DRUG UTILIZATION REVIEW (DUR) BOARD MEETING MINUTES

Hybrid: Brown Conference Room 468 & Teams Webinar

April 8, 2025

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

Members Absent: none

Presenters and Professional Staff: Margaret Clifford, RPh; Lise Farrand, RPh; Honesty Peltier, PharmD, Clinical Manager, 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
Carla McSpadden	Galderma	Nemluvio™
Domenic Mantella, PharmD, MBA	Ascendis	Skytrofa™
Lauren Warn, MSN, APRN-FPA	PTC Therapeutics	Kebilidi™
Annie Vong, PharmD	AbbVie	Skyrizi [®] , Rinvoq [®]
Gustavo Rodriguez, PharmD	Pfizer	Ngenla®
James Scanlon, PharmD	Pfizer	Paxlovid™
Elena Fernandez, PharmD, PhD	Vertex	Journavx™
Beth Zanrucha, PharmD	IntraBio	Aqneursa™
Elly Fatehi, PharmD, MPH	J&J	Tremfya [®] , Spravato [®]
Uche Ndefo, PharmD	UCB	Bimzelx [®]
Shirley Quach, PharmD	Novartis	Leqvio [®]

Meeting called to order at 1:53 PM

I. <u>INTRODUCTIONS AND WELCOME TO BOARD MEMBERS</u>

II. OLD BUSINESS

A. Dr. McCormick presented the committee with the draft minutes from the October 15, 2024 meeting.

1. Board Discussion No comments.

MOTION	To accept the proposed draft minutes from the October 15, 2024 DUR meeting with no amendments.		
MOTION PASSED In favor Opposed A			
MOTION 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 344 to 496 claims each month generated ProDUR messages from May 2024 to January 2025.
- b. The prospective DUR report for May 2024 to January 2025 was presented and reviewed. The top 5 encounters of the ProDUR modules were reviewed for each category:
 - i. Drug-Drug Interactions
 - 1. Gabapentin Diazepam
 - 2. Potassium Chloride Amitriptyline
 - 3. Lamotrigine Lacosamide
 - 4. Trazodone Quetiapine
 - 5. Buprenorphine/Naloxone Gabapentin
 - ii. Duplicate Ingredient
 - 1. Dexmethylphenidate
 - 2. Lamotrigine
 - 3. Rufinamide
 - 4. Levetiracetam
 - 5. Quetiapine
 - iii. Duplicate Therapy
 - 1. Dexmethylphenidate Dexmethylphenidate
 - 2. Lamotrigine Lamotrigine
 - 3. Rufinamide Rufinamide
 - 4. Brivaracetam Rufinamide
 - 5. Polyethylene Glycol 3350 Sennosides
 - iv. Early Refill
 - 1. Gabapentin
 - 2. Famotidine
 - 3. Mirtazapine
 - 4. Rufinamide
 - 5. Polyethylene Glycol 3350
- c. The Early Refill (ER) report from May 2024 to January 2025 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 vacation supply.

3. Utilization Reports

a. The utilization analysis report presented on pharmacy claims data from May 2024 to January 2025. There were 8,432 total claims with a total payment of \$6,306,123.29. There were changes to the pharmacy benefit during the time frame we are reviewing that impacted all measures we represent in this table. On September 1, 2024, all carved out medications were shifted back to the MCOs for claims adjudication resulting in a decrease in the total payment amount. Claim counts remained high in September 2024 due to the claim volume from COVID vaccines and test kits that remained carved out of MCO coverage until October 2024. During the most recent 4 months of utilization, SSB claims accounted for less than 5-8% of claim volume and approximately 50% of total expenditure. MSB claims accounted for 3-7% of claims. The majority of claims were for generic drugs remaining above 85% in recent months with an average payment per claim at approximately \$20.

4. Retrospective DUR Reports

- a. A RetroDUR review for May 2024 to February 2025 was presented showing a total of 11 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 March 2024 to September 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 May 2025. The board decided on the following interventions:

Summary Criteria ID	Criteria Desc	Estimated # of Exceptions
15040	Patients with claims for one or more antipsychotic in the last 90 days	34
	and no claims for metabolic testing in the last 180 days	
15045	Polypharmacy – min 2 prescribers, 2 pharmacies, 6 drugs	5
8061	Use of semaglutide diabetes agents without a diagnosis of diabetes in	3
	history	
7842	Brexpiprazole: use with caution with strong CYP2D6 inhibitors	1
New	Consistent use of 2 or more antipsychotics in adults	
New	Long term use (> 2 months) of PPIs	

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

1. Adenosine Triphosphate-Citrate Lyase

- a. Remove the requirement for co-administration of a statin when a physician attests that the patient is unable to tolerate a statin.
- b. Board Discussion
 - i. No comments.

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

2. **GLP-1 Receptor Agonist**

- a. Update on the approved indication for Byetta®.
- b. Board Discussion
 - i. No comments.

MOTION	To accept the GLP-1 Receptor Agonist Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

3. Human Growth Hormone

- a. Removal of Saizen® due to discontinuation.
- b. Removal of unapproved indication for Humatrope[®].
- c. Serostim® criteria removed from the main portion of the criteria due to differences in prior therapy and indication for use.
- d. Board Discussion
 - i. No comments.

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

4. Proprotein Convertase Subtilisin/Kexin Type 9 (PCKS9)

- a. Update the indication for Leqvio® for use with a statin.
- b. Update the Praluent® indications to include use as an adjuncti to diet and other LDL-C lowering therapies in pediatric patients ≥ 8 years of age with HeFH.

- c. Remove the discontinued syringe form of Praluent®.
- d. Modify the criteria to organize by adults and pediatric patients rather than the drugs included in the criteria.
- e. Remove the requirement for a specialist for lipid management due to expanded indications.
- f. Reduce the documentation necessary to identify the diagnosis for treatment.
- g. Remove the requirement for statin coadministration in cases where the patients has documented intolerance.
- h. Board Discussion
 - Adjust the requirement to communicate patient intolerance to a statin from documentation to a prescriber attestation.

MOTION	To accept the Proprotein Convertase Subtilisin/Kexin Type 9 (PCKS9) Criteria as presented with amendments.		
MOTIONI DACCED	In favor Opposed Abstained		
MOTION PASSED	6	0	0

5. **Pulmonary Arterial Hypertension**

- a. Adjust the title to reflect the inclusion of combination drugs.
- b. Add Opsynvi® (tadalafil/macitentan) for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II–III).
- c. Add requirement for justification of combination drug.
- d. Update the criteria for denial to clarify the drug interactions to avoid.
- e. Board Discussion
 - i. No comments.

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

6. Skin Disorders

- a. Update the presentation of indications for the drugs into a table.
- b. Add Ebglyss™ to the criteria for the treatment of moderate-to-severe atopic dermatitis in adult and pediatric patients 12 years of age and older who weigh at least 40 kg whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- c. Add Nemluvio[™] to the criteria for the treatment of moderate-tosevere atopic dermatitis in adult and pediatric patients 12 years of age and older in combination with topical corticosteroids and/or

- calcineurin inhibitors whose disease is not adequately controlled with topical prescription therapies and for the treatment of adults with prurigo nodularis.
- d. For systemic therapy, add the requirement for Nemluvio[™] to be used in combination with a topical therapy.
- e. Add the criteria for prurigo nodularis for Nemluvio™ to the "Other Indications" portion of the criteria and allow expanded specialist providers to prescriber or consult.
- f. Board Discussion
 - i. No comments.

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

7. Spravato®

- a. Update the presentation of indications for the drugs into a bulleted list.
- b. Update the indication for use in treatment resistant depression to include use as monotherapy.
- c. Board Discussion
 - i. No comments.

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

8. Systemic Immunomodulators

- a. Add Abrilada™ to the criteria with indications aligning with other adalimumab-containing formulations.
- b. Add Litfulo™ for the treatment of severe alopecia areata in patients ≥ 12 years of age.
- c. Add Steqeyma®, Wezlana™, and Yesintek™ with indications aligning with other ustekinumab-containing formulations.
- d. Adjust the available strengths and formulations for all drugs.
- e. Add the new indication for Actemra® for the treatment of cytokine release syndrome in patients ≥ 2 years of age receiving CAR-T cell therapy.
- f. Add the new indication for Amjevita[™] for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
- g. Add the new indication for Bimzelx® for the treatment of hidradenitis suppurativa in adults.

- h. Add the new indication for Omvoh™ for the treatment of moderately to severely active Crohn's disease in adults.
- i. Add the new indication for Rinvoq® for the treatment of ankylosing spondylitis in adults.
- j. Add the expanded indication for Stelara® for the treatment of psoriatic arthritis in patients ≥ 6 years of age.

k. Board Discussion

- i. Include new indication verbally presented for Tremfya® for the treatment of moderately to severely active Crohn's disease in adults.
- ii. Include new indications verbally presented for Tyenne® for the treatment of cytokine release syndrome in patients ≥ 2 years of age receiving CAR-T cell therapy and for the treatment of Hospitalized patients ≥ 18 years of age with COVID-19 who are receiving systemic corticosteroids and who require ventilation assistance.
- iii. Update the specialist requirement to include "or in consultation with".

MOTION	To accept the Systemic Immunomodulators Criteria as presented with amendments.		
MOTION DASCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

9. Weight Management

- a. Remove discontinued brand drug, Contrave®.
- b. Updating the indications for Zepbound™ to include moderate to severe obstructive sleep apnea and obesity.
- c. Add criteria for denial to include using more than one drug within this class as an acceptable reason for denial.
- d. Add the expanded indication for use of Imcivree^{\mathbf{M}} in patients \geq 2 years of age.
- e. Board Discussion
 - i. Update the age for ImcivreeTM in the indication table to align with the ≥ 2 year old expanded indication noted in the criteria.

MOTION	To accept the Weight Management Criteria as presented with amendments.		
In favor		Opposed	Abstained
MOTION PASSED	6	0	0

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

1. Brand Name Multisource Drug

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Brand Name Multisource Drug Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

2. Buprenorphine-Naloxone and Buprenorphine (Oral)

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Bupre Buprenorphine (Oral) Crite amendments.	•	
MOTION PASSED	In favor	Opposed	Abstained
IVIOTION PASSED	6	0	0

3. Carisoprodol and Combination

- a. Board Discussion
 - i. No comments.

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

4. Hetlioz®/Hetlioz LQ™

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Hetlioz®, presented with no amendn		Criteria as
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

5. Methadone (Pain Management Only)

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Methadone (Pain Management Only) Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

6. Morphine Milligram Equivalent (MME)

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Morphine Milligram Equivalent (MME) Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

7. New Drug Product

- a. Board Discussion
 - i. No comments.

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

8. Oral Isotretinoin

- a. Board Discussion
 - i. No comments.

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

9. Psychoactive Medications for Children under 5

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Psychoactive Medications for Children under 5 Criteria as presented with no amendments.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

10. Psychotropic Medications – Duplicate Therapy for Pediatric Patients 6 and above

a. Board Discussion

i. No comments.

MOTION	To accept the Psychotropic Medications – Duplicate Therapy for Pediatric Patients 6 and above Criteria as presented with no amendments.		
MOTION DASSED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

11. Roctavian™

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Roctavian [†] amendments.	[™] Criteria as pro	esented with no
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

12. 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

13. Synagis®

- a. Board Discussion
 - i. No comments.

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

14. Verquvo®

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Verquvo® amendments.	Criteria as pre	esented with no
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

15. Vuity™

- a. Board Discussion
 - i. No comments.

MOTION	To accept the Vuity™ amendments.	Criteria as pres	sented with no
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

D. Proposal of Criteria to Retire

1. Antifungal Medications for Onychomycosis

- a. Board Discussion
 - i. No comments.

MOTION	To accept the recommendation to retire Antifungal Medications for Onychomycosis Criteria.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

2. Horizant®

- a. Board Discussion
 - i. No comments.

MOTION	To accept the recommendation to retire Horizant® Criteria.		
MOTION DACCED	In favor	Opposed	Abstained
MOTION PASSED	6	0	0

E. Proposal of New Clinical Prior Authorization Criteria

1. Kebilidi™

- a. New criteria for Kebilidi™, an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.
- b. Requires patient age within the population included in the clinical trial.
- c. Requires diagnosis of AADC confirmed by genetic testing, CSF review, or plasma enzyme assessment.
- d. Requires stable dosage of standard of care for 3 months with persistent continued neurological defects.
- e. Requires inability to ambulate independently.
- f. Requires skull maturity due to injection limitations.

- g. Excludes use in patients with pyridoxine 5'-phosphate oxidase or tetrahydrobiopterin (BH4) deficiency and in patients with prior gene therapy.
- h. Excludes patients with high anti-adeno-associated virus antibody activity.
- i. Excludes patients with significant medical or neurological conditions that would create unacceptable surgical risk.
- j. Requires exclusion of positive pregnancy status and includes requirement for contraception following treatment.
- k. Board Discussion
 - i. Remove the criteria limiting the access to patients in the age range for the clinical trial. The FDA approved indication does not include any age restrictions in the label.

MOTION	To accept the Kebilidi™ Criteria as presented with amendments.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

2. Niemann-Pick Disease Type C

- a. Criteria is specific to drugs Aqneursa™ (levacetylleucine) and Miplyffa™ (arimoclomol citrate) for the treatment of Niemann-Pick disease type C.
- b. Requires prescriber specialty of genetics or specialist in NPC or consultation with one.
- c. Requires genetic testing to confirm mutation in NPC1 or NPC2 gene.
- d. Requires neurological symptoms.
- e. Miplyffa™ requires co-administration with miglustat.
- f. Board Discussion
 - i. No comments.

MOTION	To accept the criteria for Niemann-Pick Disease Type C Criteria with no amendments.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0

Winrevair™

- a. Winrevair™ is indicated for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events.
- b. Requires age and diagnosis to align with FDA approved indication.
- c. Requires diagnostic right heart catheterization to confirm PAH with a Group 1 subtype.

- d. Requires hemodynamic and lung function measures consistent with Group 1 PAH.
- e. Requires functional class identification at baseline.
- f. Requires baseline standard of care for 3 months prior to initiation of Winrevair™.
- g. Requires exclusion of positive pregnancy status and includes requirement for contraception following treatment.
- h. Requires monitoring for hemoglobin and platelets consistent with package insert.
- i. Board Discussion
 - i. No comments.

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

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

- 1. Analgesics Acute Pain Non-Opioid
 - a. Includes Journavx™, a sodium channel blocker, for the treatment of moderate to severe acute pain in adults.
- 2. Antivirals—Oral Treatment of COVID-19
 - a. Includes Paxlovid™, a protease inhibitor and antiviral, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.
- 3. Epinephrine, Self-Administered, Nasal
 - a. Includes Neffy®, an intranasal epinephrine, for the emergency treatment of type 1 allergic reactions, including anaphylaxis, in adult and pediatric patients weighing ≥ 30 kg.
- 4. Cardiovascular PCSK9 Targeted Therapies
 - a. Includes Leqvio®, Praluent®, and Repatha® indicated for LDL-C lipid lowering in various patient populations.

MOTION	To accept the addition of Analgesics – Acute Pain - Non- Opioid, Antivirals – Oral Treatment of COVID-19, Epinephrine, Self-Administered, Nasal, and Cardiovascular – PCSK9 Targeted Therapies as presented with no amendments.		
MOTION	In favor	Opposed	Abstained
PASSED	6	0	0