DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES
Hybrid: Brown Conference Room 468 & Zoom Conference
December 8, 2023

Members Present: Sue DeLeo, RPh (virtual); Tessa Lafortune-Greenberg, MD; William McCormick, PharmD; Melissa Myers, MD; Rory Richardson, MD; Kaitlyn Simoneau, PharmD

Members Absent: none

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

Agenda: Attached

1:10 PM, Ms. Clifford opened the public comment and presented the DUR policy for the public hearing.

Speaker	Company	Topic
Paul Miner, PharmD	Asendis Pharma	Skytrofa®
Omer Aziz, PharmD	Teva	Ajovy®, Austedo®, Austedo® XR
Jigna Bhalla, PharmD	AstraZeneca	Fasenra®
Mark Golick, PharmD	Neurocrine	Ingrezza®
Tyson Thompson, PharmD, MBA	Pfizer	Nurtec™ ODT, Zavzpret™
Annie Vong, PharmD	AbbVie	Qulipta™, Ubrelvy®, Rinvoq®, Skyrizi™
Dan Basoff, PharmD	Sarepta	Elevidys
Evie Knisely, PharmD, MHA	Novartis	Cosentyx®
Corey O'Brien, PharmD, BCPS	Novo Nordisk	Ozempic®, Rybelsus®
Phil Huber		Elevidys
Nicole Trask, PharmD	J&J	Spravato®
Matthew Stryker, PharmD, BCACP	Amgen	Tezspire™
Chad Bohigian, PharmD	Amgen	PCSK9
Jessica Aviles		Elevidys

Meeting called to order at 2:06 PM

I. INTRODUCTIONS AND WELCOME TO BOARD MEMBERS

II. OLD BUSINESS

a. Dr. McCormick presented the committee with the draft minutes from the June 19, 2023 meeting.
b. Board Discussion
    i. No comments.

MOTION	To accept the proposed draft minutes from the June 19, 2023 DUR meeting with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	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 499 to 732 claims each month generated ProDUR messages from February 2023 to October 2023.
    b. The prospective DUR report for February 2023 to October 2023 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. Buprenorphine/Naloxone – Gabapentin
            3. Gabapentin – Clobazam
            4. Quetiapine – Hydroxyzine
            5. Lacosamide – Lamotrigine
        ii. Duplicate Ingredient
            1. Dextroamphetamine/Amphetamine
            2. Oxcarbazepine
            3. Dexmethylphenidate
            4. Quetiapine
            5. Guanfacine
        iii. Duplicate Therapy
            1. Guanfacine – Guanfacine
            2. Buprenorphine/Naloxone – Buprenorphine/Naloxone
            3. Oxcarbazepine – Oxcarbazepine
            4. Dexmethylphenidate – Dexmethylphenidate
            5. Quetiapine – Quetiapine
        iv. Early Refill
            1. Quetiapine
            2. Buprenorphine/Naloxone
            3. Oxcarbazepine
            4. Levothyroxine
            5. Docusate

c. The Early Refill (ER) report from February 2023 to October 2023 was reviewed with the report broken down by reason for request. The most consistent reasons for requesting early refills were Increased/Variable Dose followed by requests for 2 concurrent prescriptions of the same medication.

3. **Utilization Reports**
   a. Two utilization analysis reports were presented on data from February 2023 to October 2023. The first set of reports contained the claims for COVID vaccines and OTC Home COVID test kits. There were 14,069 total claims with an average payment per claim of $655.10. 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 2023 to October 2023, there were 9,143 claims with an average payment per claim of $906.32. The average generic drug rate was consistently over 85% throughout the 9 months.
4. **Retrospective DUR Reports**
   a. A RetroDUR review for February 2023 to November 2023 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 November 2022 to May 2023 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 2023. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
New	FDA Alert (11/28/23): DRESS in antiseizure medicines levetiracetam and clobazam	To be determined
New	Antipsychotic Medications and Mortality in Children and Young Adults (JAMA Psychiatry doi:10.1001/jamapsychiatry.2023.4573)	To be determined

15008	Polypharmacy	87
7735	Atypical antipsychotics without metabolic testing	33
7980	Member 18 or older with Stimulant type ADHD meds and no ADHD diagnosis	12
7961	Update for Prescribers: ACC/AHA Guidelines for Blood Pressure Management	22

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 2,408 paid claims for COVID vaccines for Medicaid recipients from January 1, 2023 through October 31, 2023. There were 2,268 unique Medicaid IDs with claims for at least 1 vaccine dose. Over-the-Counter Home COVID test kits have been covered through the Fee-for-Service Program since January 2022. There were 4,100 claims for 30,713 test kits billed through POS between January 1, 2023 and October 31, 2023.

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

1. **Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor**
   a. Remove redundant language in Criteria for Denial that is captured in Criteria for 12-Month Renewal regarding adherence to the regimen and tolerability.
   b. Remove active smoker from the Criteria for Denial as there is no evidence of increased risk of adverse events from smoking.
   c. Board Discussion
      i. No comments.

MOTION	To accept the Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

2. **Anti-Fungal Medication for Onychomycosis**
   a. Remove brand name Kerydin® as it is no longer available.
   b. Remove criteria for ciclopirox topical solution that required a trial and failure or contraindication for systemic therapy. This change shifts the ciclopirox to first line therapy.
   c. Board Discussion
      i. No comments.

MOTION	To accept the Anti-Fungal Medication for Onychomycosis Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

3. **Asthma/Allergy Immunomodulator**
    a. Update language for indication of Xolair® due to modifications for the identification of chronic urticaria and nasal polyps reflected in the package insert.
    b. Add the new available formulation of Tezspire™.
    c. Require an inadequate response to a first or second generation H1-antihistamine prior to use of Xolair® for chronic spontaneous urticaria.
    d. Board Discussion
        i. No comments.

MOTION	To accept the Asthma/Allergy Immunomodulator Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

4. **Calcitonin Gene-Related Peptide (CGRP) Inhibitor Criteria – Migraine and Cluster Headache**
    a. Add new drug in the class, Zavzpret™ (zavegepant) approved for the acute treatment of migraine with or without aura in adults in a nasal spray formulation.
    b. Add Zavzpret to the Migraine treatment section of the criteria with the quantity limit of 8 nasal sprays/30 days per the package insert.
    c. Add throughout that the drugs in this class are on the PDL and non-preferred drugs require additional PA.
    d. Board Discussion
        i. No comments.

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

5. **Human Growth Hormone**
    a. Add new human growth hormone analogs, Ngenla® and Sogroya®.

b. Ngenla® is indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to an inadequate secretion of endogenous growth hormone.
c. Sogroya® is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH) and replacement of endogenous GH in adults with growth hormone deficiency (GHD).
d. Remove Zorbtive® as the drug is no longer available and remove SBS or short bowel syndrome from the indication table.
e. Update the medication table to show only dosage forms and strengths that are available.
f. Add a trial and failure or intolerance to short-acting somatropin prior to use of Ngenla® and/or Sogroya® based on whether we are addressing pediatric or adult patients.
g. Update the criteria for denial to note that limitations for growth hormone therapy after epiphyses are closed should only be considered for pediatric patients.
h. Board Discussion
    i. No comments.

MOTION	To accept the Human Growth Hormone Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

6. **Methadone (Pain Management Only)**
    a. In response to FDA guidance, identify patients with severe, persistent pain as those requiring long-acting opioids.
    b. Board Discussion
        i. Update the exemption language to include pain associated with sickle cell disease.

MOTION	To accept the Methadone (Pain Management Only) Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

7. **Morphine Milligram Equivalent**
    a. Exempt patients with pain associated with cancer or sickle cell disease from prior authorization as originally intended.

b. In response to FDA guidance, identify patients with severe, persistent pain as those requiring long-acting opioids.
c. Board Discussion
    i. No comments.

MOTION	To accept the Morphine Milligram Equivalents Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

8. **Movement Disorders**
    a. Add Austedo® XR formulation to criteria.
    b. Remove step through generic tetrabenazine for Huntington's chorea as all products in class carry the indication.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Movement Disorders Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

9. **Oral Isotretinoin**
    a. Update the drugs and dosage forms that are currently available.
    b. Board Discussion
        i. No comments.

MOTION	To accept the Oral Isotretinoin Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

10. **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9)**
    a. Convert the display of approved indications from paragraph to table format.
    b. Add new drug, Leqvio®, a small interfering RNA directed to PCSK9, for use as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia who require additional LDL-C reduction.
    c. Within Repatha criteria, add the requirement for use in conjunction with maximally tolerated statin.

d. Create new criteria for Leqvio® to align with HeFH criteria for other PCSK9 drugs.
e. Board Discussion
    i. No comments.

MOTION	To accept the Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

11. **Pulmonary Arterial Hypertension**
    a. Add new drug Liqrev®, a 10 mg/mL sildenafil suspension to the criteria.
    b. Add throughout that the drugs in this class are on the PDL and non-preferred drugs require additional PA.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Pulmonary Arterial Hypertension Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

12. **Spravato®**
    a. Remove requirement of antidepressant augmentation therapy with an atypical antipsychotic, lithium, or antidepressant from a different class as one of the requirements prior to use of Spravato® due to clinical study showing non-inferiority of Spravato® with an antidepressant compared to quetiapine XR with an antidepressant.
    b. Board Discussion
        i. No comments.

MOTION	To accept the Spravato® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

13. **Synagis®**
    a. Add language that prohibits use of Synagis® in patients who have received a dose of Beyfortus™.
    b. Add language that allows access to Synagis® through the prior authorization criteria when Beyfortus™ is not available.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Synagis® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

14. **Systemic Immunomodulator**
    a. Add the adalimumab biosimilars (reference product Humira®) to the Medications and Indications tables. Those drugs include: Cyltezo®, Hadlima™, Hulio®, Hyrimoz®, Idacio®, Yuflyma®, and Yusimry™.
    b. Update the available dosage forms for Cosentyx®, Entyvio®, and Skyrizi®.
    c. Extend coverage of Enbrel® for the treatment of psoriatic arthritis to pediatric patients as young as 2 years of age.
    d. Add the approved indication for Ilaris® for the treatment of gout flares in adults in whom NSAIDs and colchicine is contraindicated, not tolerated, or do not provide response and in whom repeated corticosteroids are not appropriate.
    e. Board Discussion
        i. No comments.

MOTION	To accept the Systemic Immunomodulator Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

15. **Vuity™**
    a. Update the available dosage form for Vuity™.
    b. Board Discussion
        i. No comments.

MOTION	To accept the Vuity™ Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained

	6	0	0

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

1. **Brand Name Multiple Source Prescription Drug Product**
   a. Board Discussion
      i. No comments.

MOTION	To accept the Brand Name Multiple Source Prescription Drug Product Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

2. **Carisoprodol and Combination Medication**
   a. Board Discussion
      i. No comments.

MOTION	To accept the Carisoprodol and Combination Medication Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

3. **Hetlioz®/Hetlioz LQ™**
   a. Board Discussion
      i. No comments.

MOTION	To accept the Hetlioz®/Hetlioz LQ™ Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

4. **Horizant®**
   a. Board Discussion
      i. No comments.

MOTION	To accept the Horizant® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

5. **New Drug Product**
    a. Board Discussion
        i. No comments.

MOTION	To accept the New Drug Product Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

6. **Psychoactive Medication for Children (5 Years of Age or Younger)**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Psychoactive Medication for Children (5 Years of Age or Younger) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

7. **Psychotropic Medication Duplicate Therapy (Patients 6 Years and Older)**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Psychotropic Medication Duplicate Therapy (Patients 6 Years and Older) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

8. **Second-Line Antifungal**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Second-Line Antifungal Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

9. **Verquvo® (vericiguat)**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Verquvo® (vericiguat) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

E. Proposal of Clinical Prior Authorization Criteria to Retire

1. Duloxetine
2. Pregabalin
    a. Board Discussion
    b. No comments.

MOTION	To accept the recommendation to retire the prior authorization criteria listed.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

F. Proposal of New Clinical Prior Authorization Criteria

1. **Elevidys (delandistrogene moxeparvovec-rokl)**
    a. Elevidys (delandistrogene moxeparvovec-rokl) is indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.
    b. Requires absence of deletion in exon 8 and/or exon 9 in the DMD gene.
    c. Requires baseline monitoring for pre-existing anti-AARh74 antibodies.
    d. Requires assessment of baseline ambulation.
    e. Requires discontinuation of DMD-directed antisense oligonucleotides 30 days prior to Elevidys infusion.
    f. Requires stable corticosteroid dose prior to the start of therapy and use during treatment as noted in the package insert.
    g. Requires absence of active infection.
    h. Requires monitoring of troponin-1 levels and liver function.
    i. Requires physical and/or occupational therapy to support ambulation.
    j. Approval is for a single lifetime infusion.
    k. Board Discussion
        i. Remove the limitation for inclusion of patients with mutation in exons 18 to 58 from the criteria.
        ii. Amend the time between DMD-directed antisense oligonucleotide therapy and Elevidys to 7 days.
        iii. Remove the requirement for physical and/or occupational therapy.

MOTION	To accept the Elevidys (delandistrogene moxeparvovec-rokl) Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

2. **GLP-1 Receptor Agonist**
    a. New criteria for GLP-1 receptor agonist medications approved for treatment in patients with type 2 diabetes but may be used off-label for weight loss.
    b. Requires the diagnosis of type 2 diabetes mellitus.
    c. Requires the patient age be within the FDA-approved guidelines.
    d. Requires the medication be used as an adjunct to diet and exercise.
    e. Requires a trial of metformin or a metformin-containing product.
    f. Board Discussion
        i. Amend the prior trial to any oral antihyperglycemic.

MOTION	To accept the criteria for GLP-1 Receptor Agonist Criteria with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

3. **Roctavian™ (valoctogene roxparvovec-rvox)**
    a. Roctavian™ (valoctogene roxparvovec-rvox) is indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.
    b. Requires the patient must be on a stable dose of exogenous factor VIII.
    c. Requires absence of active infection, significant hepatic fibrosis or cirrhosis, and hypersensitivity to mannitol.
    d. Requires absence of baseline AAV antibodies and avoidance in patients who have already received adeno-associated virus-vector-based gene therapy.
    e. Requires absence of negative active factor VIII inhibitors and avoidance of a bypassing agent.
    f. Requires ongoing monitoring of liver function tests and corticosteroids use as noted in the package insert.

g. Requires absence of preexisting risk factors for hepatocellular carcinoma and ongoing monitoring when necessary.
h. Requires monitoring of factor VIII activity to determine when to discontinue prophylactic exogenous factor VIII.
i. Approval is for a single lifetime infusion.
j. Board Discussion
    i. No comments.

MOTION	To accept the Roctavian™ (valoctogene roxparvovec-rvox) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	6	0	0

Meeting was adjourned at 3:52 PM