DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES
Hybrid: Brown Cafeteria & Zoom Conference
December 13, 2022

Members Present: Sue DeLeo, RPh; William McCormick, PharmD; Melissa Myers, MD; Kaitlyn Simoneau, PharmD

Members Absent: none

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

Agenda: Attached

2:15 PM, Ms. Clifford opened the public comment and presented the DUR policy for the public hearing.

Speaker	Company	Topic
Nirali Patel, PharmD	AbbVie	Rinvoq® and Skyrizi®
Mariola Vazquez, PharmD, CDES	Leo Pharma	Adbry™
Mary Fayazi, PhD, MPT	NS Pharma	Viltepso

Meeting called to order at 2:32 PM

I. INTRODUCTIONS AND WELCOME TO BOARD MEMBERS

II. OLD BUSINESS

a. Dr. McCormick presented the committee with the draft minutes from the June 2, 2022 meeting.
b. Board Discussion
i. No comments.

MOTION	To accept the proposed draft minutes from the June 2, 2022 DUR meeting with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	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 640 to 850 claims each month generated ProDUR messages from February 2022 to October 2022.
   b. The prospective DUR report for February 2022 to October 2022 was presented and reviewed. The top 5 encounters of the ProDUR modules were reviewed for each category:
      i. Drug-Drug Interactions
         1. Bupropion – Quetiapine
         2. Sertraline – Trazodone
         3. Oxcarbazepine – Zonisamide
         4. Gabapentin – Clonazepam
         5. Buprenorphine/Naloxone – Quetiapine
      ii. Duplicate Ingredient
         1. Dexmethylphenidate
         2. Guanfacine
         3. Olanzapine
         4. Quetiapine
         5. Sertraline
      iii. Duplicate Therapy
         1. Sertraline – Sertraline
         2. Guanfacine – Guanfacine
         3. Bupropion – Bupropion
         4. Dexmethylphenidate – Dexmethylphenidate
         5. Olanzapine – Olanzapine
      iv. Early Refill
         1. Polyethylene Glycol
         2. Gabapentin
         3. Oxcarbazepine
         4. Omeprazole
         5. Buprenorphine/Naloxone
   c. The Early Refill (ER) report from February 2022 to October 2022 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. Two utilization analysis reports were presented on data from February 2022 to October 2022. The first set of reports contained the claims for COVID vaccines and OTC Home COVID test kits. There were 29,086 total claims with an average payment per claim of $338.65.

COVID vaccines generally skew the utilization toward SSB (single source brands) while the OTC Home COVID test kits skew utilization toward MSB (multiple source brands). The second set of reports remove all COVID vaccine and OTC Home COVID test kits to focus on the trends within FFS. During February 2022 to October 2022, there were 10,607 claims with an average payment per claim of $830.12. The average generic drug rate was consistently over 85% throughout the 9 months.

4. **Retrospective DUR Reports**
   a. RetroDUR review for March 2022 to November 2022 was presented showing a total of 10 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.
   b. RetroDUR activities that occurred December 2021 to May 2022 were further summarized and presented to the DUR Board for consideration. Six months following the RetroDUR activity, the claims for impacted members were reviewed for changes to prescribing. The claim adjustments were summarized showing additional impact to patient care that may not be captured in the letter response.
5. **RetroDUR Interventions**
   a. The board reviewed the list of possible RetroDUR intervention topics for implementation beginning December 2022. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
15008	Polypharmacy	213
8046	Diabetes medications without diagnosis of diabetes or POS	8
8014	FDA Warning: Gabapentin or pregabalin and breathing problems	5
4768	Proton Pump Inhibitor duplication with H2 Receptor Antagonist	4
7729	Concomitant use of opioids and benzodiazepines	4
7946	Opioids and Gabapentin; concurrent use and utilization monitoring	3
7982	Concurrent use of opioids and antipsychotics	1

B. COVID-19 Status Update

1. 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 14,870 paid claims for COVID vaccines for Medicaid recipients from January 1, 2022 through October 31, 2022. There were 12,078 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 and vaccine administration in a provider's office are not captured in this pharmacy program summary. Over-the-Counter Home COVID test kits have been covered through the Fee-for-Service Program since January 2022. There were 8,576 claims for 61,616 test kits billed through POS between January 1, 2022 and October 31, 2022.

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

1. **Atopic Dermatitis**
   a. Change the name of the criteria to Skin Disorders Criteria.
   b. Addition of language to direct providers to appropriate criteria for additional indications for drugs covered on Skin Disorders Criteria.
   c. Update FDA-approved indication for Opzelura™ to include topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.
   d. Board Discussion
      i. No comments.

MOTION	To accept the Skin Disorders Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

2. **Bowel Disorders/GI Motility, Chronic**
   a. Removal of Zelnorm™ due to manufacturer discontinuation.
   b. Addition of Ibsrela® to the criteria for the treatment of adults with irritable bowel syndrome with constipation.
   c. Addition of language requiring additional PDL prior authorization for non-preferred drugs.
   d. Board Discussion
      i. No comments.

MOTION	To accept the Bowel Disorders/GI Motility, Chronic Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Buprenorphine/Naloxone and Buprenorphine (Oral)**
   a. Extend coverage of preferred products without a prior authorization to doses greater than 24 mg/day.

b. Extend dispensing limit to 32 mg/day.
c. Board Discussion
    i. No comments.

MOTION	To accept the Buprenorphine/Naloxone and Buprenorphine (Oral) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

4. **CNS Stimulant and ADHD/ADD Medications**
    a. Update minimum age for Evekeo® ODT and the available strengths.
    b. Board Discussion
        i. No comments.

MOTION	To accept the CNS Stimulant and ADHD/ADD medications Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

5. **Dupixent® (dupilumab)**
    a. Update 100 mg/0.67 mL dosage form to prefilled syringe.
    b. Update FDA-approved indication for Dupixent® for atopic dermatitis in children as young as 6 months of age.
    c. Update to include FDA-approved indication of eosinophilic esophagitis in patients 12 years of age and older and weighing at least 40 kg.
        i. Include requirement that prescriber is a gastroenterologist, immunologist, or allergist (or that one has been consulted).
    d. Update to include FDA-approved indication of prurigo nodularis in adults.
        i. Include requirement that prescriber is a dermatologist, immunologist, or allergist (or that one has been consulted).
    e. Board Discussion
        i. No comments.

MOTION	To accept the Dupixent (dupilumab) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

6. **Hematopoietic Agent**
    a. Update available dosage forms for Aranesp® and Epogen®.
    b. Board Discussion
        i. No comments.

MOTION	To accept the Hematopoietic Agent Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

7. **Systemic Immunomodulator**
    a. Add Olumiant® 4 mg tablet dosage form and indication for the treatment of severe alopecia areata in adults.
    b. Add Rinvoq® 45 mg tablet and indication for non-radiographic axial spondyloarthritis with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.
    c. Add Sotyktu™ (deucravacitinib) 6 mg tablet for the treatment of moderate to severe plaque psoriasis in adults.
    d. Add Spevigo® (spesolimab-sbzo) IV infusion for the treatment of generalized pustular psoriasis in adults.
    e. Add additional strengths for Skyrizi® and indication for moderately to severely active Crohn's Disease in adults.
    f. Add Xeljanz® solution to the medication table.
    g. Board Discussion
        i. No comments.

MOTION	To accept the Systemic Immunomodulator Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

8. **Weight Management**
    a. Add heading to separate adult baseline criteria for initial 6 month approval.
    b. Add heading and new criteria for pediatric assessment at baseline for initial 3 month approval.
    c. Update special approval instructions to set target weight loss at 5% reduction from baseline every 6 months for adults. This target is 4% for Saxenda®.
    d. Add special approval instructions to set target weight loss at 1% reduction from baseline every 6 months for pediatric patients.

e. Add FDA-approved indication for Imcivree™ for Bardet-Biedl Syndrome in patients 6 years of age and older.
f. Board Discussion
    i. Remove limitation for Xenical® approval for a maximum of 4 years due to limited clinical justification.

MOTION	To accept the Weight Management Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

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

1. **Allergen Extract**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Allergen Extract Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

2. **Benign Prostatic Hyperplasia (BPH) Medication**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Benign Prostatic Hyperplasia (BPH) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Duchenne Muscular Dystrophy**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Duchenne Muscular Dystrophy Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

4. **Short-Acting Fentanyl Analgesic**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Short-Acting Fentanyl Analgesic as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

5. **Spravato® (esketamine)**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Spravato® (esketamine) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

E. Proposal of Clinical Prior Authorization Criteria to Retire

1. Direct Renin Inhibitor and Combination
2. Evrysdi™ (risdiplam)
3. Spinraza® (nusinersin)
4. Zolgensma®
5. Board Discussion
    a. No comments.

MOTION	To accept the recommendation to retire the prior authorization criteria listed.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

F. Proposal of New Clinical Prior Authorization Criteria

1. **Skysona® (elivaldogene autotemcel)**
    a. Skysona® (elivaldogene autotemcel) is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active cerebral adrenoleukodystrophy refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9
    b. Requires baseline screening for hepatitis B virus, hepatitis C virus, human T-lymphotrophic virus 1 & 2 and human immunodeficiency virus 1 & 2.
    c. Requires assessment and prophylaxis against infection.

d. Requires vaccine administration holiday 6 weeks prior to and during treatment course.
e. Requires attestation of life-long monitoring for hematologic malignancies.
f. Does not allow concurrent anti-retroviral medications one month prior to stem cell mobilization through all cycles of apheresis.
g. Should not be used in patients with head trauma induced disease or to prevent or treat adrenal insufficiency.
h. Should not be used in patients with a history of hematopoietic stem cell transplant.
i. Should not be used in patients with a known or available HLA-matched family donor.
j. Approval is for a single lifetime infusion.
k. Board Discussion
    i. Insert "willing" to describe any HLA-matched family donor in the criteria.

MOTION	To accept the Skysona® (elivaldogene autotemcel) Criteria as presented with amendment.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

2. **Spinal Muscular Atrophy**
    a. New criteria to combine Evrysdi™, Spinraza®, and Zolgensma® into a single form with separation for the ongoing therapy and the single-lifetime dose.
    b. Board Discussion
        i. Renewal criteria for Evrysdi™ and Spinraza® contains an extra Quantity Limit: 1 kit and Length of Approval: 1 administration per lifetime. This additional language should be removed as it is relevant only to Zolgensma®.

MOTION	To accept the criteria for Spinal Muscular Atrophy Criteria with amendment.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Zynteglo® (betibeglogene autotemcel)**
    a. Zynteglo® (betibeglogene autotemcel) is indicated for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions.

b. Requires age and diagnosis information aligned with FDA approved indication.
c. Should not have evidence of elevated iron levels in major organs.
d. Requires baseline screening for hepatitis B virus, hepatitis C virus, human T-lymphotrophic virus 1 & 2 and human immunodeficiency virus 1 & 2.
e. Does not allow concurrent anti-retroviral medications or hydroxyurea for one month prior to stem cell mobilization through all cycles of apheresis.
f. Iron chelation therapy must be discontinued at least 7 days prior to initiating myeloablative conditioning therapy.
g. Requires a negative pregnancy test for females of reproductive potential throughout therapy
h. Requires use as monotherapy.
i. Requires attestation of life-long monitoring for hematologic malignancies.
j. Should not be used in patients with a history of hematopoietic stem cell transplant.
k. Approval is for a single lifetime infusion.
l. Board Discussion
    i. No comments

MOTION	To accept the criteria for Zynteglo® (betibeglogene autotemcel) Criteria with no amendment.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

Meeting was adjourned at 4:07 PM