discussion
 - i. Amend the criteria for denial "diagnosis of erectile dysfunction" to include the additional language of "without a diagnosis of pulmonary arterial hypertension."

MOTION	To accept the Pulmona (Phosphodiesterase Type presented with amendmen	5) Inhibitors C	
MOTION DASCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

2. Rho Kinase Inhibitor

- a. Board Discussion
 - i. No comment

MOTION	To accept the Rho Kin presented with no amendn		Criteria as
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

E. Proposal of New Clinical Prior Authorization Criteria

1. Aduhelm™ (aducanumab-avwa)

- a. New criteria for FDA-approved indication of Alzheimer's disease.
- b. Requires baseline testing to confirm diagnosis of mild cognitive impairment or mild Alzheimer's Disease.
- c. Requires the patient to not have had cerebrovascular, cardiovascular, or behavioral health conditions as noted in the exclusion criteria of the clinical trials.
- d. Requires prescribing in consultation with a specialist.
- e. Requires MRI monitoring at baseline, prior to the 7th and the 12th infusions.
- f. Requires dosing consistent with product labeling for initial titration and maintenance dose.
- g. Board Discussion
 - i. The criteria were determined to be too restrictive and may not allow access for eligible patients. A motion was made to table the discussion until the CMS coverage determination policy is available for consideration alongside the proposed clinical prior authorization criteria.

MOTION	To table the criteria for Aduhe Criteria until the next meeting.	elm™ (aducanumab	o-avwa)
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

2. Codeine in Pediatric Patients

- New criteria for adolescents aged 12 to 18 when codeine is prescribed for pain management based on a 2017 FDA Safety Alert.
- b. Requires the patient to not be obese and not have obstructive sleep apnea or severe lung disease due to risk of respiratory depression.
- Requires trial and failure of at least two of the following:
 Topical nonsteroidal anti-inflammatory drugs (NSAIDs), Oral NSAIDs, or acetaminophen.

d. Board Discussion

i. No comments

MOTION	To accept the criteria for Code Criteria with no amendment.	eine in Pediatric F	Patients
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

3. Convenience Kits (Rx)

- a. New criteria for copackaged kits containing at least one active ingredient when there is at least one ingredient available as a generic.
- b. Requires use with FDA-approved indication for all active ingredients.
- c. Requires trial and failure of all active ingredients or a drug shortage of separate components.
- d. May require an additional prior authorization for nonpreferred convenience kits.
- e. Board Discussion
 - i. No comments

MOTION	To accept the criteria for Convenience Kits (Rx) Criteria with no amendment.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

4. Hetlioz®/Hetlioz LQ™

- a. New criteria for Non-24 Hour Sleep-Wake Disorder in adults who are blind.
- b. New criteria for Smith-Magenis Syndrome (SMS) in patients aged 3-15 years of age (Hetlioz LQTM) or ≥ 16 years (Hetlioz[®]).
- c. Requires the prescriber be or consult with a physician who specializes in the treatment of sleep disorders.
- d. Board Discussion
 - i. No comments

MOTION	To accept the criteria for Hetlioz®/Hetlioz LQ™ Criteria with no amendment.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

5. Juxtapid® (lomitapide)

- a. New criteria for adults with Homozygous Familial Hypercholesterolemia (HoFH) who have failed, have an intolerance to, or a contraindication to a 3-month trial of a high-intensity statin and one other cholesterol-lowering agent.
- b. Requires the prescriber be or consult with a cardiologist, lipidologist, or endocrinologist.
- c. Requires the patient be enrolled in the Juxtapid REMS program.
- d. Board Discussion
 - i. No comments

MOTION	To accept the criteria for Juxtapid® (lomitapide) Criteria with no amendment.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

6. Stromectol® (ivermectin)

- a. New criteria requiring diagnosis of a parasitic infection or scabies after failure with a topical treatment.
- b. Establishes the length of therapy for 1 month with 10 tablets.
- c. The purpose is to minimize coverage of ivermectin in large doses to treat COVID-19 due to insufficient evidence.
- d. Board Discussion
 - i. No comments

MOTION	To accept the criteria for Stromectol® (ivermectin) Criteria with no amendment.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

A. Proposal of Additions to Preferred Drug List (PDL)

- 1. Weight Management Agents several drugs approved as adjunct therapy to a reduced-calorie diet and increased physical activity in patients with an initial body mass index (BMI) $30 \text{ kg/m}^2 \text{ or } \ge 27 \text{ kg/m}^2$ with other risk factors.
 - a. Board Discussion
 - i. No comments

MOTION	To accept the addition of Weight Management Agents as a		
managed class on the Preferred Drug List.			
	In favor Opposed Abstained		

MOTION	6	0	0
PASSED			

Meeting was adjourned at 4:07 PM