NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

July 16, 2025

http://www.state.nj.us/humanservices/dmahs/boards/durb/

AGENDA

I. Call to order in accordance with New Jersey Open Public Meeting Act

II. Roll Call

III. Review of meeting transcript for April 23, 2025, meeting
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2025/April_2025_DURB_meeting_transcript_Post_State_review.pdf

IV. Review of draft meeting summary for April 23, 2025, meeting (pages 4-8)

V. Secretary's report (page 9)

VI. Old Business
- A. Utilization Trends of SGLT-2 inhibitors, GLP-1/GIP Agonists, and CGRP Inhibitors (pages 10-12)
- B. Updated protocol for Attention Deficit Hyperactivity Disorder (ADHD) for Children <6 years old (pages 13-14)
- C. Updated protocol for Spravato® (esketamine) (page 15)

VII. New Business
- A. Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products (pages 16-18)
- B. Proposed addendum to the protocol for Imcivree® (setmelanotide) (pages 19-21)
- C. Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products (pages 22-24)
- D. Proposed Addendum to the protocol for Chimeric Antigen Receptor (CAR) T Cell Products (pages 25-30)
- E. Proposed addendum to the protocol for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) and Glucagon-Like Peptide-1 Receptor Agonist (GLP-1RA)/Glucose-Dependent-Insulinotropic-Polypeptide (GIP) Agonist for Type 2 Diabetes (pages 31-33)

VIII. A. Informational Highlights/Reports

1. Gainwell Technologies/NJ MCO 1st Quarter 2025 Prior Authorization Report (page 34)
2. Summary of DURB Action Items (pages 35-39)
3. DHS/DOH Pharmacy Programs Top Drugs Report/Physicians Administered Drugs Report (by amount paid and by category)

FFS top drugs:
http://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/7-2025/FFS_Top_Drugs_Report_April-2025.pdf

MCO top drugs:
http://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/7-2025/MCO_Top_Drugs_Report_March-2025.pdf

FFS top drugs by category:
http://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/7-2025/FFS_Top_Drugs_by_Category_April-2025.pdf

MCO top drugs by category:
http://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/7-2025/MCO_Top_Drugs_by_Category_March-2025.pdf

FFS antiviral drugs:
http://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/7-2025/FFS_Antiviral_Drugs_April-2025.pdf

B. Medication/Medical information

1. Discontinuing glucagon-like peptide-1 receptor agonists and body habitus: A systemic review and meta-analysis
   Discontinuing glucagon-like peptide-1 receptor agonists and body habitus: A systematic review and meta-analysis - Berg - Obesity Reviews - Wiley Online Library

2. Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV – CDC Recommendations, United States, 2025

Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025 | MMWR

3. Genitourinary Syndrome of Menopause: AUA/SUFU/AUGS Guideline 2025
Genitourinary Syndrome of Menopause: AUA/SUFU/AUGS Guideline (2025) - American Urological Association

4. Phase 3 Trial of Semaglutide in Metabolic Dysfunction – Associated Steatohepatitis
Phase 3 Trial of Semaglutide in Metabolic Dysfunction–Associated Steatohepatitis | New England Journal of Medicine

April 23, 2025, DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Ms. Olson, Dr. Barberio, Dr. Lind (ex-officio). Unable to attend: Dr. Slim (ex-officio) and Mr. Schafer
Dr. Swee's pre-meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the Board's meeting: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the filings in the Trenton Times, Star Ledger, and Atlantic City Press.
Review of Minutes	Approved	Minutes from January 15, 2025, meeting was reviewed and approved. The approved meeting summary will also be posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		- The Commissioners signed off on the DURB-recommended protocols from July 2024, October 2024, and January 2025 meetings. - The Department is working with the Commissioners to review and sign off on the State Fiscal Year (SFY) 2024 Annual Report. - In response to an inquiry by the Board during the January 2025 meeting regarding the percentage of the managed care organizations' total drug expenditure, the State Fiscal Unit provided the total spending for the pharmacy benefit is 15.2%.
Old Business		
(A) Utilization Trends of GLP-1/GIP Agonists, SGLT-2 Inhibitors, and CGRP Inhibitors	Continue to monitor	The Board reviewed utilization reports for GLP-1/GIP agonists, SGLT-2 inhibitors and CGRP inhibitors. Dr. Swee requested ongoing reports to monitor utilization of these three therapeutic classes. Dr. Swee commented on the continued rise in utilization of GLP-1/GIP agonist and SGLT-2 inhibitors and that this rise in utilization maybe a reflection of increased awareness of diabetes and hopefully not an increase in the number of new cases of diabetes. He also stated there is a larger increase in utilization within the SGLT2 inhibitor

Issue	Action	Notes
		category versus the GLP-1/GIP agonists. Dr. Marcus added the combination of increased cases of diabetes and the awareness that these drugs are useful in treating diabetes may have contributed to the overall increase. Dr. Swee stated he would like to continue monitoring CGRP inhibitors because the drugs are effective in treating migraines and headaches. The low utilization trend in the graph could be a result of access barriers. Dr. Marcus also questioned if these drugs are being underutilized.
(B) Updated Protocol for Alopecia Areata Products		The Board reviewed an updated version of the Alopecia Areata Products protocol with the recommended addition to test and treat syphilis if it is present. There was no further discussion.
(C) Updated Protocol for Lyfgenia® (lovotibeglogene autotemcel)		The Board reviewed an updated version of the Lyfgenia® protocol with the recommended addition of the black box warning. There was no further discussion.
(D) Updated Protocol for Casgevy® (exagamglogene autotemcel)		The Board reviewed an updated version of the Casgevy® protocol with the recommended additional criteria for administration of this product to occur at a Qualified Treatment Center. There was no further discussion.
New Business		
(A) Proposed Protocol for Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Treatment for Children < 6 Years Old	Recommended	The Board reviewed a proposed protocol for the use of stimulant medications for the treatment of ADHD for children less than six years of age. Dr. Swee questioned if Medicaid provides coverage for parent training and behavioral management (PTBM). The State confirmed coverage for these services. Dr. Gochfeld stated parent involvement is very important in management of these children and PTBM may lead to managing the condition without the utilization of drugs. Ms. Olson expressed concern with the continuation of therapy criterion #1 and stated that patients with manageable or minimal side effects may still continue therapy. Dr. Swee suggested adding "significant" in reference to side effects to allow continuation of therapy when manageable or minimal side effects are present. Ms. Olson agreed with that update to the criterion #1.

Issue	Action	Notes
		The Board recommended approval of the protocol with the suggested addition.
(B) Proposed Protocol for Zepbound® (tirzepatide) for Obstructive Sleep Apnea (OSA)	Recommended	The Board reviewed a proposed Zepbound® protocol for the treatment of OSA. Dr. Swee stated the continuation criteria can be complicated and cumbersome because as the patient loses weight on Zepbound they may not present with moderate to severe OSA. The Board recommended approval of the protocol.
(C) Proposed Addendum to Protocol for Spravato® (esketamine) Nasal Spray	Recommended	The Board reviewed a proposed addendum to the protocol for Spravato® monotherapy for treatment-resistant depression. In addition, criteria was updated to ensure trial of at least two different classes of antidepressants at optimal therapeutic dosages for a minimum of four weeks each prior to Spravato for the diagnosis of treatment-resistant depression. Dr. Swee recommended updating the monitoring criteria to ensure patients will be appropriately monitored post administration of Spravato. The Board recommended approval of the protocol with the addition of Dr. Swee's recommendation.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor	The Board reviewed the 4th Quarter 2024 prior authorization (PA) denial report for FFS and MCOs. Dr. Swee stated the Board should focus on drugs that are denied at a high percentage most likely due to formulary issues. He requested the Board receive utilization reports on antidiabetic, ADHD and dermatologic drugs.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (April 2024 through January 2025). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols through January 2025.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for January 2025 (FFS) and December 2024 (MCOs) was provided for review.
Drug expenditures during the reporting period are noted below:

<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>January 2025</td><td>$ 2,841,231*</td><td>$ 3,135,173*</td></tr>
<tr><td>MCOs</td><td>December 2024</td><td>$ 115,620,665</td><td>$ 164,886,638</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
</table>

Dr. Swee and Dr. Marcus noted that the total monthly drug expenditures are millions of dollars. Dr. Swee also stated that despite applicable drug rebates, the total spend is still high. Dr. Marcus mentioned an article in the Journal of Medical Toxicology highlighting increased utilization of tianeptine between 2018 and 2023, and increased overdose reports to poison control centers. Dr. Agrawal stated a Drug Enforcement Agency report from April 2025 mentioned this drug is not FDA-approved in the United States and has emerged as an illicit drug on the market. Dr. Swee requested a report be provided to the Board on tianeptine utilization.</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:
1. FDA Approved Journavx™ (suzetrigine), a first-in-class treatment for adults with moderate to severe acute pain
2. Update to American Diabetes Association Diabetes Guidelines
3. Novo Nordisk Press Release January 28, 2025 – FDA Approves Ozempic® as the only GLP-1 Receptor Agonist to Reduce the Risk of Worsening Kidney Disease and Cardiovascular Death in Adults with Type 2 Diabetes Mellitus and Chronic Kidney Disease</td></tr>
</table>

Issue	Action	Notes
		4. Centers for Medicare & Medicaid Services (CMS) Infographic Released October 2024. 2024 Medicaid & CHIP Beneficiaries at a Glance: Attention Deficit/Hyperactivity Disorder 5. Centers for Disease Control and Prevention (CDC) – State Medicaid Policies Prescribing ADHD Medications to Children
Follow-up items:		1. Provide utilization reports for GLP-1/GIP agonists, SGLT2 inhibitors, and CGRP inhibitors to continue to monitor. 2. Provide utilization reports for Lyfgenia and Casgevy, as well as monitor if requests go beyond twelve months. 3. Provide reports to review top PA denials for antidiabetic, ADHD, and dermatologic drugs. 4. Provide a report on tianeptine utilization.

Secretary's Report

New Jersey Drug Utilization Review Board
July 16, 2025

1. The Department is working with the Commissioners to review and sign off on the SFY 2024 Annual Report

2. The Commissioners signed off on the April 2025 DURB recommended protocols

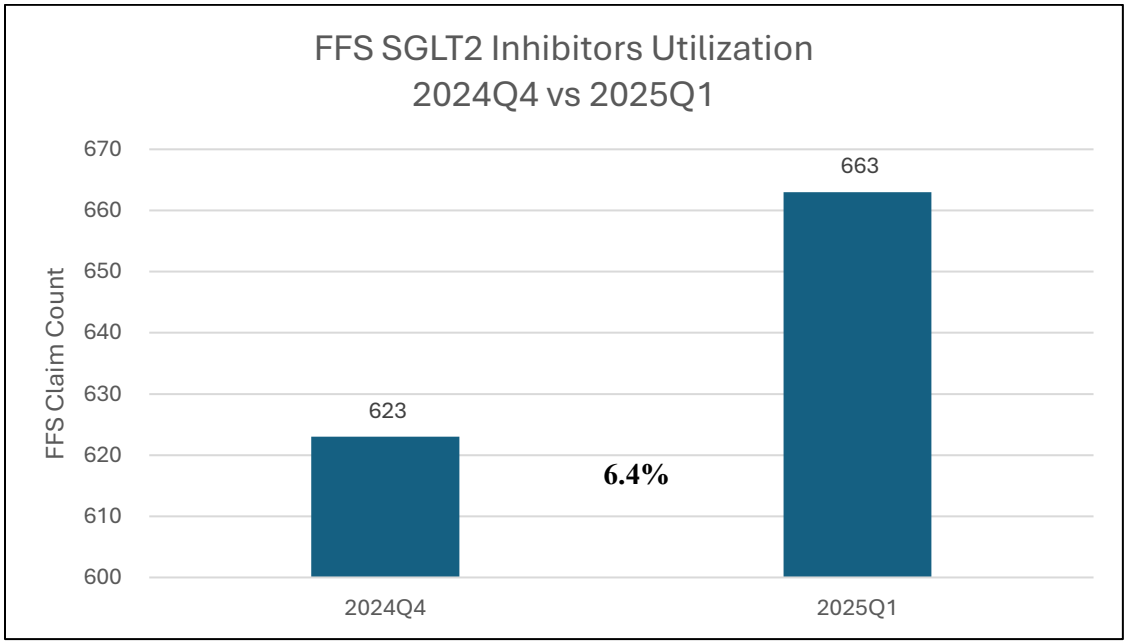
    - Utilization Trends of SGLT-2 inhibitors, GLP-1/GIP Agonists, and CGRP Inhibitors
    - Updated protocol for Attention Deficit Hyperactivity Disorder (ADHD) for Children <6 years old
    - Updated protocol for Spravato® (esketamine)

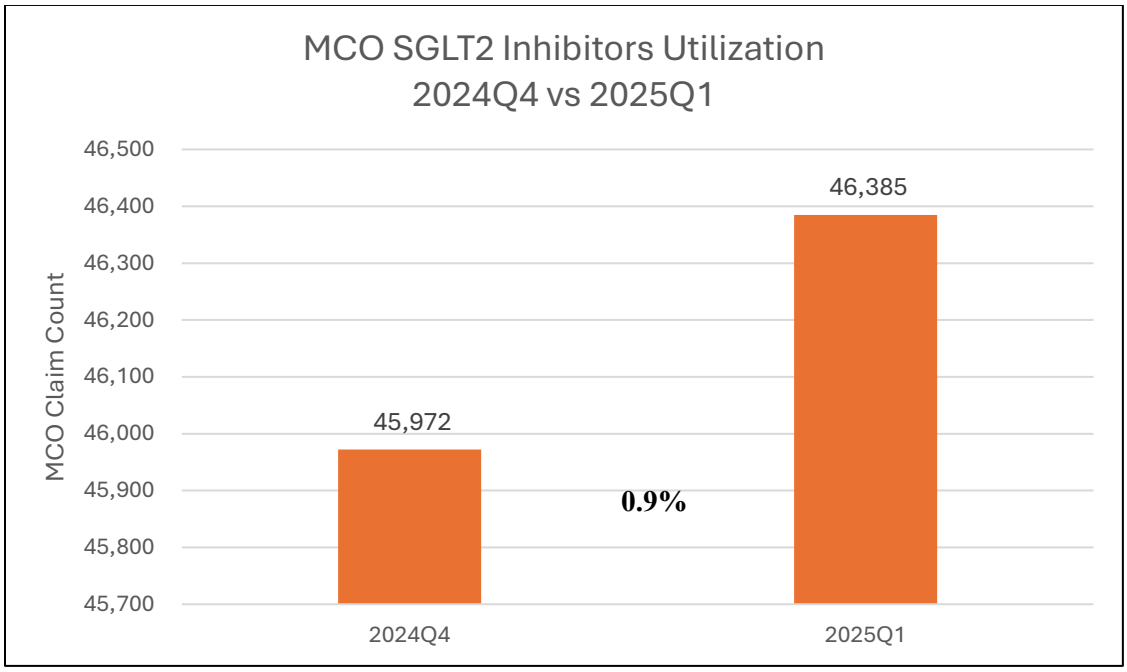
3. Tianeptine is approved in other countries however it is not approved in the United States and therefore there is currently no utilization in Medicaid

4. The Department does not have any new updates for the Board's vacant positions

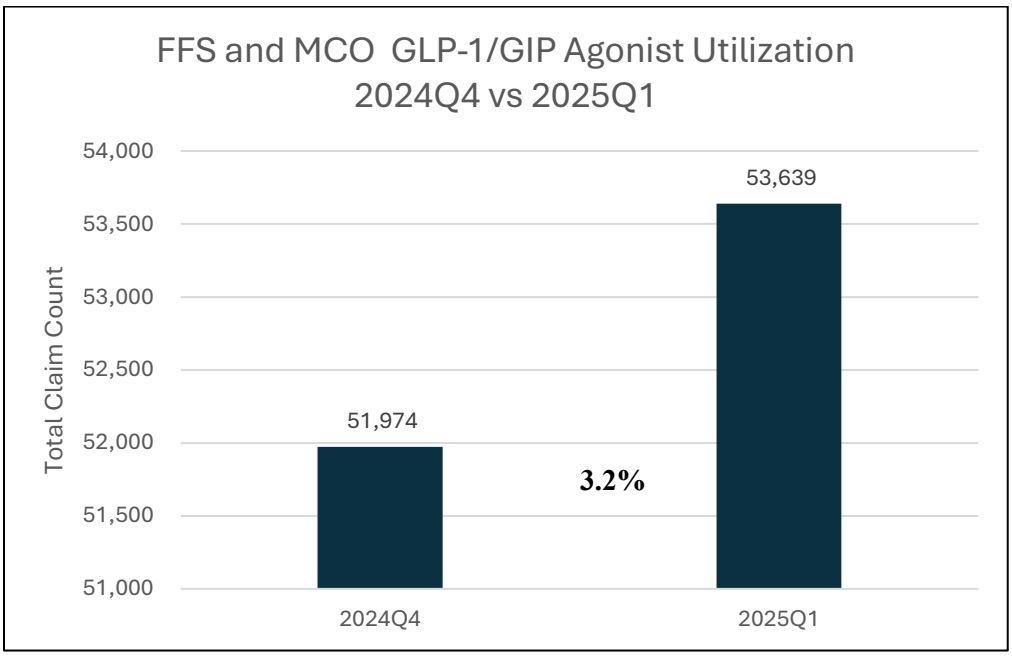
Utilization Trends (July 2025)

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors Utilization

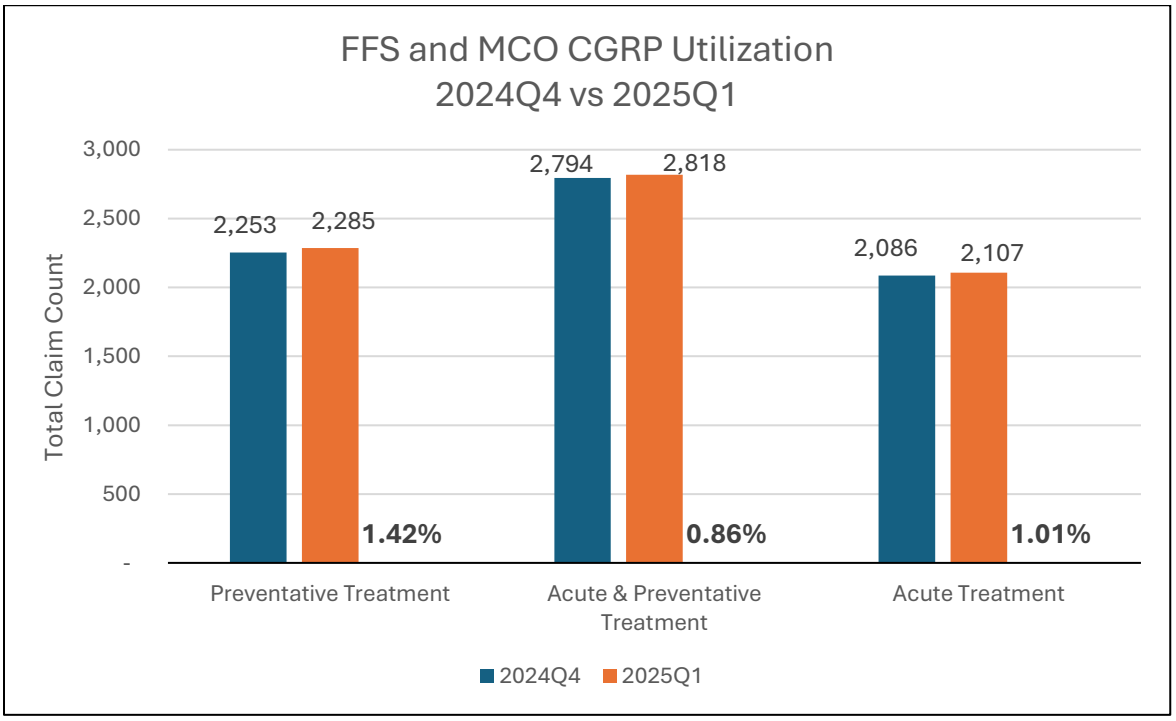




Utilization of Glucagon-like peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-dependent Insulinotropic Polypeptide (GIP) Agonist for Diabetes Mellitus



Utilization of Calcitonin Gene-Related Peptide (CGRP) Inhibitors



Protocol for Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Treatment in Children Under 6 Years of Age

Approved April 2025

Criteria for Approval:

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) confirmed by a standardized rating scale (e.g., Conners, Vanderbilt, Brown, SNAP-IV) with moderate to severe dysfunction

2. Patient is between their 4th and 6th birthday

3. Symptoms and/or behavior have persisted for 9 months or more in at least 2 settings.

4. Patient has been screened for:

    a. Emotional or behavioral conditions,
    b. Developmental conditions, and
    c. Physical conditions

5. Attestation that Parent Training in Behavior Management (PTBM) and/or behavioral classroom intervention has been attempted, but a moderate to severe continued disturbance in function exists

6. The clinician weighed the risks of starting treatment before the age of six against the harm of delaying treatment

7. The patient is continuing PTBM and/or behavior classroom intervention together with prescribed ADHD medication

8. Medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of Therapy:

1. Patient is not experiencing any significant side effects or worsening of negative signs/symptoms

2. Documentation of positive response to stimulant therapy (sign/symptom reduction)

3. The patient is continuing PTBM and/or behavior classroom intervention together with prescribed ADHD medication

4. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

References:

1. Eiland LS, Gildon BL. Diagnosis and Treatment of ADHD in the Pediatric Population. J Pediatr Pharmacol Ther. 2024 Apr;29(2):107-118. doi: 10.5863/1551-6776-29.2.107. Epub 2024 Apr 8. PMID: 38596418; PMCID: PMC11001204.
2. Wolraich KL, Hagan JF, Allan C et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. The American Academy of Pediatrics, Clinical Practice Guideline. October 2019. Accessed online on February 3, 2025 at: https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-the-Diagnosis?autologincheck=redirected
3. DSM-5 Diagnostic and Statistical Manual of Mental Disorders, 5th edition; ADHD: attention deficit hyperactivity disorder (AAFP National Research (Network)

Protocol for Spravato® (esketamine) Nasal Spray
Approved April 2025

DURB Approval Date	**7/2020, 1/2022, 4/2025**
Commissioners Approval Date	**5/2021, 11/2022**

Background:

Spravato nasal spray is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated for the treatment of treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant and for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant.

This protocol is being updated to add criteria to allow for monotherapy of Spravato nasal spray for the indication of treatment resistant depression.

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age

2. Patient was assessed and determined not to be at risk for abuse and misuse of Spravato nasal spray

3. Patient does not have any of the following contraindications to therapy:
    a. Aneurysmal vascular disease (including in the brain, chest and abdominal aorta, and peripheral arterial vessels), **OR**
    b. Arteriovenous malformation, **OR**
    c. History of bleeding in the brain

4. Spravato nasal spray is being administered under the supervision of a healthcare provider and the patient is going to be appropriately monitored for at least 2 hours after administration

5. Patient has one of the following diagnoses:
    a. Treatment-resistant depression, **OR**
    b. Depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior

6. Treatment-resistant depression is defined by the patient having documentation demonstrating a therapeutic failure of at least two (2) different classes of antidepressants at optimal therapeutic dosages each for a minimum of 4 weeks unless the patient has contraindications to all antidepressants

7. For the diagnosis of MDD with suicidal ideation or behavior, patient is using Spravato nasal spray in conjunction with an oral antidepressant therapy

8. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient is using Spravato nasal spray in conjunction with an oral antidepressant therapy for the treatment of MDD with suicidal ideation or behavior

2. Spravato nasal spray is being administered under the supervision of a healthcare provider and the patient is going to be appropriately monitored for at least 2 hours after administration

3. Documentation showing the patient responded to therapy is demonstrated by an improvement from baseline in a clinician-rated tool/scale (e.g., The Montgomery-Asberg Depression Rating Scale (MADRS), Beck Depression Inventory, or Hamilton Depression Rating Scale)

4. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

Warning: Because of the risks of serious adverse outcomes resulting from sedation, dissociation, abuse and misuse.

References:

1. Spravato [package insert]. Janssen Pharmaceuticals, Inc., Titusville, NJ 08560. January 2025. Accessed February 4, 2025
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2025. Updated periodically
3. Canuso C, Singh J, et al: Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Depression and Suicidality in Patients at Imminent Risk for Suicide: Results of a Double-Blind, Randomized, Placebo-Controlled Study. Am J Psychiatry. 2018. Accessed online on May 24, 2019 at: https://adaa.org/sites/default/files/Canuso-AJP-2018.pdf
4. Practice guideline for the treatment of patients with major depressive disorder (revision). American Psychiatric Association. Am J Psychiatry. 2010:1-152. URL: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf Accessed February 5, 2025.

Proposed Addendum to the Protocol for Transthyretin-Mediated Amyloidosis (ATTR) Products

July 2025

DURB Approval Date	**10/2019, 10/2024**
Commissioners Approval Date	**1/2025**

Onpattro® (patisiran)
Vyndaqel® and Vyndamax® (tafamidis meglumine)
Tegsedi® (inotersen)
Amvuttra® (vutrisiran)
Wainua® (eplontersen)
Attruby® (acoramidis)

Addendum:
The purpose of this addendum is to add Attruby, a new drug approved by the FDA in November 2024. In addition, the protocol is updated to include a new indication approved by the FDA on March 2025 for Amvuttra.

Background:
Onpattro (patisiran) and Amvuttra (vutrisiran) contain a transthyretin-directed small interfering RNA and are indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Amvuttra is also FDA approved for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.

Vyndaqel (tafamidis meglumine), **Vyndamax** (tafamidis), and Attruby (acoramidis) are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Tegsedi (inotersen) and **Wainua (eplontersen)** are a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Criteria for approval:

1. Documentation of diagnosis is confirmed by genotyping, biopsy, immunohistochemical analysis, scintigraphy, or mass spectrometry

2. Medication is prescribed by or in consultation with a neurologist, cardiologist, or another specialist in the treatment of ATTR

3. Patient has clinical signs and symptoms of the disease (e.g., peripheral

sensorimotor polyneuropathy, motor disability, cardiovascular dysfunction, carpal tunnel syndrome)

4. Weight should be made available for drugs that have weight-based dosing. Height and weight should be made available for drugs that have dosing based on body surface area

5. Patient is of the FDA-labeled or compendial approved age

6. Patient has no FDA-labeled contraindications to the requested drug

7. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

8. Medication will not be used concurrently with other transthyretin-mediated amyloidosis (ATTR) products

9. For Onpattro, Amvuttra, Tegsedi and Wainua requests patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis

10. For Vyndaqel and Vyndamax, Amvuttra, and Attruby requests patient is using medication to treat cardiomyopathy of wild type or hereditary/variant transthyretin-mediated amyloidosis (ATTR-CM) to reduce any one of the following:
    a. Cardiovascular mortality (Amvuttra, Attruby, Vyndaqel and Vyndamax)
    b. Cardiovascular-related hospitalization (Amvuttra, Attruby, Vyndaqel and Vyndamax)
    c. Urgent heart failure visits (Amvuttra)

~~11. **For Tegsedi® requests:**~~

~~a. Patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis~~

Continuation of therapy:

1. Documentation that patient has experienced a positive clinical response to medication (e.g., improved neurologic impairment, motor function, quality of life)

2. Medication is not used concurrently with other transthyretin-mediated amyloidosis (ATTR) products

3. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing

according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

4. For dose increases, weight should be made available for drugs that have weight-based dosing. Height and weight should be made available for drugs that have dosing based on body surface area

NOTE: There is a BOXED WARNING OF THROMBOCYTOPENIA AND GLOMERULONEPHRITIS for Tegsedi. Tegsedi is available only through a restricted distribution program called the Tegsedi REMS Program.

References:

1. Onpattro® [package insert]. Alnylam Pharmaceuticals, Inc. San Diego, CA 92121. January 2023.
2. Vyndaqel® (tafamidis meglumine) and Vyndamax® (tafamidis) [package insert]. Pfizer Labs Inc. NY, NY 10017. May 2019.
3. Tegsedi® [package insert]. Ionis Pharmaceuticals, Inc. Carlsbad, CA 92010. January 2024.
4. Amvuttra® [package insert]. Alnylam Pharmaceuticals, Inc., Cambridge, MA 02142. March 2025.
5. Wainua® (eplontersen) [package insert] AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. April 2025.
6. Attruby® (acoramidis) [package insert]. BridgeBio Pharma, Inc. Palo Alto, CA 94304. November 2024
7. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases 2013, 8:31
8. Maurer MS, Schwartz JH, Gundepaneni B, et al. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2018; 379:1007-1016.
9. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically.
10. Donnelly JP, et al. Cardiac amyloidosis: An update on diagnosis and treatment. Cleve Clin J Med. 2017;84(12 suppl 3):12-26. Available at https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/hanna_.cardiacamyloidosis.pdf. Accessed September 12, 2019.
11. Nativi-Nicolau J, Maurer MS. Amyloidosis cardiomyopathy: update in the diagnosis and treatment of the most common types. Curr Opin Cardiol. 2018;33(5):571 -579.
12. Rigopoulos AG, et al. Advances in the diagnosis and treatment of transthyretin amyloidosis with cardiac involvement. Heart Fail Rev. 2019 Jul;24(4):521-533.
13. Gertz, MA. Hereditary ATTR Amyloidosis: Burden of Illness and Diagnostic Challenges. Am J Manag Care. 2017;23:S107-S112.
14. Adams D, Gonzales-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med 2018;379:11 -21.
15. Benson MD, Waddington-Cruz M, Berk JL. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. N Engl J Med 2018;379:22 -31
16. Ando Y, Waddington-Cruz M, Sekijima Y, Koike H, Ueda M, Konishi H, Ishii T, Coelho T. Optimal practices for the management of hereditary transthyretin amyloidosis: real-world experience from Japan, Brazil, and Portugal. Orphanet J Rare Dis. 2023 Oct 12;18(1):323. doi: 10.1186/s13023-023-02910-3. PMID: 37828588; PMCID: PMC10571420.
17. Poli L, Labella B, Cotti Piccinelli S, Caria F, Risi B, Damioli S, Padovani A and Filosto M (2023) Hereditary transthyretin amyloidosis: a comprehensive review with a focus on peripheral neuropathy. *Front.Neurol.* 14:1242815. doi: 10.3389/fneur.2023.1242815.

Proposed Addendum to the Protocol for Imcivree® (setmelanotide)

July 2025

DURB Approval Dates	**10/2021; 1/2023**
Commissioners Approval Dates	**5/23/2022; 2/7/2024**

Addendum:

The purpose of this addendum is to update the age and allow Imcivree® for patients 2 years of age and older based on the recent FDA approval. Initial criteria defining obesity updated based on Centers for Disease Control and Prevention (CDC). The continuation of therapy criteria pertaining to therapy response updated based on prescribing information changes.

Background:

- Obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency is an ultra-rare disease caused by variants in POMC, PCSK1 or LEPR genes that impair the melanocortin-4 receptor (MC4R) pathway, which is a pathway in the hypothalamus that is responsible for regulating hunger, energy expenditure and consequently body weight. People living with obesity due to POMC, PCSK1 or LEPR deficiency struggle with extreme, insatiable hunger beginning at a young age, resulting in early-onset, severe obesity.

- Bardet-Biedl syndrome is a rare genetic disorder with highly variable symptoms which may include retinal degeneration, obesity, reduced kidney function, polydactyly (extra digits of the hands or feet) among many other features.

Imcivree is MC4 receptor agonist indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:

- POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

- Bardet-Biedl syndrome (BBS)

As an MC4R agonist, Imcivree is designed to restore impaired MC4R pathway activity arising due to genetic deficits upstream of the MC4 receptor.

Criteria for approval:
Patient meets **ALL** the following:

1. Diagnosis of obesity defined by Centers for Disease Control and Prevention (CDC) as:
   a. ~~Adults~~ Patients ~~18~~ 20 years or older with BMI ≥ 30 kg/m^2
   b. ~~Children~~ Patients less than 20 years of age ~~(younger than 18 years old)~~ with BMI ≥ 95th percentile ~~weight percentile based on growth charts~~

2. Documented diagnosis of obesity due to one of the following:
   a. POMC, PCSK1, or LEPR deficiency with genetic testing confirming that

variants in the POMC, PCSK1, and/or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance

b. Confirmed Bardet-Biedl syndrome (BBS) ~~confirmed by identification of characteristic findings (e.g., rod-cone dystrophy, polydactyly)~~

3. Patient is of the FDA-labeled or compendial approved age

4. Medication is prescribed by or in consultation with an endocrinologist or expert in rare genetic disorders of obesity

5. Documentation of estimated glomerular filtration rate [eGFR] ≥ 15 mL/min/1.73 m^2 is provided

6. Patient does not have any contraindications to therapy

7. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Exclusions:

Imcivree is not indicated for the treatment of patients with the following conditions as it would not be expected to be effective:

a. Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
b. Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity

Continuation of therapy:

1. For patients ≥6 years of age and older with obesity due to one of the following:
   a. POMC, PCSK1, or LEPR deficiency there is a documented positive response to therapy as evidenced by at least a 10% reduction in BMI at 1 year from baseline
   b. Bardet-Biedl Syndrome there is a documented positive response to therapy as evidenced by at least a 5% reduction in BMI at 1 year from baseline
   c. ~~Patient is responding positively to therapy as evidenced by one of the following~~
   ~~d. After 16 weeks of treatment: reduction in weight compared with baseline (at least 5% body weight or 5% of BMI)~~
   ~~e. After 1 year: ≥ 10% reduction in weight compared with baseline~~
   ~~f. After > 1 year: maintenance of ≥ 10% reduction in weight compared with baseline~~
2. For patients aged 2 to less than 6 years of age with obesity due POMC, PCSK1, or LEPR deficiency, or Bardet-Biedl Syndrome, there is a documented positive response to therapy as evidenced by a reduction in BMI at 1 year from baseline
   ~~a. For children younger than 18 years old: ≥ 5% reduction of baseline BMI~~

~~b. For 18 years and older: ≥ 5% reduction of baseline body weight~~

3. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

References:

1. Imcivree® injection [prescribing information]. Rhythm Pharmaceuticals, Inc. Boston, MA 021116. December 2024.
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically.
3. Ayers KL, Glicksberg BS et al. Melanocortin 4 Receptor Pathway Dysfunction in Obesity: Patient Stratification Aimed at MC4R Agonist Treatment. J Clin Endocrinol Metab. 2018 Jul; 103(7): 2601–2612.
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Proposed Addendum to the Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

July 2025

DURB Approval Dates	**7/2022, 10/2024**
Commissioners Approval Dates	**3/2023, 1/2025**

Empaveli® (pegcetacoplan)
Soliris® (eculizumab)
Ultomiris® (ravulizumab-cwvz)
Fabhalta® (iptacopan)
PiaSky® (crovalimab-akkz)
Voydeya™ (danicopan)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
The purpose of this addendum is to update the continuation of therapy criteria.

Background:
Paroxysmal nocturnal hemoglobinuria (PNH) is a chronic, multi-systemic, progressive, and life-threatening disease characterized by intravascular hemolysis, thrombotic events, serious infections, and bone marrow failure.

Empaveli is a complement inhibitor indicated for the treatment of adult patients with PNH.

Soliris is a complement inhibitors indicated for the treatment of patients with PNH to reduce hemolysis.

Ultomiris is a complement inhibitor indicated for the treatment of pediatric and adult patients with PNH.

Fabhalta is a complement factor B inhibitor, indicated for the treatment of adults with PNH.

PiaSky is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with PNH and body weight of at least 40 kg

Voydeya is a complement factor D inhibitor indicated as an add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with PNH

Criteria for approval:

1. Diagnosis of PNH is confirmed by flow cytometry
2. Patient is of the FDA-labeled or compendial approved age

3. Patient does not have any FDA-labeled contraindications to requested medication

4. Patient is not on concomitant therapy with another complement inhibitor for the treatment of PNH, unless indicated for add-on therapy ~~with the exception of Voydeya for the treatment of PNH~~

5. Patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria

6. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

7. For Ultomiris and PiaSky requests patient's current weight is documented

8. For Fabhalta requests the medication is prescribed by or in consultation with a hematologist, oncologist, or immunologist

9. For Voydeya Requests:
    a. Patient has evidence of extravascular hemolysis while on a C5 inhibitor such as eculizumab, ravulizumab, or crovalimab
    b. Medication is used concomitantly with a C5 inhibitor
    c. Hemoglobin is ≤ 9.5 g/dL

NOTE: Empaveli, Soliris, Bkemv, Epysqli, Ultomiris, Fabhalta, PiaSky, Voydeya are available only through a restricted distribution program

Continuation of therapy:

1. The patient has responded to treatment compared to baseline as defined by at least one of the following:
    a. Decrease in serum LDH from pre-treatment level
    b. Increase in hemoglobin levels from pre-treatment level
    c. Decrease in number of transfusions needed
    d. Increase in reticulocyte count from pre-treatment level
    ~~e. Absence of unacceptable toxicity from the drug~~

2. Patient is not on concomitant therapy with another complement inhibitor for the treatment of PNH, unless indicated for add-on therapy

3. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

References:

1. Empaveli® [prescribing information]. Apellis Pharmaceuticals Inc; Waltham MA. February 2024.
2. Soliris® [prescribing information]. Alexion Pharmaceuticals, Inc. Cheshire, CT. February 2025.
3. Ultomiris® [prescribing information]. Alexion Pharmaceuticals, Inc. Boston, MA. September 2024.
4. Fabhalta® [prescribing information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. March 2025.
5. PiaSky® [prescribing information]. Genentech, Inc. South Francisco, CA. June 2024.
6. Voydeya® [prescribing information]. Alexion Pharmaceuticals. Boston, MA. March 2024.
7. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically.
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Addendum to Protocol for Chimeric Antigen Receptor (CAR) T Cell Products

July 2025

DURB Approval Dates	**7/2023**
Commissioners Approval Dates	**7/2024**

Abecma® (idecabtagene vicleucel)
Breyanzi® (lisocabtagene maraleucel)
Carvykti® (ciltacabtagene autocel)
Kymriah® (tisagenleleucel)
Tecartus® (brexucabtagene autoleucel)
Yescarta® (axicabtagene ciloleucel)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum: The purpose of the addendum is to remove the criteria referencing the risk evaluation and mitigation strategies (REMS) program. The REMS program for chimeric antigen receptor t-cell therapy was eliminated by the Food and Drug Administration. In addition, Breyanzi criteria is updated to include remaining FDA approved indications. Criteria pertaining to age and contraindications is added to the protocol.

Background: *Chimeric Antigen Receptor (CAR)-T cell therapy is a targeted, personalized therapy that contains patients' autologous T cells reengineered to fight cancer. T cell therapy is approved by the Food and Drug Administration (FDA) to treat certain types of leukemia, lymphoma, and most recently, myeloma.*

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age

2. Patient does not have any contraindications to therapy

3. Medication is prescribed by or in consultation with an oncologist, hematologist, or other specialist in the treatment of the specified disease

4. Diagnosis has been confirmed using appropriate tests (e.g., histology for Non-Hodgkin Lymphoma (NHL); immunophenotyping for Acute lymphocytic leukemia (ALL), etc.) prior to initiating therapy

5. Patient is not currently pregnant

6. Patient has no previous history of CAR-T cell therapy

7. Patient has no active infections or inflammatory disorders

8. ~~The treating facility is certified under the Risk Evaluation and Mitigation Strategy (REMS) System program appropriate for the requested CAR-T product.~~

9. ~~Patient is educated on possible drug specific severe adverse reactions with treatment like Cytokine Release Syndrome (CRS), neurologic toxicities, etc.~~

10. Treatment is one time

11. The medication requested is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

12. For Abecma requests patient meets i. and ii.:
    i. Documentation is received of relapsed or refractory multiple myeloma
    ii. Documentation is received of trial of at least four ~~or more~~ prior ~~lines of~~ therap~~y~~ies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody

~~a. Patient is 18 years or older or age is appropriate based on National Comprehensive Cancer Network (NCCN) compendium 2B or better off-label recommendation; **AND**~~
~~b. The request meets one of the following:~~
~~i. Documented diagnosis of relapsed or refractory multiple myeloma; **AND** documentation of **at least** four or more prior lines of therapy**ies**, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **OR**~~
~~ii. Request meets NCCN compendium 2B or better off-label recommendations~~

13. For Breyanzi requests patient meets one of the following (i. ii. iii. or iv.):
    i. Documentation is received of large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma and follicular grade 3B AND meets one of the following (a. b. or c.):
        a. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy
        b. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT)
        c. Relapsed or refractory disease after 2 or more lines of systemic therapy

ii. Documentation is received of relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least two prior lines of therapy including, a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor
iii. Documentation is received of relapsed or refractory follicular lymphoma who have received 2 or more prior lines of systemic therapy
iv. Documentation is received of relapsed or refractory mantle cell lymphoma who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor

~~a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**~~
~~a. Documented diagnosis of large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:~~
~~i. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first line chemoimmunotherapy; or~~
~~ii. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or~~
~~iii. Relapsed or refractory disease after two or more lines of systemic therapy **OR** b. Request meets NCCN compendium 2B or better off-label recommendations~~

14. For Carvykti requests patient meets all of the following (i. ii. and iii.):
i. Documentation is received of relapsed or refractory multiple myeloma
ii. Documentation is received of trial of at least four ~~or more~~ prior ~~lines of~~ therap~~y~~ies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
iii. Documentation is received patient is refractory to lenalidomide treatment

~~a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**~~
~~b. The request meets one of the following:~~
~~a. Documented diagnosis of relapsed or refractory multiple myeloma; **AND**~~
~~Documentation of four or more prior lines of therapy, including and immunomodulatory agent, a proteasome inhibitor, and anti-CD38 monoclonal antibody **OR**~~
~~b. Request meets NCCN compendium 2B or better off-label recommendations~~

15. For Kymriah requests the patient meets one of the following (i. ii. or iii.):
i. Documentation received of B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse in patients up to 25 years of age
ii. Documentation received of relapsed or refractory large B-cell lymphoma (including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular

lymphoma) after two or more lines of systemic therapy

iii. Documentation is received of relapsed or refractory follicular lymphoma after two or more lines of systemic therapy

~~a. The request meets one of the following:~~
~~a. Patient is up to 25 years old with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse **OR**~~
~~b. Patient is 18 years or older with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma **OR**~~
~~c. Patient is 18 years or older with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.~~
~~d. Request meets NCCN compendium 2B or better off-label recommendations~~

16. For Tecartus requests the patient meets i. or ii.:

i. Documentation is received of relapsed or refractory mantle cell lymphoma

ii. Documentation is received of relapsed or refractory B-cell precursor acute lymphoblastic leukemia

~~a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**~~
~~b. The request meets one of the following:~~
~~a. Documented diagnosis of relapsed or refractory mantle cell lymphoma (MCL) **OR**~~
~~b. Documented diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **OR**~~
~~c. Request meets NCCN compendium 2B or better off-label recommendations~~

17. For Yescarta requests patient meets one of the following (i. ii. or iii.):

i. Documentation is received of large B-cell lymphoma that is refractory to 1st line chemoimmunotherapy or that relapses within 12 months of 1st line chemotherapy

ii. Documentation is received of relapsed or refractory large B-cell lymphoma (includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma) after two or more lines of systemic therapy

iii. Documentation is received of relapsed or refractory follicular lymphoma after two or more lines of systemic therapy

~~a. Patient is 18 years or older or age is appropriate based on NCCN compendium 2B or better off-label recommendation; **AND**~~
~~b. The request meets one of the following:~~
~~a. Patient has large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy **OR**~~
~~b. Patient has any of the following diagnosis that has not responded to or have~~

~~relapsed following two or more lines of systemic therapy:~~
~~i. Diffuse large B-cell lymphoma (DLBCL) not otherwise specified ii.~~
~~Primary mediastinal large B-cell lymphoma~~
~~iii. High grade B-cell lymphoma~~
~~iv. DLBCL arising from follicular lymphoma **OR**~~
~~c. Patient has relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy **OR**~~
~~d. Request meets NCCN compendium 2B or better off-label recommendations~~

Note:
There is BOXED WARNING of Cytokine Release Syndrome, Neurologic Toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), Prolonged Cytopenia, and Secondary Hematological Malignancies for Abecma.

There is BOXED WARNING of Cytokine Release Syndrome, Neurologic Toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), Recurrent Cytopenia, and Secondary Hematological Malignancies for Carvykti.

There is a BOXED WARNING of Cytokine Release Syndrome, Neurologic Toxicities, and Secondary Hematological Malignancies for Yescarta, Tecartus, Breyanzi, and Kymriah.

References:

1. Abecma [package insert]. Bristol-Myers Squibb Company. Summit, NJ. June 2025. ~~March 2021~~
2. Carvykti [package insert]. Janssen Biotech, Inc. Horsham, PA. June 2025. ~~February 2023~~
3. Kymriah [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ. June 2025. ~~May 2022~~
4. Tecartus [package insert]. Kite Pharma, Inc. Santa Monica, CA. June 2025. ~~October 2021~~
5. Yescarta [package insert]. Kite Pharma, Inc. Santa Monica, CA. June 2024. ~~November 2022~~
6. Breyanzi [package insert]. Bristol-Myers Squibb Company. Summit, NJ. June 2025.
7. Clinical Pharmacology. Gold Standard Series [Internet database]. Tampa, FL. Elsevier 2021. Updated Periodically
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Accessed 7/7/2025. FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T cell Immunotherapies | FDA

16. National Cancer Institute. CAR T Cells: Engineering Patients' Immune Cells to Treat Their Cancers. March 10, 2022. Accessed online: May 5, 2023. https://www.cancer.gov/about-cancer/treatment/research/car-t-cells

~~1. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 1.2023. 4/4/23. [70 screens] https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf~~

~~2. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 2.2023. 3/10/2023. [130 screens] https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf~~

~~3. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: pediatric aggressive mature b-cell lymphomas. Version 1.2023. 3/31/2023. [145 screens] https://www.nccn.org/professionals/physician_gls/pdf/all.pdf~~

Proposed Addendum to the Protocol for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) and Glucagon-Like Peptide-1 Receptor Agonist (GLP-1RA)/Glucose-Dependent-Insulinotropic-Polypeptide (GIP) Agonist for Type 2 Diabetes

July 2025

DURB Approval Dates	**10/2022; 1/2023**
Commissioners Approval Dates	**2/7/2024**

Adlyxin® (lixisenatide)
~~**Bydureon®, Bydureon Pen®, Bydureon Bcise®** (exenatide microspheres)~~
Exenatide
Mounjaro® (tirzepatide)
Ozempic® (semaglutide)
Rybelsus® (semaglutide)
Soliqua™ (insulin glargine/lixisenatide)
Trulicity® (dulaglutide)
Victoza® (liraglutide) ~~10 years of age~~
Xultophy® (insulin degludec/liraglutide)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
The purpose of this addendum is to include additional indications for the GLP-1RAs. Brand exenatide products are no longer available on the market and are removed from the drug list above.

Background:

- The GLP-1RAs have been shown to significantly improve glycemic parameters and reduce body weight. These agents work by activating GLP-1 receptors in the pancreas, which leads to enhanced insulin release and reduced glucagon release-responses that are both glucose-dependent-with a consequent low risk for hypoglycemia.
- Tirzepatide is a GIP receptor and GLP-1 receptor agonist. Tirzepatide targets two different receptors that lower fasting and postprandial glucose concentration, decrease food intake and reduce body weight in patients with type 2 diabetes mellitus.

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age

2. Patient does not have any contraindications to therapy

3. Patient is not using requested medication concurrently with other GLP-1 (glucagon-like

peptide-1) agonists

4. Documentation of HbA1C ≥ 7 measured within the past 6 months is provided

5. Patient has one of the following:

    a. Requests for type 2 diabetes mellitus must meet (i) and (ii)
        i. Confirmed diagnosis of type 2 diabetes mellitus
        ii. Patient has had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons:
            1. Has a diagnosis of Crohn's Disease, Irritable Bowel Syndrome, or Ulcerative Colitis
            2. Has severe renal impairment (eGFR below 45ml/min/1.73m^2)
            3. Has an intolerance or contraindication to metformin therapy
    b. Requests to reduce the risk of major adverse cardiovascular events must meet (i.) and (ii.)
        i. Confirmed diagnosis of type 2 diabetes mellitus
        ii. Established cardiovascular disease ~~patient has a diagnosis of type 2 diabetes mellitus and atherosclerotic cardiovascular disease (ASCVD) or heart failure, irrespective of metformin use~~
    c. Requests to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death must meet (i.) and (ii.)
        i. Confirmed diagnosis of type 2 diabetes mellitus
        ii. Documentation of chronic kidney disease is provided

6. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

~~1. Patient has contraindication for treatment~~

~~2.~~ The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

NOTE: There is a BOXED WARNING RISK OF THYROID C-CELL TUMORS. GLP-1 analogues are associated with thyroid cancer in patients with diabetes.

References:

1. Adlyxin [package insert]. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. July 2021.
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Gainwell Technologies/NJ MCO 1st Quarter 2025 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**104,527**	**111,606**	**88,941**	**989,777**	**351,503**	**181,222**
Total # of Pharmacy Claims Processed	**535,177**	**524,498**	**344,284**	**3,420,332**	**931,941**	**1,055,675**
Total # of Members Requesting Prior Authorization*	**1,760**	**3,477**	**2,506**	**21,379**	**8,517**	**6,230**
Total Prior Authorizations Requests Received**	**4,680**	**4,648**	**3,958**	**32,264**	**11,587**	**9,071**
Percentage of Claims Requiring Prior Authorization	**0.9%**	**0.9%**	**1.1%**	**0.9%**	**1.2%**	**0.9%**
Received Requests Denials**	**76 (2%)**	**2,326 (50%)**	**1,689 (42.7%)**	**10,365 (32.1%)**	**4,587 (39.6%)**	**3,817 (42.1%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	69 (91%)	810 (35%)	301 (18%)	3,651 (35%)	1,403 (31%)	1,193 (31%)
Excluded Benefit	7 (9%)	44 (2%)	5 (0%)	65 (1%)	217 (5%)	345 (9%)
Non-formulary	0 (0%)	1,472 (63%)	1,383 (82%)	6,649 (64%)	2,967 (65%)	2,279 (60%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	13.2%	1.2%	2.1%	3.6%	4.4%	2.8%
Antidepressants	0.0%	0.9%	0.7%	1.5%	1.0%	0.6%
Antihypertensives	0.0%	0.7%	0.8%	0.4%	0.4%	0.6%
Antianxiety	1.3%	0.3%	0.1%	0.2%	0.1%	0.1%
Antidiabetics (oral and insulin)	7.9%	17.5%	27.2%	21.9%	25.3%	16.7%
Anticoagulants	0.0%	0.1%	0.2%	0.1%	0.2%	0.1%
Thyroid agents	0.0%	0.4%	0.1%	0.3%	0.2%	0.1%
Ulcer Drugs/Antispasmodics/Anticholinergics	0.0%	1.8%	1.1%	2.2%	2.0%	0.7%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	19.1%	10.2%	4.9%	3.9%	10.9%
Antipsychotic/Antimanic agents	0.0%	1.2%	1.4%	3.5%	0.7%	1.8%
Antiasthmatic and Bronchodilator agents	9.2%	5.4%	3.4%	5.9%	8.2%	2.8%
Antivirals (includes both HIV and Hep C)	0.0%	0.2%	0.5%	0.4%	0.5%	0.4%
Digestive Aids (Digestive Enzymes)	2.6%	0.3%	0.4%	0.1%	0.0%	0.2%
Anticonvulsants	1.3%	0.9%	2.2%	1.1%	2.2%	1.0%
Migraine Products	2.6%	5.4%	3.4%	5.6%	4.4%	3.3%
Analgesics Anti-inflammatory	3.9%	1.8%	2.3%	2.9%	2.6%	1.5%
Analgesic Opioids	10.5%	4.8%	1.3%	1.2%	1.4%	5.4%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.3%	1.7%	1.2%	1.2%	2.4%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.8%	0.5%	0.7%	0.6%	0.8%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%	0.1%	0.0%	0.1%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	15.2%	13.3%	16.6%	11.1%	15.0%

* Value represents unduplicated data and will not include a member more than once, even if multiple requests are made. ** Denominator for percentage is Total Number of Pharmacy Claims Processed. *** See below for explanation of categories:

Clinical Criteria Not Met: includes categories such as Clinical Criteria Not Met, Drug-Drug Interaction, Therapeutic Duplication, Unacceptable Diagnosis. Excluded Benefit: includes categories such as Duration Exceeded, Excessive Dose, Mandatory Generic. Other: includes categories such as Directed Intervention, Multiple Pharmacies, Multiple Prescribers, Other DUR related rejections.

**** Denominator contains total drug prior authorization requests denied. Breakdown of Therapeutic Drug Classification categories is a sample of prior authorization claims data and is not inclusive of all drug classes. Denial percentages will not equal one hundred percent.

Summary of DURB Recommendations

July 16, 2025

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
April 2025	Proposed protocol for Attention Deficit Hyperactivity Disorder (ADHD) for children <6 years of old	• The Board recommended approval of the protocol with the suggested change to add "significant" prior to side effects to the continuation of therapy criteria #1	
	Proposed protocol for Zepbound®	• The Board recommended approval of the protocol	
	Proposed protocol for Spravato®	• The Board recommended approval of the protocol with the suggested change to add "appropriately" for monitoring the patient post treatment to the initial criteria # and continuation of therapy criteria #2	
January 2025	Proposed addendum to the protocol for Ingrezza® (valbenazine)	• The Board recommended the addendum to the protocol	
	Proposed protocol for Alopecia Areata products	• The Board recommended approval of the protocol with a suggested change to add "syphilis" to examples in criterion #3	Updated information was presented at the April 2025 meeting
	Proposed protocol for Lyfgenia™	• The Board recommended approval of the protocol with suggested addition of the black box warning	Updated information was presented at the April 2025 meeting
	Proposed protocol for Casgevy®	• The Board recommended approval of the protocol with the additional criteria for the product to be administered at a Qualified Treatment Center.	

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
			Updated information was presented at the April 2025 meeting
October 2024	Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products	• The Board recommended the addendum to the protocol	
	Proposed protocol for ileal bile acid transporter (IBAT) inhibitor products	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products	• The Board recommended the addendum to the protocol pending further clarification from the manufacturer, Genentech regarding age of eligibility	Information was provided at the January 2025 meeting
	Proposed Protocol for Winrevair® (sotatercept-csrk)	• The Board recommended the addendum to the protocol pending more information from specialists in the disease state	Will monitor and revisit any potential hindering criteria
July 2024	Proposed addendum to the protocol for Dupixent (dupilumab)	• The Board recommended the addendum to the protocol	

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec)	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Duchenne Muscular Dystrophy products	• The Board recommended the protocol with suggested changes to: - Criterion #5 to read: Medication is prescribed by or in consultation with a pediatric/adult neurologist, or a specialist who is an expert in the treatment of DMD and other neuromuscular disorders - Same as above for criterion #4 in the continuation of therapy section - Delete criterion #4 in the continuation of therapy section which referred to making patient's weight available	These changes were presented at the October 2024 meeting
	Proposed protocol for Qelbree (viloxazine)	• The Board recommended the protocol with suggested change to delete criterion #3 which required treatment failure with atomoxetine, clonidine, or guanfacine	This change was presented at the October 2024 meeting

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)	• The Board recommended the protocol	
April 2024	Proposed protocol for Ingrezza® (valbenazine)	• The Board recommended the protocol	
	Proposed protocol for Egrifta® (tesamorelin)	• The Board recommended the protocol with suggested change to delete criterion #4c (waist circumference)	Updated information was presented at the July 2024 meeting
	Proposed addendum to the protocol for Spinal Muscular Atrophy (SMA) products	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products	• The Board recommended the protocol suggested change to criterion #B3 to read: Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected	Updated information was presented at the July 2024 meeting
	Proposed addendum to Zurzuvae (zuranolone) protocol	• The Board recommended the protocol with suggestion to change criterion #3 to read: Medication is prescribed by or in consultation with an	Updated information was presented at the July 2024 meeting

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
		appropriate healthcare provider with planned follow up.	