NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

April 23, 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 January 15, 2025, meeting
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/January_2025_DURB_meeting_transcript_updated.pdf

IV. Review of draft meeting summary for January 15, 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 Alopecia Areata products (pages 13-14)
- C. Updated protocol for Lyfgenia™ (lovotibeglogene autotemcel) (page 15)
- D. Updated protocol for Casgevy® (exagamglogene autotemcel) (page 16)

VII. New Business
- A. Proposed protocol for Attention Deficit Hyperactivity Disorder (ADHD) for children < 6 years old (pages 17-18)
- B. Proposed protocol for Zepbound® (tirzepatide) (pages 19-20)
- C. Proposed protocol for Spravato® (esketamine) (pages 21-23)

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 4th Quarter 2024 Prior Authorization Report (page 24)
2. Summary of DURB Action Items (pages 25-28)
3. DHS/DOH Pharmacy Programs Top Drugs Report/Physicians Administered Drugs Report (by amount paid and by category)

FFS top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/FFS_Top_Drugs_Report_January_2025.pdf

MCO top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/MCO_Top_Drugs_Report_December_2024.pdf

FFS top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/FFS_Top_Drugs_by_Category_January_2025.pdf

MCO top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/MCO_Top_Drugs_by_Category_December_2024.pdf

FFS antiviral drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2025/FFS_Antiviral_Drugs_January_2025.pdf

B. Medication/Medical information

1. FDA Approved Journavx™ (suzetrigine), a first-in-class treatment for adults with moderate to severe acute pain

https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain

2. Update to American Diabetes Association Diabetes Guidelines

https://ada.silverchair-cdn.com/ada/content_public/journal/care/issue/48/supplement_1/6/standards-of-care-2025.pdf?Expires=1744317313&Signature=lhEzH38-q8CwB72XbawcXwo1Nkwh10P9B97JedemqjMG4Jifo6vV2~uGJKxEgijLegNRBRmR43C~zmSTpunG-WD1thcGPVzahNr7Wc7-1xDSm38gPAQOoQPcOmQsl4VeLEcR9JtWiCISiumCv5P9~HhZdD1orGatGgV3Ni5-60wfih2lgPQuq1O7HinJPQ~gQVZwfmfOLVsdQS0xSF-~4ql2buJf65cGAZJhnwB9yw~Z3tX06ZBNYS0IdJEyQL198-iEGZ5vKAuYqf4F~N-ZF78Mb2b8yWOZDqT7jnDUfpot2~X4lIrEC4TROL72iXqord7o1yqnoweg--AElCudhA__&Key-Pair-Id=APKAIE5G5CRDK6RD3PGA

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

https://urldefense.com/v3/__https:/www.novonordisk-us.com/media/news-archive/news-details.html?id=915253__;!!J30X0ZrnC1oQtbA!KBW7gFEFNm1h17y8nUdUNrmHBZBOLkcc0HpuDpaXfsHc8S9jSoDrnsUIVUlWSjr6ztXtsQrhUsUpwKqaOVE8U0tmpC4ZP31j4AnumYQkecBL$

4. Centers for Medicare & Medicaid Services (CMS) Infographic Released October 2024. 2024 Medicaid & CHIP Beneficiaries at a Glance: Attention Deficit/Hyperactivity Disorder

https://urldefense.com/v3/__https:/www.medicaid.gov/medicaid/benefits/downloads/2024-ADHD-infographic.pdf__;!!J30X0ZrnC1oQtbA!KBW7gFEFNm1h17y8nUdUNrmHBZBOLkcc0HpuDpaXfsHc8S9jSoDrnsUIVUlWSjr6ztXtsQrhUsUpwKqaOVE8U0tmpC4ZP31j4AnumfuJpeQo$

5. Centers for Disease Control and Prevention (CDC) – State Medicaid Policies Prescribing ADHD Medications to Children

https://urldefense.com/v3/__https:/www.cdc.gov/adhd/media/pdfs/fact-sheet-adhd-medicaid-policies.pdf__;!!J30X0ZrnC1oQtbA!KBW7gFEFNm1h17y8nUdUNrmHBZBOLkcc0HpuDpaXfsHc8S9jSoDrnsUIVUlWSjr6ztXtsQrhUsUpwKqaOVE8U0tmpC4ZP31j4Anumdj5hKgO$

January 15, 2025, DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Ms. Olson, Dr. Lind (ex-officio), Dr. Slim (ex-officio). Unable to attend: Dr. Barberio 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 first annual meeting of the Board: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the following filings: • On January 6, 2025, it was posted to the DHS/DMAHS website and published in the NJ Register at 54 N.J.R. 2410(a) • On December 17, 2024, it was published in the Atlantic City Press, the Bergen Record, the Camden Courier Post, the Newark Star-Ledger, and the Trenton Times. • It was sent to the Local Medical Assistance Customer Centers and County Social Service Agencies to be posted in an area accessible to both employees and the general public. • It was also sent to the Statehouse Press Office
Review of Minutes	Approved	Minutes from October 16, 2024, 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 department is working with the Commissioners to review and sign off on DURB-recommended protocols for July and October 2024 meetings. - The DURB annual report for SFY 2024 was updated with feedback received from Board members and will be sent to the Commissioners for review and sign off.

Issue	Action	Notes
		- Response from Genentech to the Board's question from the October 2024 meeting regarding the age limit for PiaSky® was discussed.
Old Business		
(A) Utilization Trends of Bupropion, GLP-1/GIP Agonists, SGLT-2 Inhibitors, and CGRP Inhibitors	Continue to monitor	The Board reviewed utilization reports for bupropion, GLP-1/GIP agonists, SGLT-2 inhibitors and CGRP inhibitors. Dr. Swee requested ongoing reports to monitor utilization for GLP-1/GIP agonists, SGLT-2 inhibitors, and CGRP inhibitors. Ms. Olson expressed satisfaction in the way the reports were created.
(B) Expansion of Antidiabetic Denials	Continue to monitor	The Board reviewed a detailed Medicaid MCOs antidiabetic drugs denials report for the second quarter (April- June) of 2024. Dr. Elizabeth Bailey, with the State's Pharmacy unit, called attention to a typo under Horizon's section, missing incomplete information, the correct number is 444. Dr. Swee emphasized the importance of the report shared and requested the Board continue to monitor.
(C) Examples of Clinical Criteria Not Met Denials (Antidiabetics)		The Board reviewed examples of clinical criteria not met denials for antidiabetic agents. This information was previously requested by the Board to review the disparity of denials among the MCOs. Dr. Bailey explained that not all the MCOs distinguish their denied claims between clinical criteria not met and incomplete information. Dr. Swee expressed concern with the potential that some of the incomplete information denials may be due to the MCOs not contacting the appropriate caregiver or poor communication with the provider.
New Business		
(A) Proposed addendum to the protocol for Ingrezza® (valbenazine)	Recommended	The Board reviewed a proposed addendum to the protocol for Ingrezza® (valbenazine). The two major updates were to include all vesicular monoamine transporter 2 (VMAT2) inhibitors used in the treatment of tardive dyskinesia and Huntington's chorea and remove the prescriber restriction. The two new additional products are Austedo® (deutetrabenazine) and Xenazine® (tetrabenazine). The Board recommended approval of the protocol.
(B) Proposed protocol for Alopecia Areata products	Recommended	The Board reviewed a proposed protocol for alopecia areata. Dr. Marcus recommended adding syphilis to the examples listed in criterion number three due to its increased incidence. Dr. Jihad Slim concurred with Dr. Marcus' recommendation. The Board recommended approval of the protocol.

Issue	Action	Notes
(C) Proposed protocol for Lyfgenia™ (lovotibeglogene autotemcel)	Recommended and continue to monitor	The Board reviewed a proposed protocol for Lyfgenia™ (lovotibeglogene autotemcel), a product indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. Dr. Marcus recommended offline to add the black box warning to the protocol. Dr. Swee expressed concern about the difference in the number of vaso-occlusive events (VOEs) between Lyfgenia and Casgevy which potentially may be due to the inclusion criteria of the clinical studies. Dr. Swee requested to reevaluate approval criteria for this protocol if requests are received below the recommended number of VOEs. The Board recommended approval of the protocol pending the addition of the black box warning.
(D) Proposed protocol for Casgevy® (exagamglogene autotemcel)	Recommended and continue to monitor	The Board reviewed a proposed protocol for Casgevy® (exagamglogene autotemcel), another product indicated for the treatment of sickle cell disease with recurrent vaso-occlusive crises or transfusion-dependent β-thalassemia. The Board recommended offline to add the criterion for the product to be administered at a Qualified Treatment Center. Dr. Dalia Hanna addressed a panel member's offline inquiry about why the Casgevy protocol did not require the product to be administered at a Qualified Treatment Center like the protocol for Lyfgenia. This criterion will be added to the protocol. Dr. Swee requested to monitor requests and utilization for Lyfgenia and Casgevy. The Board recommended approval of the protocol with the additional criteria for the product to be administered at a Qualified Treatment Center.
DURB Annual Report	Approved	Dr. Hanna expressed appreciation for the feedback and updates received from the Board concerning the DURB Annual Report for SFY 2024. She explained the department will be sending the report to the Commissioners for their review and sign-off. The Board will be notified when the report is published in the State Register. Dr. Swee also requested the Board be notified if there are any updates to the report as a result of the Commissioners' review.
Informational Highlights/Reports		

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor</td><td>The Board reviewed the 3rd Quarter 2024 prior authorization (PA) denial report for FFS and MCOs.

Dr. Swee mentioned new PA regulations effective 1/1/2025, to improve timing of decisions for PA requests. He expressed concerns about the high rate of denials for ADHD medications. Dr. Marcus explained the disparity in percentages related to ADHD medications could potentially be associated with the MCOs formulary coverage of these products.

Dr. Hanna suggested restructuring this denial report to assist the Board with their review and oversight of FFS and MCO denials. Dr. Swee suggested continuing to review the top therapeutic categories and the activity associated with those denials.</td></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (January 2024 thru October 2024). Dr. Swee expressed his appreciation to the department for their quick turnaround to the Board’s requests.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for November 2024 (FFS) and October 2024 (MCOs) was provided for review.
Drug expenditures during the reporting period is noted below:

<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>November 2024</td><td>$ 2,388,384*</td><td>$ 2,704,425*</td></tr>
<tr><td>MCOs</td><td>October 2024</td><td>$ 115,966,998</td><td>$ 164,917,315</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
</table>

Dr. Swee commented on the cost of insulin regardless of the government efforts to reduce their costs. He also inquired about what percentage is the MCOs total spend for drugs from their total expenditures. Dr. Thomas Lind indicated he would need to obtain this information from the State’s fiscal department.</td></tr>
</table>

Issue	Action	Notes
4. Medication Information		Medical information was provided with links for further reading on the topics below: 1. Scripts for GLP-1, SGLT2 Drugs on the Rise in Type 1 Diabetes Patients 2. Old Drugs, New Tricks: The Power of Medication Repurposing 3. Real-World Study Confirms RSV Vaccine's, Arexvy and Abrysvo, Protective Power for Seniors 4. Shorter Course of Antibiotics Works for Bloodstream Infections 5. Study: OUD Patients More Likely to Stay on Methadone Than Buprenorphine/Naloxone 6. Cephalosporin May Hold Potential for Early Syphilis Dr. Swee commented that the CDC released new guidelines regarding syphilis. Dr. Slim confirmed the guidelines were for the use of doxycycline for postexposure prophylaxis which has helped slow down the rate of incidences.
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 by therapeutic categories 4. Provide the percentage of MCOs total drug expenditure

Secretary's Report

New Jersey Drug Utilization Review Board
April 23, 2025

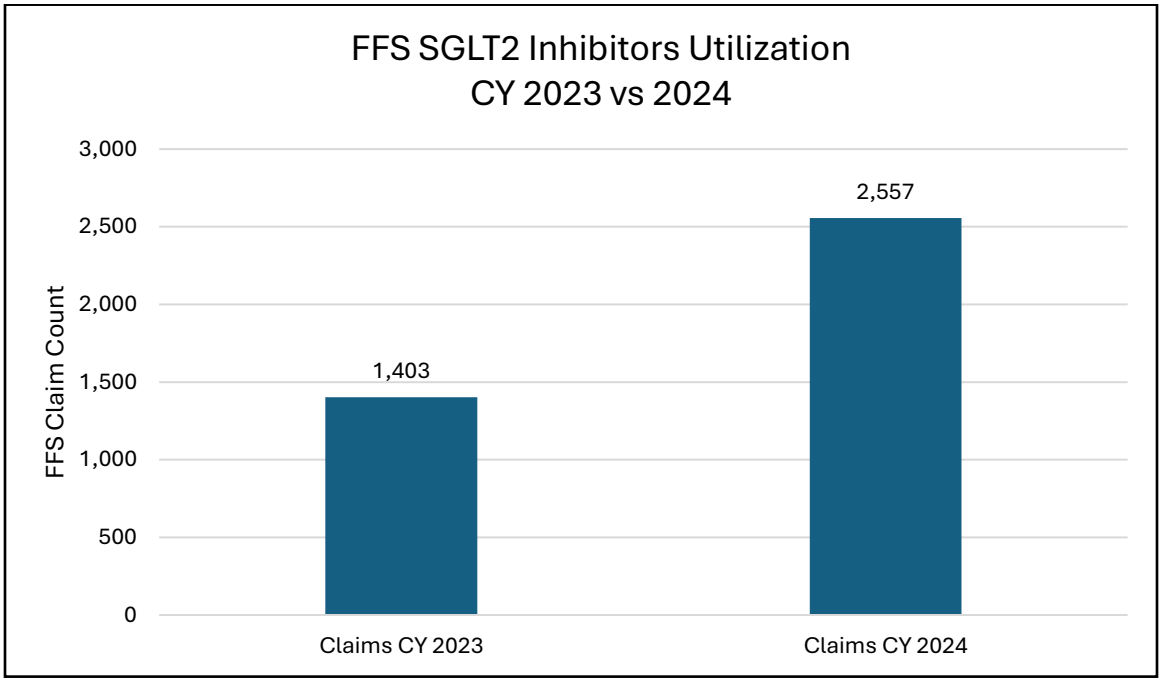
1. The Commissioners have signed off on the DURB-recommended protocols from July 2024, October 2024, and January 2025.

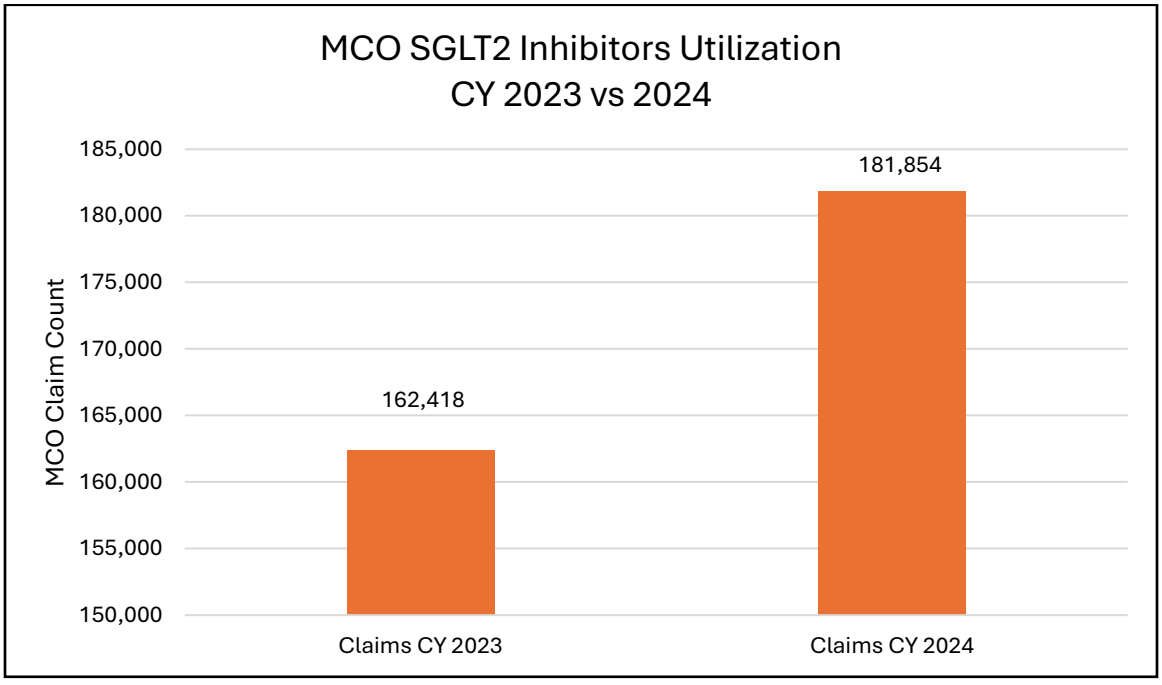
2. The Department is working with the Commissioners to review and sign off on the SFY 2024 Annual Report.

3. Follow up to question from DURB: At the January 2025 DURB meeting, the DURB asked for the percentage of the MCOs' total drug expenditure. According to the State's fiscal unit, the MCOs total spending for the pharmacy benefit is 15.2%.

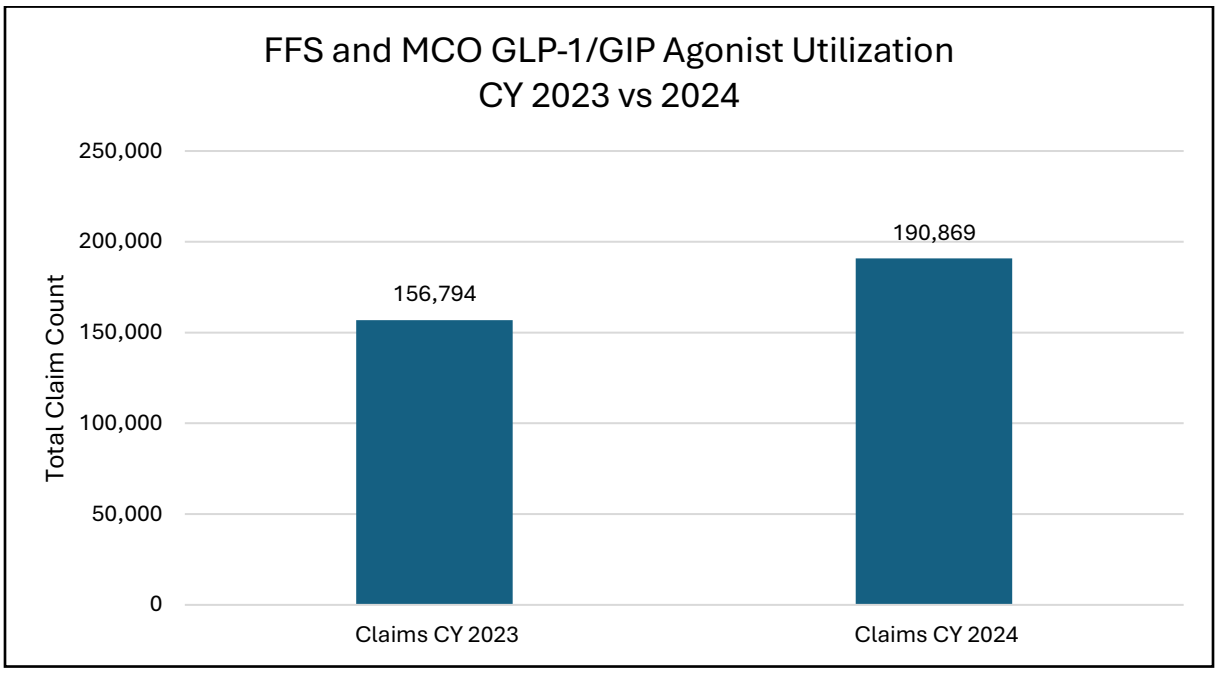
Utilization Trends (April 2025)

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors Utilization

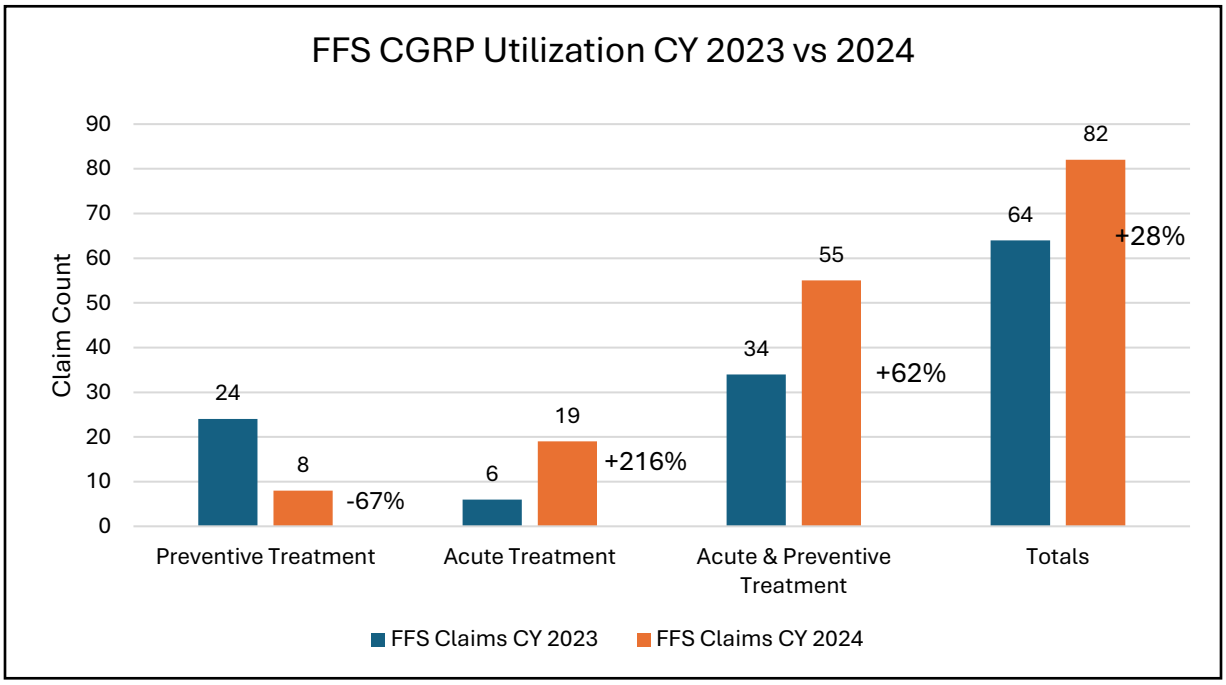




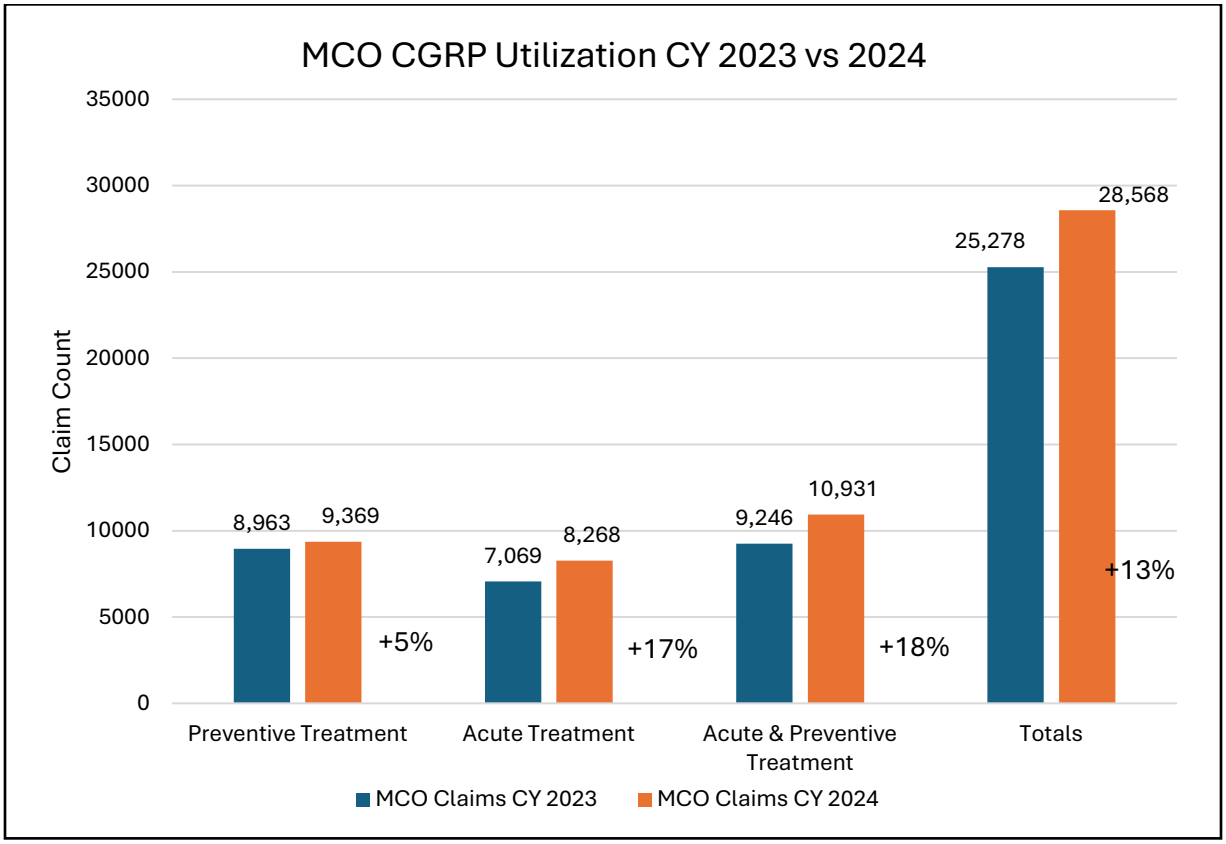
Utilization of Glucagon-like peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-dependent Insulinotropic Polypeptide (GIP) Agonist for Diabetes Mellitus



Utilization of Calcitonin Gene-Related Peptide (CGRP) Inhibitors



Utilization of Calcitonin Gene-Related Peptide (CGRP) Inhibitors



Proposed Protocol for Alopecia Areata Products
Approved January 2025

Litfulo™ (ritlecitinib)
Olumiant® (baricitinib)
Leqselvi™ (deuruxolitinib)

Background:
Alopecia areata is a chronic, relapsing, immune-mediated, inflammatory disorder that affects hair follicles and results in nonscarring hair loss. The severity of the disorder ranges from small patches of alopecia on any hair-bearing area to the complete loss of scalp, eyebrow, eyelash, and body hair.

Criteria for Approval:

1. Patient meets the FDA-approved or compendial supported age for the product being requested

2. Patient has a diagnosis of severe alopecia areata

3. Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, tinea capitis, triangular alopecia, trichotillomania, and syphilis)

4. Prior to initiation of therapy, recommended laboratory monitoring is done as indicated by the appropriate prescribing information (e.g. complete blood count with differential white count and platelet count, liver function tests, pregnancy screening, etc.)

    a. Screening for latent tuberculosis, hepatitis B (including testing for hepatitis B virus [HBV] surface antigen and HBV core antibody), and hepatitis C virus (HCV)

5. Patient has no contraindication to therapy

6. Patient is not using or planning to use in combination with other JAK inhibitors, biologic immunomodulators or potent immunosuppressants (e.g., azathioprine, cyclosporine)

7. Initial prescription is written by or in consultation with a dermatologist or another appropriate specialist

8. 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

Continuation of therapy:

1. Documentation of positive clinical response to therapy

2. Patient is not using or planning to use in combination with other JAK inhibitors, biologic immunomodulators or potent immunosuppressants (e.g., azathioprine, cyclosporine)

3. Patient is routinely monitored for possible complications are referenced in the prescribing information

NOTE: Black box warnings exist for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis

References:

1. Litfulo™ [packet insert] Pfizer Labs Division of Pfizer Inc. New York, NY 10001. June 2023
2. Olumiant® [packet insert] Lilly USA, LLC Indianapolis, IN 46285. May 2022
3. Shawky AM, Almalki FA, Abdalla AN, Abdelazeem AH, Gouda AM. A Comprehensive Overview of Globally Approved JAK Inhibitors. Pharmaceutics. 2022 May 6;14(5):1001
4. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically
5. Messenger AG. Alopecia Areata: Management. UpToDate November 2, 2023. Accessed online 11.4.24 @ https://www.uptodate.com/contents/alopecia-areata-management?csi=aa393cbe-625a-4f90-a3f7-2c8bad50fef8&source=contentShare
6. Bolduc C. Alopecia Areata Treatment & Management. June 27, 2023. Medscape Dermatology. Accessed online September 18, 2023 at: https://emedicine.medscape.com/article/1069931-treatment

Proposed Protocol for Lyfgenia™ (lovotibeglogene autotemcel)

Approved January 2025

Background:

Lyfgenia™ is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.

Criteria for approval:

1. Diagnosis has been confirmed by genetic testing
2. Patient has had a failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past
3. Patient is ≥ twelve (12) years of age at the expected time of gene therapy administration
4. Patient is clinically stable for transplantation
5. Medication is prescribed by or in consultation with a board-certified hematologist with SCD expertise
6. Patient's treatment center is a Qualified Treatment Center for the product
7. Either a or b (based on provider attestation):
    a. Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); or
    b. Experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the patient's treating clinician
8. Any prior authorization, once approved, will be valid for at least twelve (12) months

NOTE: Black box warnings exist for hematologic malignancy. Patients should be monitored closely for evidence of malignancy through complete blood counts.

References:

1. Lyfgenia™ [package insert]. Somerville, MA: bluebird bio, Inc.; December 2023

Protocol for Casgevy® (exagamglogene autotemcel) for Sickle Cell Disease
Approved January 2025

Background:

Casgevy® is an autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of patients aged 12 years and older with: (a) sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or (b) transfusion-dependent β-thalassemia (TDT).

Criteria for approval:

1. Diagnosis has been confirmed by genetic testing
2. Patient has prior use of, or intolerance to hydroxyurea (per health care professional judgement) at any point in the past
3. Patient is ≥ twelve (12) years of age
4. Patient is clinically stable for transplantation
5. Medication is prescribed by or in consultation with a board-certified hematologist with SCD expertise
6. Patient's treatment center is a Qualified Treatment Center for the product
7. Patient has experienced recurrent vasooclusive crisis VOCs (defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation)
8. Any prior authorization, once approved, will be valid for at least twelve (12) months

References:

1. Casgevy® [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024

Proposed Protocol for ADHD Stimulant Treatment in Children Under 6 Years of Age

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's age is between a 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 all of the following comorbid conditions:

    a. Emotional or behavioral conditions (e.g., anxiety, depression, oppositional defiant disorder, conduct disorders, substance use)
    b. Developmental conditions (e.g., learning and language disorders, autism spectrum disorders)
    c. Physical conditions (e.g., sleep apnea, tics)

5. Attestation that Parent Training in Behavior Management (PTBM) and/or behavioral classroom intervention has been attempted as primary intervention, 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 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)

Proposed Protocol for Zepbound® (tirzepatide) for Obstructive Sleep Apnea (OSA)
April 2025

Background:

Zepbound® is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Criteria for Approval:

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

2. Patient does not have any contraindications to Zepbound

3. Patient has a documented diagnosis of moderate to severe obstructive sleep apnea (OSA) shown by an apnea-hypopnea index (AHI) ≥ 15 respiratory events per hour of sleep within the past 12 months

4. Documentation is provided that the patient has a body mass index (BMI) ≥30 kg/m^2

5. The medication is used in combination with a reduced-calorie diet and increased physical activity

6. Patient is not utilizing another GLP-1 receptor agonist or tirzepatide-containing products

Continuation of therapy:

1. Patient is responding positively to therapy at optimal dosage

2. Patient is not utilizing another GLP-1 receptor agonist or tirzepatide-containing products

References:

1. Zepbound® [package insert]. Lilly; 2024. Accessed January 28, 2025
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Epstein LJ, Kristo D, Strollo PJ, et al. Adult obstructive sleep apnea task force of the American Academy of Sleep Medicine: Clinical guideline for the evaluation,

management, and long-term care of obstructive sleep apnea in adults. Journal of Clinical Sleep Medicine 2009. 5(3): 263-276.
4. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. Journal of Clinical Sleep Medicine 2017. 13(3):479-504.
5. Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. Journal of Clinical Sleep Medicine 2019. 15(2): 335-343.
6. Hudgel DW, Patel SR, Ahasic AM, et al. The role of weight management in the treatment of adult obstructive sleep apnea. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2018 Sep 15;198(6):e70-e87.

Proposed Addendum to Protocol for Spravato® (esketamine) Nasal Spray
April 2025

DURB Approval Date	**7/2020, 1/2022**
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 ~~will be~~ administered under the supervision of a healthcare provider and the patient ~~member~~ ~~must~~ is going to be 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. ~~For~~ Treatment-resistant depression is defined by the patient having ~~must have~~ documentation demonstrating ~~showing that the member patient~~ ~~had~~ a therapeutic failure of ~~or intolerance to~~ at least two (2) different classes of antidepressants at optimal therapeutic dosages each for a minimum of ~~3~~ 4 weeks unless the patient has contraindications to all antidepressants

7. For the diagnosis of MDD with suicidal ideation or behavior, patient ~~must use~~ 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 ~~must use~~ 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 ~~will be~~ administered under the supervision of a healthcare provider and the patient ~~member~~ ~~must be~~ is going to be 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.

Gainwell Technologies/NJ MCO 4th Quarter 2024 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**105,168**	**108,472**	**88,356**	**970,029**	**347,184**	**184,295**
Total # of Pharmacy Claims Processed	**485,512**	**508,471**	**161,919**	**3,374,970**	**911,218**	**1,020,921**
Total # of Members Requesting Prior Authorization*	**1,807**	**3,192**	**2,361**	**20,226**	**7,345**	**5,742**
Total Prior Authorizations Requests Received**	**4,464**	**4,154**	**3,785**	**30,896**	**10,090**	**8,273**
Percentage of Claims Requiring Prior Authorization	**0.9%**	**0.8%**	**2.0%**	**0.9%**	**1.1%**	**0.8%**
Received Requests Denials**	**80 (2%)**	**1,984 (48%)**	**1,570 (41%)**	**9,628 (31%)**	**4,450 (44%)**	**3,507 (42%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	68 (85%)	640 (32%)	285 (18%)	3,485 (36%)	1,377 (31%)	1,166 (33%)
Excluded Benefit	12 (15%)	79 (4%)	7 (0.5%)	69 (1%)	235 (5%)	361 (10%)
Non-formulary	0 (0%)	1,265 (64%)	1,278 (81%)	6,074 (63%)	2,838 (64%)	1,980 (56%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	7.5%	2.3%	2.6%	3.4%	4.1%	3.0%
Antidepressants	2.5%	1.5%	0.6%	1.5%	1.1%	0.8%
Antihypertensives	2.5%	1.6%	0.2%	0.7%	0.4%	0.5%
Antianxiety	0.0%	0.1%	0.0%	0.2%	0.1%	0.2%
Antidiabetics (oral and insulin)	15.0%	15.1%	28.1%	22.1%	23.5%	12.7%
Anticoagulants	0.0%	0.2%	0.2%	0.1%	0.4%	0.0%
Thyroid agents	0.0%	0.2%	0.1%	0.4%	0.5%	0.0%
Ulcer Drugs/Antispasmodics/Anticholinergics	0.0%	2.2%	1.2%	2.5%	2.2%	0.9%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	1.3%	15.7%	8.0%	4.3%	4.2%	9.9%
Antipsychotic/Antimanic agents	2.5%	1.9%	2.4%	3.5%	0.8%	1.9%
Antiasthmatic and Bronchodilator agents	13.8%	4.8%	3.7%	6.3%	8.6%	3.2%
Antivirals (includes both HIV and Hep C)	0.0%	0.5%	0.4%	0.7%	0.5%	0.4%
Digestive Aids (Digestive Enzymes)	2.5%	0.7%	0.1%	0.1%	0.0%	0.1%
Anticonvulsants	0.0%	2.4%	2.0%	1.5%	1.9%	1.4%
Migraine Products	1.3%	5.1%	2.9%	4.9%	5.2%	3.8%
Analgesics Anti-inflammatory	8.8%	2.0%	3.4%	4.2%	2.0%	1.4%
Analgesic Opioids	6.3%	5.2%	0.8%	1.2%	2.1%	6.1%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.6%	2.0%	1.3%	1.2%	2.3%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.2%	1.3%	0.8%	0.6%	1.1%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%	0.0%	0.0%	0.0%	0.1%
Dermatologics (Antipsoriatics-Systemic)	0.0%	14.4%	13.3%	14.4%	12.6%	13.9%

* 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

April 23, 2025

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
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	
	Proposed protocol for Lyfgenia™	• The Board recommended approval of the protocol with suggested addition of the black box warning	
	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.	
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	

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	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	
	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:	These changes were presented at the October 2024 meeting

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
		- 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	
	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
	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

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	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 appropriate healthcare provider with planned follow up.	Updated information was presented at the July 2024 meeting