DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES
Hybrid: Brown Conference Room 468 & Teams Webinar
October 15, 2024

Members Present: Tessa Lafortune-Greenberg, MD; William McCormick, PharmD; Melissa Myers, MD; Kaitlyn Simoneau, PharmD

Members Absent: Sue DeLeo, RPh; Rory Richardson, MD

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

Agenda: Attached

1:55 PM, Ms. Clifford opened the public comment and presented the DUR policy for the public hearing.

Speaker	Company	Topic
Omer Aziz, PharmD	Teva	Ajovy®, Austedo® XR
Patrick Moeschen	Parent Project Muscular Dystrophy	Elevidys
Mark Golick, PharmD	Neurocrine Biosciences	Ingrezza® Sprinkle
Kristin Duffey, PharmD	Novartis	Cosentyx®
Brian Denger	Parent Project Muscular Dystrophy	Elevidys
Dominic Marchese, PharmD	Krystal Biotech	Vyjuvek®
Nicole Trask, PharmD	J&J	Tremfya®
Tyson Thompson, PharmD, MBA	Pfizer	Nurtec™ ODT, Zavzpret™
Alain Nguyen, PharmD	Gilead	Livdelzi®
Rick Melbye, PharmD	UCB	Bimzelx®

Meeting called to order at 2:35 PM

I. INTRODUCTIONS AND WELCOME TO BOARD MEMBERS

II. OLD BUSINESS

A. Dr. McCormick presented the committee with the draft minutes from the May 7, 2024 meeting.

1. Board Discussion
   No comments.

MOTION	To accept the proposed draft minutes from the May 7, 2024 DUR meeting with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

B. Sickle Cell Gene Therapy Criteria-Prior therapy Data.

1. Clinical trial endpoints and FDA approved indications were reviewed concerning the May approval for prior therapy requirements present in Casgevy™ and Lyfgenia® criteria. Hydroxyurea remains the standard first-line therapy. Oxbryta® was removed from the market in September 2024. Adakveo® is also indicated for the reduction of vaso-occlusive crises. The criteria was recommended to be amended to read "Patient has symptomatic disease despite treatment with hydroxyurea or add-on therapy (e.g., crizanlizumab)."

2. Board Discussion

No comments.

MOTION	To accept the Casgevy™ and Lyfgenia® Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

C. Opioid Naïve Quantity Limit.

1. Following a RetroDUR activity to letter prescribers of greater than 7 days supplies of opioids to opioid naïve members, the DUR board reviewed a plan to recommend prior authorization for new opioid prescriptions in opioid naïve members.

2. Board Discussion

No comments.

MOTION	To recommend a 7-day supply quantity limit on all opioid claims in opioid naïve members 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 446 to 595 claims each month generated ProDUR messages from December 2023 to August 2024.
    b. The prospective DUR report for December 2023 to August 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. Lamotrigine – Lacosamide
4. Diazepam – Gabapentin
5. Trazodone – Quetiapine

ii. Duplicate Ingredient
1. Lamotrigine
2. Dexmethylphenidate
3. Rufinamide
4. Factor IX Recom, Albumin Fusion
5. Antihemophilic Factor, Human/VWF, Human

iii. Duplicate Therapy
1. Lamotrigine – Lamotrigine
2. Rufinamide – Rufinamide
3. Dexmethylphenidate – Dexmethylphenidate
4. Fluoxetine – Fluoxetine
5. Antihemophilic Factor/VWF – AHF, Human/VWF, Human

iv. Early Refill
1. Buspirone
2. Gabapentin
3. Buprenorphine/Naloxone
4. Rufinamide
5. Polyethylene Glycol 3350

c. The Early Refill (ER) report from December 2023 to August 2024 was reviewed with the report broken down by reason for request. The most consistent reasons for requesting early refills were Facility Transitions followed by requests due to Increased/Variable dose.

3. **Utilization Reports**
   a. Two utilization analysis reports were presented on data from December 2023 to August 2024. The first set of reports contained the claims for COVID vaccines and OTC Home COVID test kits. There were 9,747 total claims with a total payment of $11,647,061.61. 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 December 2023 to August 2024, there were 7,507 claims with a total payment of $11,362,947.15. 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 December 2023 to August 2024 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.

b. RetroDUR activities that occurred November 2023 to March 2024 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 November 2024. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
8026	Diabetes medication claims with no claims for Blood Glucose Monitoring supplies • Exclude metformin	23
7734	Diabetics without an ACEI or ARB in history	16
15044	Buprenorphine Dental Warning	30
7892	Non-compliance with non-Coumadin anticoagulants	3
8087	Buprenorphine adherence – 10 day gap	1
7910	Diabetics ages 40-75 with no statins	1
7879	Non-compliance with anticonvulsant medications	5
7548	Medications that increase the risk of falls in the elderly	3

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 1,596 paid claims for COVID vaccines for Medicaid recipients from January 1, 2024 through August 31, 2024. Over-the-Counter Home COVID test kits have been covered through the Fee-for-Service Program since January 2022. There were 669 claims for 6,072 test kits billed through POS between January 1, 2024 through August 31, 2024.
2. As of October 1, 2024, COVID vaccines and test kits are covered by the MCO or FFS depending on the members eligibility. Reimbursement for COVID vaccines was updated to follow standard payment methodology. COVID test kits have a limitation of 4 kits/claim and 8 kits/30 days for FFS.
3. COVID will no longer be presented as a separate discussion topic for DUR Board meetings.

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

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

a. Remove the requirement for prior therapy of any of the following medications for migraine prevention: antidepressants, beta blockers, anti-epileptics, angiotensin converting enzyme inhibitors/angiotensin II receptor blockers.
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
	4	0	0

2. Convenience Kits

a. Remove Naprotin™ and Sumadan XLT® from the criteria as these drugs are no longer available.
b. Board Discussion
    i. No comments.

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

3. Dupixent®

a. Expand coverage for use as add-on maintenance treatment in patients with inadequately controlled chronic rhinosinusitis with nasal polyposis in pediatric patients 12 years of age and older.
b. Expand coverage for use in eosinophilic esophagitis in pediatric patients 1 year of age and older and weighing at least 15 kg.
c. Add new criteria subsection aligned with new indication as add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
    i. Requires provider specialty of pulmonologist or use in consultation with one.
    ii. Requires GOLD 2 or 3 classification of COPD characterized by FEV-1% between 30% - 70%).

iii. Requires a blood eosinophil count ≥ 300 cells/µL in the past 12 months.
iv. Requires LAMA/LABA/ICS therapy (or LAMA/LABA if ICS is contraindicated).
v. Requires 1 severe exacerbation (hospitalization or ER visit) or 2 moderate exacerbations (oral corticosteroids or antibiotics) in the past 12 months.

d. Board Discussion
   i. No comments.

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

4. **Elevidys**
   a. Add indication for the treatment of non-ambulatory patients aged 4 years and older with Duchenne Muscular Dystrophy (DMD) and a confirmed mutation in the DMD gene.
   b. Adjust the approved age for use to ≥ 4 years of age.
   c. Remove the ambulatory requirement determined by the North Star Ambulatory Assessment scale.
   d. Board Discussion
      i. No comments.

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

5. **Juxtapid®**
   a. Remove discontinued strengths of this medication.
   b. Board Discussion
      i. No comments.

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

6. **Long-Acting Opioid Analgesics**
   a. Remove discontinued strengths and brands of medications in this class.
   b. Board Discussion
      i. No comments.

MOTION	To accept the Long-Acting Opioid Analgesics Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

7. **Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease**
    a. Add Kisunla™ (donanemab-azbt) to the criteria for the treatment of Alzheimer's disease.
    b. Update the criteria to include the MRI monitoring and maintenance dosing recommendations for Kisunla™.
    c. Board Discussion
        i. No comments.

MOTION	To accept the Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

8. **Movement Disorders**
    a. Add new strengths for Austedo® XR.
    b. Add Ingrezza® Sprinkle to the criteria for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.
    c. Board Discussion
        i. No comments.

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

9. **Skin Disorders**
    a. Add Zoryve® 0.15% cream for the topical treatment of mild to moderate atopic dermatitis in patients 6 years of age and older.
    b. Remove discontinued brand drugs and add strengths of listed drugs.
    c. Update the topical treatment criteria to include Zoryve® 0.15% cream as a second-line option for atopic dermatitis.
    d. Update the systemic treatment criteria to cover patients 12 years of age and older for all drugs in the subclass.

e. Remove the criteria that treatment is limited to 6 weeks of therapy for non-continuous intermittent therapy up to 1 year for topical and systemic treatment.
f. 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

10. **Systemic Immunomodulators**
    a. Add Omvoh™ (mirikizumab-mrkz) to the criteria for the treatment of moderately to severely active ulcerative colitis in adults.
    b. Add Rinvoq® LQ (upadacitinib) to the criteria for the treatment of psoriatic arthritis in patients ≥ 2 years of age and pediatric juvenile idiopathic arthritis in patients ≥ 2 years of age.
    c. Add Simlandi®, a new biosimilar to Humira®.
    d. Add Tofidence™ and Tyenne®, new biosimilars of Actemra®.
    e. Add Zymfentra™, a new biosimilar to Remicade®.
    f. Add new indication for Kevzara® for the treatment of pediatric juvenile idiopathic arthritis in patients weighing at least 63kg.
    g. Expand the indication for Otezla® for the treatment of plaque psoriasis in patients ≥ 6 years of age and weighing ≥ 20 kg.
    h. Expand the indication of Rinvoq® for the treatment of psoriatic arthritis in patients ≥ 2 years of age.
    i. Add new indication for Skyrizi® for the treatment of moderately to severely active ulcerative colitis in adults.
    j. Add new indications for Bimzelx® for the treatment of adults with psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondylarthritis.
    k. Add new indication for Cimzia® for the treatment of polyarticular juvenile idiopathic arthritis in patients ≥ 2 years of age.
    l. Add new indication for Tremfya® for the treatment of moderately to severely active ulcerative colitis in adults.
    m. Board Discussion
        i. No comments.

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

11. **Topical Retinoids**
    a. Remove discontinued brands of medications in these criteria.
    b. Board Discussion
        i. No comments.

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

12. **Wakix®**
    a. Expand the indication for Wakix® for the treatment of excessive daytime sleepiness in adults and pediatric patients ≥ 6 years of age with narcolepsy.
    b. Board Discussion
        i. No comments.

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

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

1. **Benign Prostatic Hyperplasia**
    a. Board Discussion
        i. No comments.

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

2. **Codeine for Pediatric Use**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Codeine for Pediatric Use Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Hepatitis C**
    a. Board Discussion
        i. No comments.

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

4. **Hyaluronic Acid Derivatives**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Hyaluronic Acid Derivatives Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

5. **Rho Kinase Inhibitor**
    a. Board Discussion
        i. No comments.

MOTION	To accept the Rho Kinase Inhibitor Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

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

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

E. Proposal of Criteria to Retire

1. **Hemgenix®**
    a. Board Discussion
        i. No comments.

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

F. Proposal of New Clinical Prior Authorization Criteria

1. **Cholestatic Pruritus**
    a. Criteria is specific to drugs Bylvay® (odevixibat) and Livmarli® (maralixibat) for the treatment of cholestatic pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) or Alagille syndrome (ALGS).
    b. Requires diagnosis of PFIC type 1 or 2 confirmed by a genetic test.
        i. Requires age of patient to align with label.
        ii. Requires prescriber specialty of gastroenterology, hepatology, dermatology or use in consultation with one.
        iii. Requires elevated serum bile acid.
        iv. Requires persistent moderate to severe pruritic.
        v. Requires attestation that the benefit outweighs the risks when used in patients with noted warnings and precautions.
        vi. Requires prior therapy with at least one pruritic treatment.
    c. Requires diagnosis of Alagille syndrome.
        i. Requires age of patient to align with label.
        ii. Requires prescriber specialty of gastroenterology, hepatology, dermatology or use in consultation with one.
        iii. Requires evidence of cholestasis with laboratory abnormalities.
        iv. Requires persistent moderate to severe pruritic.
        v. Requires attestation that the benefit outweighs the risks when used in patients with noted warnings and precautions.
        vi. Requires prior therapy with at least one pruritic treatment.
    d. Board Discussion
        i. The concern over requiring prior therapy with at least one pruritic treatment that is not indicated for cholestatic pruritus was discussed. Since the options listed do not require any prior authorization, it was agreed that including the step is acceptable.

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

2. **Epidermolysis Bullosa**
    a. Criteria is specific to drugs Filsuvez® (birch triterpenes) and Vyjuvek® (beremagene geperpavec-svdt) for the treatment of specific types of epidermolysis bullosa in patients 6 months of age and older.
    b. Requires prescriber specialty of dermatology or genetics or use in consultation with one.
    c. Filsuvez® use requires diagnosis of dystrophic or junctional epidermolysis bullosa confirmed with laboratory testing or genetic testing.
    d. Filsuvez® use requires absence of current or history of squamous cell carcinoma in the area of treatment.
    e. Filsuvez® use requires absence of active infection in the area of treatment.
    f. Vyjuvek® use requires diagnosis with dystrophic epidermolysis bullosa with a mutation in the COL7A1 gene.
    g. Vyjuvek® use requires absence of skin grafting in the 3 months prior to treatment.
    h. Vyjuvek® use requires that the cutaneous wounds are clean with adequate granulation tissue, excellent vascularization, and are not infected.
    i. Board Discussion
        i. The proposed initial approval period is 4 months. The board requested an extension of the initial approval period to 6 months in line with the clinical trial endpoint.

MOTION	To accept the criteria for Epidermolysis Bullosa Criteria with amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

3. **Hemophilia B Gene Therapy**
    a. Hemgenix® (etranacogene dezaparvovec-drlb) is indicated for treatment of adults with hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes. Beqvez™ (fidanacogene elaparvovec-dzkt) is indicated for treatment with moderate to severe hemophilia B (congenital factor IX deficiency) who currently use factor IX

prophylaxis therapy, or have current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes and do not have neutralizing antibodies to adeno-associated virus serotype Rh74var capsid as detected by an FDA-approved test.

b. Requires management by a hemophilia treatment center.
c. Requires negative factor IX inhibitor titers at baseline and periodically after treatment.
d. Requires liver function monitoring at baseline and periodically after treatment.
e. Requires abdominal ultrasounds and alpha-fetoprotein monitoring in select patients with pre-existing risk factors.
f. Approval is for a single lifetime infusion.
g. Board Discussion
    i. No comments.

MOTION	To accept the Hemophilia B Gene Therapy Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

4. **Primary Biliary Cholangitis**
    a. The medications in the criteria are for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) who have had an inadequate response to UDCA monotherapy or are unable to tolerate. The medications are: Iqirvo® (elafibranor), Livdelzi® (seladelapar), and Ocaliva® (obeticholic acid).
    b. Requires the patient to be ≥ 18 years of age.
    c. Requires prescriber consult with or practice as a gastroenterologist or hepatologist.
    d. Requires confirmation of PBC with at least 2 laboratory assessments.
    e. Requires baseline alkaline phosphatase and total bilirubin levels.
    f. Requires prior treatment with UDCA monotherapy for 1 year or intolerance, hypersensitivity, or contraindication to UDCA.
    g. Requires absence of decompensated cirrhosis and complete biliary obstruction.
    h. Requires attestation of monitoring of potential adverse reactions to drug therapy.
    i. Ocaliva® was reviewed by the FDA Advisory Committee on September 13, 2024 and it was voted that Ocaliva® did not have a favorable benefit-risk profile for the indicated patient population. Ocaliva® was to be considered by the FDA on October 15. If Ocaliva® is discontinued before the criteria is finalized, Ocaliva® is acceptable to be removed from the criteria.

j. Board Discussion
    i. No comments.

MOTION	To accept the Primary Biliary Cholangitis Criteria as presented with no amendments.		
MOTION PASSED	In favor	Opposed	Abstained
	4	0	0

Meeting was adjourned at 3:50 PM