DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES
Hybrid: Brown Conference Room 468 & Teams Webinar
May 7, 2024

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

Members Absent: Tessa Lafortune-Greenberg, MD

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

Agenda: Attached

1:26 PM, Ms. Clifford opened the public comment and presented the DUR policy for the public hearing.

Speaker	Company	Topic
Sunny Hirpara, PharmD	AstraZeneca	Fasenra®
Annie Vong, PharmD	AbbVie	Qulipta™, Ubrelvy®, Rinvoq®, Skyrizi™
Ronnie DePue, PharmD, BCGP, FASCP	Axsome	Sunosi®
Shirley Quach, PharmD	Novartis	Cosentyx®
Matthew Stryker, PharmD, BCACP	Amgen	Tezspire™
Shari Orbach, MPH	Madrigal	Rezdiffra™
Paul Isikwe, PharmD, MS	Biogen	Spinraza™, Zurzuvae™
Omer Aziz, PharmD	Teva	Ajovy®
Tyson Thompson, PharmD, MBA	Pfizer	Nurtec™ ODT, Zavzpret™
Adam Bradshaw, PharmD, MS	Vertex	Casgevy™
Rick Melbye, PharmD	UCB	Bimzelx®

Meeting called to order at 2:13 PM

I. INTRODUCTIONS AND WELCOME TO BOARD MEMBERS

II. OLD BUSINESS

a. Dr. McCormick presented the committee with the draft minutes from the December 8, 2023 meeting.

b. Board Discussion

i. No comments.

MOTION	To accept the proposed draft minutes from the December 8, 2023 DUR meeting with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	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 595 claims each month generated ProDUR messages from July 2023 to March 2024.
    b. The prospective DUR report for July 2023 to March 2024 was presented and reviewed. The top 5 encounters of the ProDUR modules were reviewed for each category:
        i. Drug-Drug Interactions
            1. Buprenorphine/Naloxone – Gabapentin
            2. Sertraline – Metoprolol
            3. Torsemide – Digoxin
            4. Trazodone – Fluoxetine
            5. Buprenorphine/Naloxone – Quetiapine
        ii. Duplicate Ingredient
            1. Dextroamphetamine/Amphetamine
            2. Buprenorphine/Naloxone
            3. Dexmethylphenidate
            4. Lamotrigine
            5. Guanfacine
        iii. Duplicate Therapy
            1. Buprenorphine/Naloxone – Buprenorphine/Naloxone
            2. Guanfacine – Guanfacine
            3. Dexmethylphenidate – Dexmethylphenidate
            4. Lamotrigine – Lamotrigine
            5. Fluoxetine – Fluoxetine
        iv. Early Refill
            1. Buprenorphine/Naloxone
            2. Gabapentin
            3. Apixaban
            4. Emicizumab-kxwh
            5. Metoprolol
    c. The Early Refill (ER) report from July 2023 to March 2024 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 due to Facility Transitions.

3. **Utilization Reports**
   a. Two utilization analysis reports were presented on data from July 2023 to March 2024. The first set of reports contained the claims for COVID vaccines and OTC Home COVID test kits. There were 12,041 total claims with an average payment per claim of $700.32. 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 July 2023 to March 2024, there were 7,797 claims with an average payment per claim of $1,008.87. Utilization and average payment per claim for SSBs increased in 2024 due to additions to the carve drug list. The average generic drug rate was consistently over 80% throughout the 9 months.
4. **Retrospective DUR Reports**
   a. A RetroDUR review for June 2023 to March 2024 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 June 2023 to October 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 June 2024. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
New	SMART Asthma: GINA guidelines and albuterol overutilization without inhaled corticosteroid (> 3 inhalers/year)	To be determined
7979	Members aged 18 and over with claims for stimulant type ADHD treatments	14
8047	Opioid prescriptions with greater than 7 days supply • Opioid naïve only	5

7942	Members with 6 or more opioid claims, with risk factors and no claims for naloxone in 180 days	2
7741	Leukotriene inhibitor without asthma diagnosis	10
6359	Benzodiazepines duplicate therapy	5

b. During the selection discussion for upcoming RetroDUR activities, the board requested an agenda addition for the next meeting to discuss a proposal for a prior authorization requirement on opioid prescriptions > 7 days in opioid naïve patients.

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 2,796 paid claims for COVID vaccines for Medicaid recipients from October 1, 2023 through March 31, 2024. There were 2,784 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 918 claims for 6,724 test kits billed through POS between October 1, 2023 through March 31, 2024.

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

1. **Asthma/Allergy Immunomodulator**
   a. Add new indication for Xolair® for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.
   b. Add new dosage form for Xolair® in 300 mg/2 mL strength.
   c. Add expanded indication for Fasenra® for add-on maintenance treatment of patients with severe asthma who are ≥ 6 years of age with an eosinophilic phenotype.
   d. Add new dosage form for Fasenra® of 10 mg/0.5 mL for pediatric dosing.
   e. Limit criteria for "Non-smoker status" to requests for asthma indications.
   f. Remove peanut allergy from criteria for denial and amend the active smoker to be an acceptable reason for denial in asthma requests.

g. Board Discussion
    i. No comments.

MOTION	To accept the Asthma/Allergy Immunomodulator Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

2. **Drugs for Bowel Disorders/GI Motility, Chronic**
    a. Add new indication for Linzess® for the treatment of functional constipation in pediatric patients 6 to 17 years of age.
    b. Remove criteria limiting approval in pediatric patients.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Drugs for Bowel Disorders/GI Motility, Chronic Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

3. **Calcitonin Gene-Related Peptide (CGRP) Inhibitor Criteria – Migraine and Cluster Headache**
    a. Add request for trial/failure of an injectable CGRP for the prevention of migraine to access Nurtec® ODT or Qulipta™.
    b. 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
	5	0	0

4. **CNS Stimulant and ADHD/ADD Medications**
    a. Add new drug in the class, Xelstrym® (dextroamphetamine) approved for treatment of ADHD in adults and pediatric patients ≥ 6 years of age.
    b. Adjust the available dosage forms and brand name drugs that are available in the class.
    c. Remove Wakix® (pitolisant) from the criteria to create separate criteria.
    d. Add Xelstrym® to the criteria that it would be approved in patients with swallowing issues.

e. Board Discussion
    i. Combine Kapyvay® and Intuniv® criteria for denial in patients with low blood pressure or low heart rate and strike line 2.

MOTION	To accept the CNS Stimulant and ADHD/ADD Medications Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

5. **Skin Disorders**
    a. Within the Systemic Therapy subsection, decrease the prior therapy steps to a topical corticosteroid and another topical preferred drug (pimecrolimus, tacrolimus, crisaborole).
    b. Add reminder language that this is a PDL class.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Skin Disorders Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

6. **Spinal Muscular Atrophy**
    a. Expand eligible diagnosis criteria for Zolgensma® to include patients with up to 4 copies of the SMN2 gene.
    b. Board Discussion
        i. No comments.

MOTION	To accept the Spinal Muscular AtrophyCriteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

7. **Systemic Immunomodulators**
    a. Add Bimzelx® (bimekizumab-bkzx) to the criteria for the treatment of moderate to severe chronic plaque psoriasis in patients ≥ 18 years of age.
    b. Add Velsipity® (etrasimod) to the criteria for the treatment of moderately to severely active ulcerative colitis in patients ≥ 18 years of age.

c. Add new indication for Cosentyx® (secukinumab) for the treatment of hidradenitis suppurativa in patients ≥ 18 years of age.
d. Add new indications for Idacio® (adalimumab-aacf) and Yusimry™ (adalimumab-aqvh) for the treatment of non-infectious intermediate, posterior, and panuveitis in patients ≥ 18 years of age.
e. Add expanded indication for Orencia® (abatacept) for the treatment of psoriatic arthritis to pediatric patients ≥ 2 years of age.
f. Add expanded indication for Spevigo® (spesolimab-sbzo) for the treatment of generalized pustular psoriasis (GPP) in patients ≥ 12 years of age and weighing at least 40 kg. New age and weight added prior to meeting.
g. Board Discussion
    i. No comments.

MOTION	To accept the Systemic Immunomodulators Criteria as presented to include the Spevigo changes.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

8. **Weight Management**
    a. Add a new table to include the indications for all drugs included in the clinical criteria.
    b. Add Zepbound® (tirzepatide) to the criteria for use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with BMI ≥ 30 kg/m^2 or adults with ≥ BMI 27 kg/m^2 in the presence of at least one weight-related comorbid condition.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Weight Management Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

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

1. **Buprenorphine/Naloxone and Buprenorphine Oral**
    a. 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
	5	0	0

2. **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
	5	0	0

3. **Hematopoietic Agents**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Hematopoietic Agents Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

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

MOTION	To accept the Short-Acting Fentanyl Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

5. **Skysona®**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Skysona® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

6. **Zynteglo®**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Zynteglo® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

E. Proposal of New Clinical Prior Authorization Criteria

1. **Casgevy™ (exagamglogene autotemcel)**
    a. Casgevy™ (exagamglogene autotemcel) is indicated for the treatment of patients 12 years of age and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises or with transfusion dependent β-thalassemia (TDT).
    b. Requires seizure prophylaxis prior to myeloablative conditioning.
    c. Requires negative screening for hepatitis B virus, hepatitis C virus, and HIV viruses prior to leukapheresis.
    d. Requires absence of dimethyl sulfoxide (DMSO) or dextran 40.
    e. Requires absence of prior gene therapy.
    f. Requires discontinuation of iron chelators and disease-modifying drugs.
    g. Requires patient would be eligible for autologous hematopoietic stem cell transplant and that patient does not have a 10/10 HLA matched, willing donor.
    h. Requires avoidance of live vaccines.
    i. SCD only: Requires diagnosis of sickle cell disease with at least 2 vaso-occlusive events/crises in the last year.
    j. SCD only: Requires patient to have symptoms while on hydroxyurea and add-on therapy.
    k. SCD only: Transfusion requirements align with package insert.
    l. SCD only: Requires avoidance of granulocyte-colony stimulating factor.
    m. TDT only: Requires diagnosis of β-thalassemia in patients who are transfusion dependent.
    n. TDT only: Transfusion requirements align with package insert.
    o. TDT only: Requires avoidance of several cardiac and hepatic comorbidities.
    p. Approval is for a single lifetime infusion.
    q. Board Discussion
        i. Request clarification on the use of hydroxyurea with an additional therapy (e.g. crizanlizumab, voxelotor). DUR Board would like a presentation of the data related to hydroxyurea with add-on therapy related to vaso-occlusive events during next DUR meeting.

MOTION	To accept the Casgevy™ (exagamglogene autotemcel) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	5	0	0

2. **Lyfgenia® (lovotibeglogene autotemcel)**
   a. Lyfgenia® (lovotibeglogene autotemcel) is indicated for the treatment of patients 12 years of age and older with sickle cell disease and a history of vaso-occlusive events.
   b. Requires diagnosis of sickle cell disease with at least 2 vaso-occlusive events/crises in the last year.
   c. Requires patient to have symptoms while on hydroxyurea and add-on therapy.
   d. Requires absence of >2 α-globin gene deletions.
   e. Requires seizure prophylaxis prior to myeloablative conditioning.
   f. Requires negative screening for hepatitis B virus, hepatitis C virus, and HIV viruses prior to leukapheresis.
   g. Requires absence of dimethyl sulfoxide (DMSO) or dextran 40.
   h. Requires absence of prior gene therapy.
   i. Requires discontinuation of iron chelators and disease-modifying drugs.
   j. Requires patient would be eligible for autologous hematopoietic stem cell transplant and that patient does not have a 10/10 HLA matched, willing donor.
   k. Requires avoidance of live vaccines.
   l. Requires monitoring for hematologic malignancies periodically after treatment.
   m. Approval is for a single lifetime infusion.
   n. Board Discussion
      i. Request clarification on the use of hydroxyurea with an additional therapy (e.g. crizanlizumab, voxelotor). DUR Board would like a presentation of the data related to hydroxyurea with add-on therapy related to vaso-occlusive events during next DUR meeting.

MOTION	To accept the criteria for Lyfgenia® (lovotibeglogene autotemcel) Criteria with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Lenmeldy™ (atidarsagene autotemcel)**
    a. Lenmeldy™ (atidarsagene autotemcel) is indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).
    b. Requires use as a single agent.
    c. Requires absence of history of allogeneic stem cell transplant or duration of time since allogeneic stem cell transplant that residual donor cells are absent.
    d. Requires absence of prior gene therapy.
    e. Requires negative screening for hepatitis B virus, hepatitis C virus, and HIV viruses prior to leukapheresis.
    f. Requires mobilization of stem cells, myeloablative conditioning, and infection prophylaxis during therapy.
    g. Requires monitoring for hematologic malignancies periodically after treatment.
    h. Requires patient would be eligible for autologous hematopoietic stem cell transplant and that patient does not have a 10/10 HLA matched, willing donor.
    i. Requires avoidance of live vaccines.
    j. Requires negative pregnancy testing for females of childbearing potential.
    k. Approval is for a single lifetime infusion.
    l. Board Discussion
        i. No comments.

MOTION	To accept the Lenmeldy™ (atidarsagene autotemcel) Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

4. **Rezdiffra® (resmetirom)**
    a. Rezdiffra® (resmetirom) is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).
    b. Requires prescriber consult with or practice as a gastroenterologist or hepatologist.
    c. Requires diagnosis of noncirrhotic nonalcoholic steatohepatitis with advanced liver disease using one of several tests to determine severity.
    d. Requires magnetic resonance imaging (MRI) with proton density fat fraction ≥ 8% liver fat.
    e. Requires hemoglobin A1C < 9%.

f. Requires treatment with a statin unless the patient is unable to take one.
g. Requires lifestyle modifications (e.g., diet and exercise).
h. Requires absence of several comorbid conditions and history including significant alcohol consumption, hepatocellular carcinoma, uncontrolled hypertension, other liver disease, model for end-stage liver disease score ≥ 12, and history of bariatric surgery in past 5 years.
i. Requires absence of strong drug interactions.
j. Board Discussion
    i. Recommend removal hemoglobin A1C < 9% require due to challenges achieving that goal for many patients that may not exempt the patient from needing access to Rezdiffra®.
    ii. Recommend removal of uncontrolled hypertension from the comorbidities as it is not directly related to the disease state in treatment.
    iii. Recommend adjusting the timeline for exclusion post-bariatric surgery to 1 year from 5 years.

MOTION	To accept the Rezdiffra® (resmetirom) Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

5. **Wakix® (pitolisant)**
    a. Wakix® (pitolisant) is indicated for the treatment of excessive daytime sleepiness in adults with narcolepsy.
    b. Requires prescriber consult with or practice as a sleep specialist or neurologist.
    c. Requires documented sleep testing confirming excessive daytime sleepiness associated with narcolepsy.
    d. Requires daily periods of excessive daytime sleepiness for at least 3 months.
    e. Requires at least a 30-day trial of a CNS stimulant or has contraindications for use.
    f. Requires at least a 30-day trial of a CNS wakefulness drug or has contraindications for use.
    g. Requires sleep logs for the previous 30 days.
    h. Requires absence of history or risks of prolonged QT interval.
    i. Requires avoidance with sedative hypnotic agents.
    j. Board Discussion
        i. No comments

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

6. **Zurzuvae™ (zuranolone)**
    a. Zurzuvae™ (zuranolone) is indicated for the treatment of postpartum depression in adults.
    b. Requires prescriber consult with or practice as a psychiatrist or obstetrician/gynecologist.
    c. Requires onset of postpartum depression symptoms during the third trimester of pregnancy (week 27 of pregnancy) up to four weeks after delivery.
    d. Requires time since delivery ≤ 6 months on the date of the medication request and is using effective contraception.
    e. Requires avoidance of providing breast milk from prior to the first dose to 7 days after the last dose of the medication.
    f. Requires patient counseling related to sedation risks and administration with food.
    g. Requires stable treatment with a different antidepressant if relevant.
    h. Requires avoidance of severe drug interaction and dose adjustment if needed.
    i. Requires assessment of renal and hepatic function and dose adjustment if needed.
    j. Board Discussion
        i. Recommend expanding the time to onset of postpartum depression up to 1 year after delivery.
        ii. Recommend expanding the time since delivery to the request for the medication to ≤ 12 months.
        iii. Recommend removal of language that patient is using effective contraception and substitute that the patient has received counseling concerning potential risk of fetal harm.

MOTION	To accept the Zurzuvae™ (zuranolone) Criteria as presented with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

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

1. Duchenne Muscular Dystrophy
    a. These products are indicated for the treatment of patients with Duchenne Muscular Dystrophy and meet various criteria

for one-time gene therapy or ongoing maintenance treatment.

2. Sickle Cell Gene Therapy
    a. These products are gene therapies that are indicated for the treatment of sickle cell disease with vaso-occlusive crises or vaso-occlusive events.
3. Spinal Muscular Atrophy
    a. These products are all indicated for the treatment of spinal muscular atrophy in one-time gene therapy or in ongoing maintenance therapy.

MOTION	To accept the addition of Duchenne Muscular Dystrophy, Sickle Cell Gene Therapy, and Spinal Muscular Atrophy Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

Meeting was adjourned at 4:17 PM