New Jersey Drug Utilization Review Board
Virtual Platform
October 22, 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 July 16, 2025, meeting https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2025/July-2025_DURB_Meeting_Transcript.pdf

IV. Review of draft meeting summary for July 16, 2025, meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
   - A. Utilization Trends of SGLT-2 inhibitors (pages 9-10)
   - B. Utilization Trends of GLP-1/GIP Agonists (pages 11-12)
   - C. Updated Protocol for Imcivree® (pages 13-15)
   - D. Updated Protocol for Chimeric Antigen Receptor (CAR) T Cell Products (pages 16-19)
   - E. Updated Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products (pages 20-22)

VII. New Business
   - A. Proposed Addendum to Protocol for Biologics in Moderate to Severe Asthma (pages 23-25)
   - B. Proposed Addendum to Protocol for Dupixent® (pages 26-30)
   - C. Proposed Addendum to Protocol for Hereditary Angioedema (pages 31-33)
   - D. Proposed Addendum to Protocol for Wegovy® (pages 34-36)

VIII. A. Informational Highlights/Reports

1. Gainwell Technologies/NJ MCO 2nd Quarter 2025 Prior Authorization Report (page 37)
2. Summary of DURB Action Items (pages 38-42)
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/10-2025/FFS_Top_Drugs_Report_July-2025.pdf

MCO top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2025/MCO_Top_Drugs_Report_June-2025.pdf

FFS top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2025/FFS_Top_Drugs_by_Category_July-2025.pdf

MCO top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2025/MCO_Top_Drugs_by_Category_June-2025.pdf

FFS antiviral drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2025/FFS_Antiviral_Drugs_July-2025.pdf

B. Medication/Medical information

American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults With Dyslipidemia - Endocrine Practice

New AACE 2025 Dyslipidemia Management Guidelines Released – Top 7 Takeaways

https://www.jacc.org/doi/10.1016/j.jacc.2025.05.007?_gl=1*1uisott*_ga*NTM2MjMwMTIuMTc1NTYxNjMwMw..*_ga_2V8VW4Y237*czE3NTU2MTYzMDIkbzEkZzEkdDE3NTU2MTYzNDYkajE2JGwwJGgw

July 16, 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), Dr. Slim (ex-officio) Unable to attend: 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 April 23, 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 the April 2025 meeting. - 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 April 2025 meeting pertaining to tianeptine use in the Medicaid population, the Department informed the Board there is no utilization for this drug based on claims data. The drug is not approved in the United States.
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 receptor agonists and GLP-1/GIP agonists, SGLT-2 inhibitors and CGRP inhibitors. Dr. Swee requested the utilization trends be presented in a different format to better display the differences. Dr. Agrawal stated the Department will work on changing how the utilization trend information is presented.

Issue	Action	Notes
(B) Updated Protocol for Attention-Deficit Hyperactivity Disorder (ADHD) for Children <6 years old		The Board reviewed an updated version of the Attention-Deficit Hyperactivity Disorder (ADHD) for Children <6 years old protocol with the recommended addition of the word significant to the continuation of therapy criteria pertaining to side effects. There was no further discussion.
(C) Updated Protocol for Spravato® (esketamine)		The Board reviewed an updated version of the Spravato® (esketamine) protocol. Dr. Swee recommended updating the monitoring criteria post administration with the addition of the word appropriately. There was no further discussion.
New Business		
(A) Updated Protocol for Transthyretin-mediated Amyloidosis (ATTR) Products	Recommended	The Board reviewed a proposed addendum to the protocol for the ATTR products. The update added Attruby®, a new drug approved by the Food and Drug Administration (FDA). In addition, the protocol was updated to include a new indication for Amvuttra®. The Board recommended approval of the protocol.
(B) Updated Protocol for Imcivree® (setmelanotide)	Recommended	The Board reviewed a proposed addendum to the protocol for Imcivree. The criteria was updated to allow use in patients 2 years of age and older and the Centers for Disease Control and Prevention (CDC) definition of obesity was included. In addition, Dr. Swee recommended the continuation of therapy criteria be updated with the removal of a specific percentage reduction in body mass index (BMI) and be replaced to accept any reduction in BMI in one year compared to baseline BMI. The Board recommended approval of the protocol with the suggested update.
(C) Updated Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products	Recommended	The Board reviewed a proposed addendum to the PNH products protocol. The continuation of therapy criteria was updated to include decrease or normalization in reticulocyte count from pre-treatment level. In addition, the absence of unacceptable toxicity from the drug criteria was removed as it does not assess response to PNH treatment. Dr. Agrawal stated protocols for biologic drugs will also cover respective biosimilars and their related indications and dosages. The Board recommended approval of the protocol.

Issue	Action	Notes
(D) Updated Protocol for Chimeric Antigen Receptor (CAR) T Cell Products	Recommended	The Board reviewed a proposed addendum to the protocol for CAR T Cell products. In June 2025, the FDA no longer requires the Risk Evaluation and Mitigation Strategies (REMS) for CAR T cell drugs. The protocol was updated to remove the REMS criteria. The protocol was updated to include the statement covering biosimilars and their related indications and dosages for their respective reference biologic drugs. Jay Patel a pharmacist with Bristol Myers Squibb stated Abecma labeling was updated from trial of four or more prior lines of therapy to trial of at least two prior lines of therapy. The protocol criteria was updated to at least two prior lines of therapy for Abecma. The Board recommended approval of the protocol with the updated information Dr. Jay Patel provided.
(E) Updated Protocol for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) and GLP-1RA/Glucose-Dependent-Insulinotropic-Polypeptide (GIP) Agonists for Type 2 Diabetes	Recommended	The Board reviewed a proposed addendum to the protocol for GLP-1RA and GLP-1RA/GIP products. The protocol was updated to include the statement covering biosimilars and their related indications and dosages for their respective reference biologic drugs. The following two indications were added to the protocol: reduce the risk of major adverse cardiovascular events and reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-state kidney disease and cardiovascular death. The criteria pertaining to these two indications are aligned with the updated 2025 Diabetes Guidelines. Discussion took place around the need for including the statement for coverage of biosimilars and contraindications criteria in each protocol. Dr. Swee questioned if the type of documentation required for requests to reduce the risk of sustained eGFR and kidney disease would be an attestation from the physician. Pinali Agrawal stated the documentation would need to include labs showing the patient has chronic kidney disease. Similarly in response to Dr. Swee regarding the requirement to obtain A1c levels, Pinali Agrawal stated the A1c would be collected for initial requests only for documentation of a diabetes diagnosis. Dr. Swee asked to confirm if the criteria is still requiring trial of metformin despite the American Diabetes Association's (ADA) recommendation that patients do not need to start with metformin therapy. Pinali Agrawal stated the metformin criteria still applies. The Board recommended approval of the protocol.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor</td><td>The Board reviewed the 1st Quarter 2025 prior authorization (PA) denial report for FFS and MCOs. Dr. Swee stated Fidelis' denial percentage for the non-formulary category is an outlier when compared to the other MCOs. The Department is working with Fidelis to identify reasons for the outlying denial percentages. Dr. Swee mentioned the denials in the clinical criteria not met category is worrisome as it can include requests where prescribers did not respond with the appropriate clinical information. Pinali Agrawal stated clinical criteria not met category can include any of the following: missing information, missing diagnosis, not an approved indication, off-label use not supported by the compendia, duplicate therapy, and drug-drug interaction.</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 (April 2025). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols through April 2025.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for April 2025 (FFS) and March 2025 (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 for All Drugs</th></tr>
<tr><td>FFS</td><td>April 2025</td><td>$ 2,450,955*</td><td>$ 2,733,071*</td></tr>
<tr><td>MCOs</td><td>March 2025</td><td>$ 82,146,911</td><td>$117,827,004</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. Swee stated drugs like insulin are surprisingly always at the top of the list based on amount paid. Dr. Barberio stated buprenorphine-naloxone is required to be prescribed if a patient is receiving an opioid or a benzodiazepine and that is why this drug is seen on the top drugs list.</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:</td></tr>
</table>

Issue	Action	Notes
		1. Discontinuation glucagon-like peptide-1 receptor agonists and body habitus: A systemic review and meta-analysis 2. Antiretroviral postexposure prophylaxis after sexual, injection drug use or other nonoccupational exposure to HIV-CDC recommendations, United States, 2025 3. Genitourinary syndrome of menopause: AUA/SUFU/AUGS guideline 2025 4. Phase 3 trial of semaglutide in metabolic dysfunction-associated steatohepatitis
Follow-up items:		1. Update utilization charts and continue to monitor

Secretary's Report

New Jersey Drug Utilization Review Board
October 22, 2025

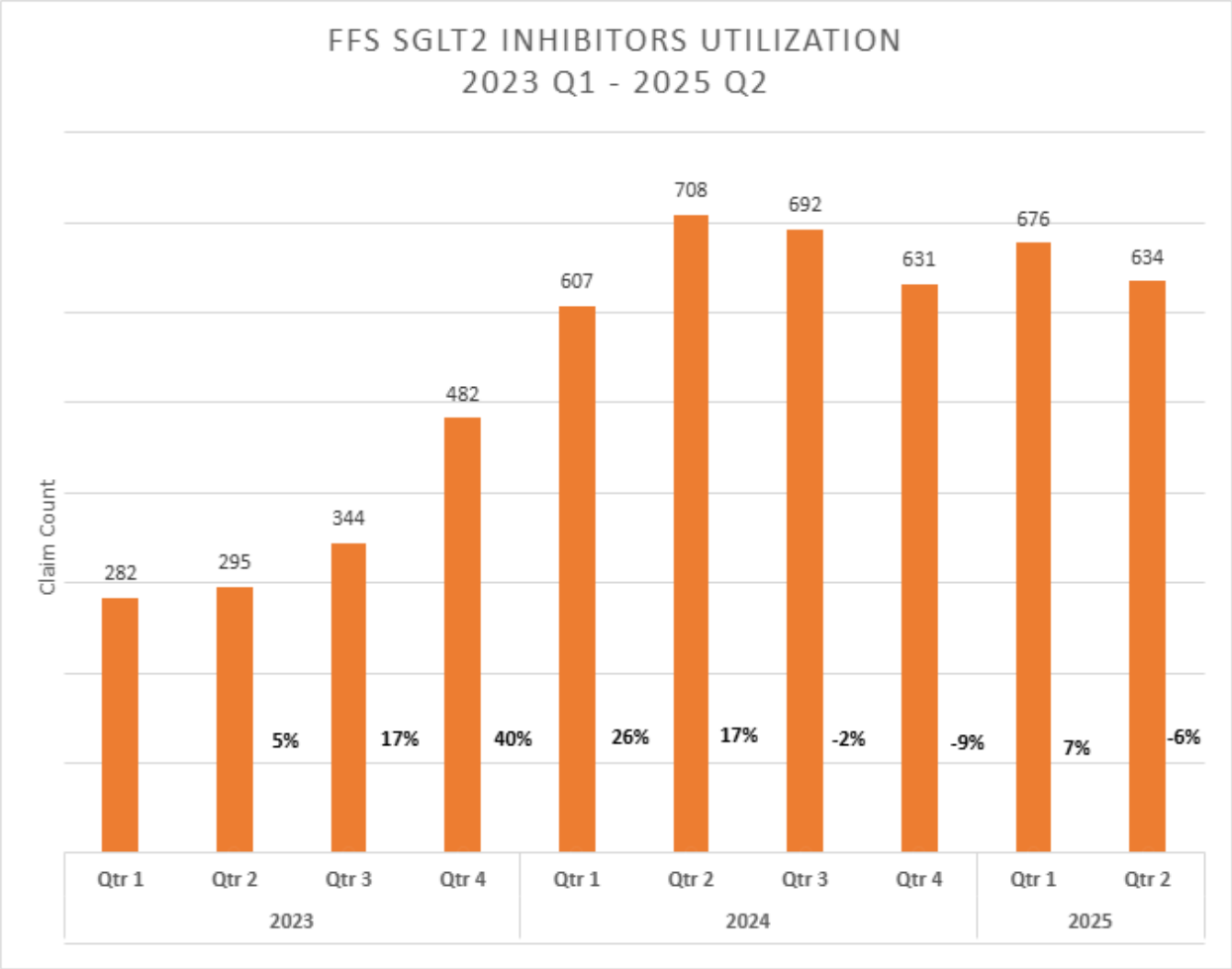
1. The Department is working with the Commissioners to review and sign-off on the July 2025 DURB recommended protocols

2. DURB Meeting Dates in 2026:
   Wednesday, January 28, 2026
   Wednesday, April 2026 - TBD
   Wednesday, July 15, 2026
   Wednesday, October 21, 2026

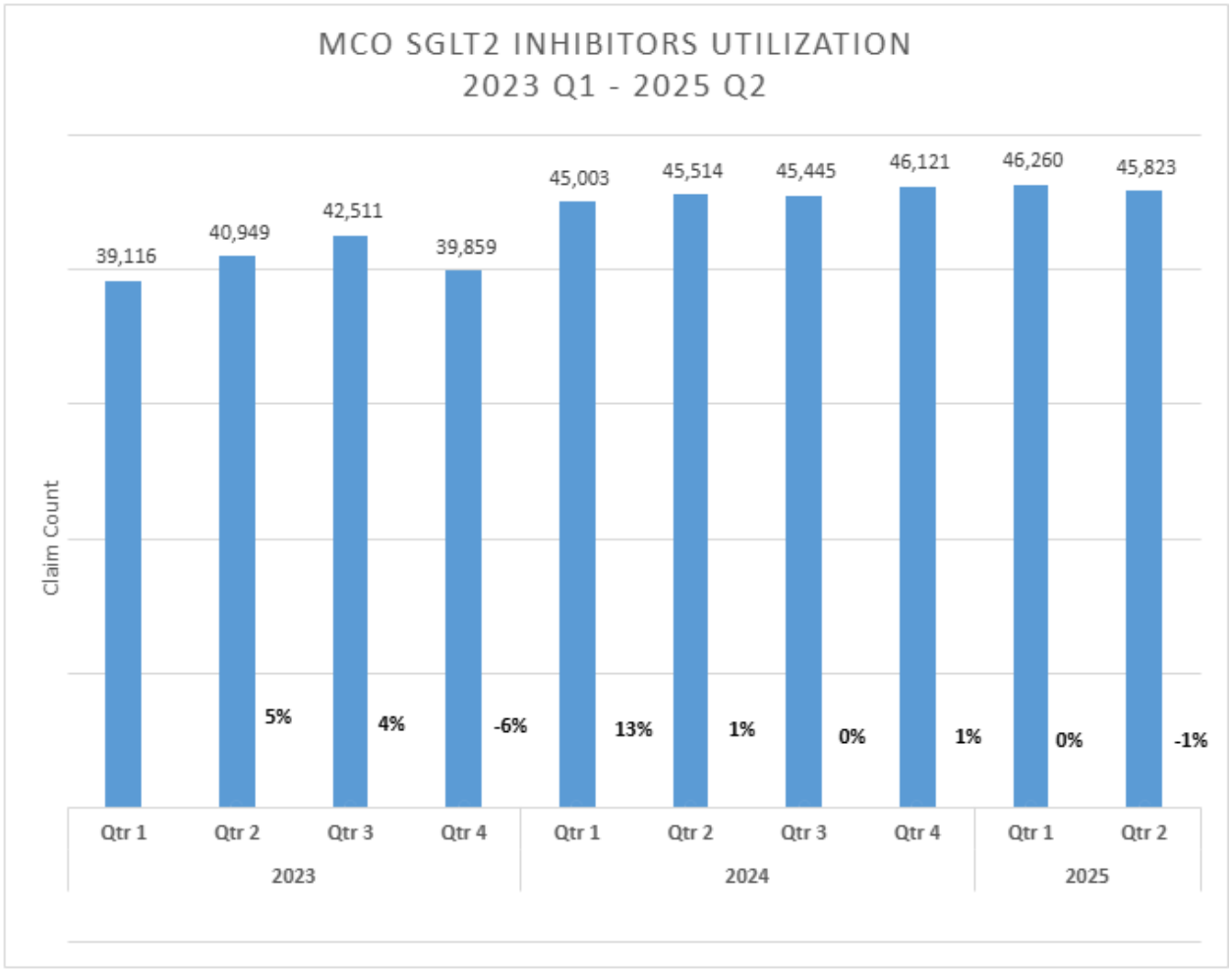
3. The Department does not have any new updates for the Board's positions

Utilization Trends

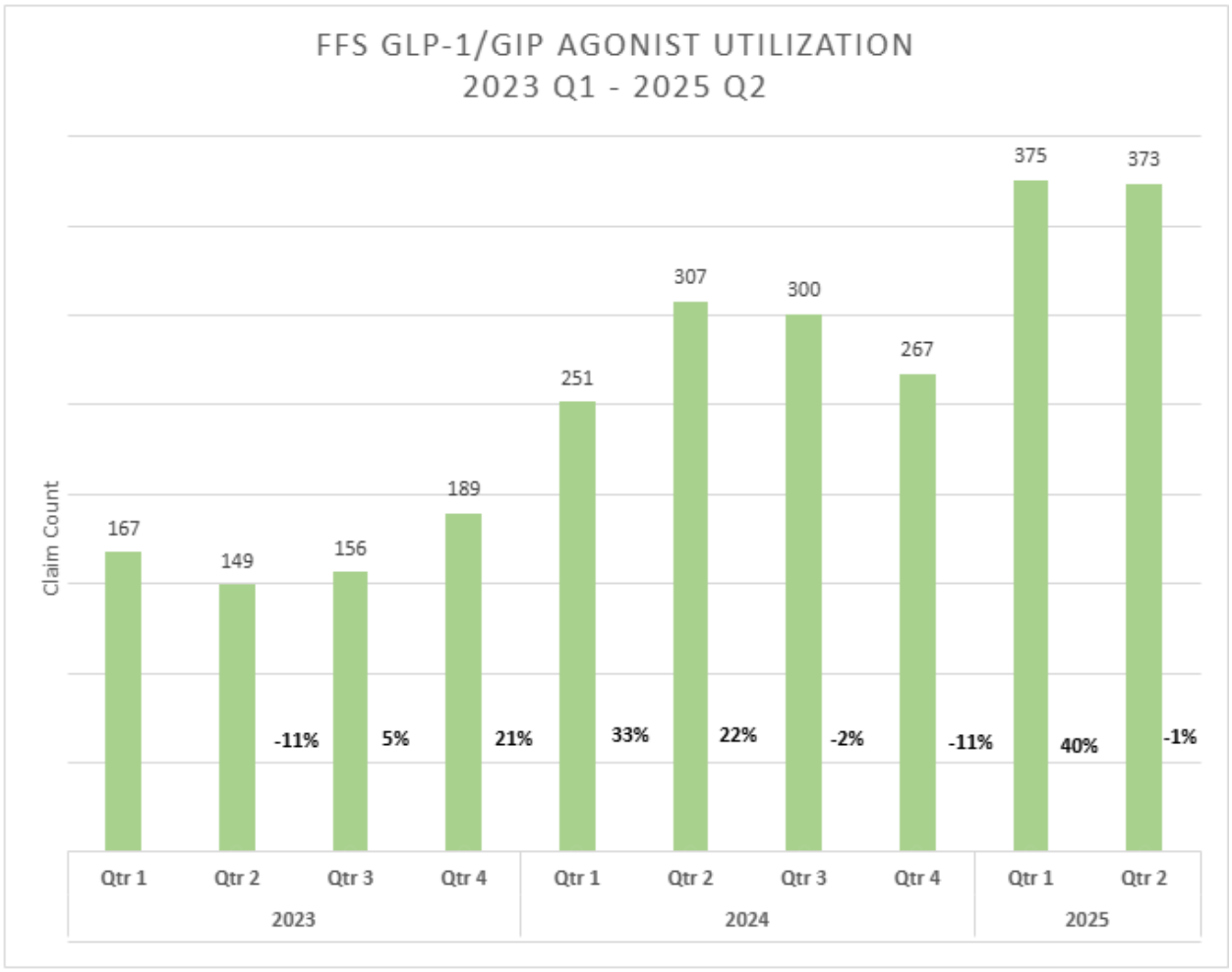
FFS Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors Utilization



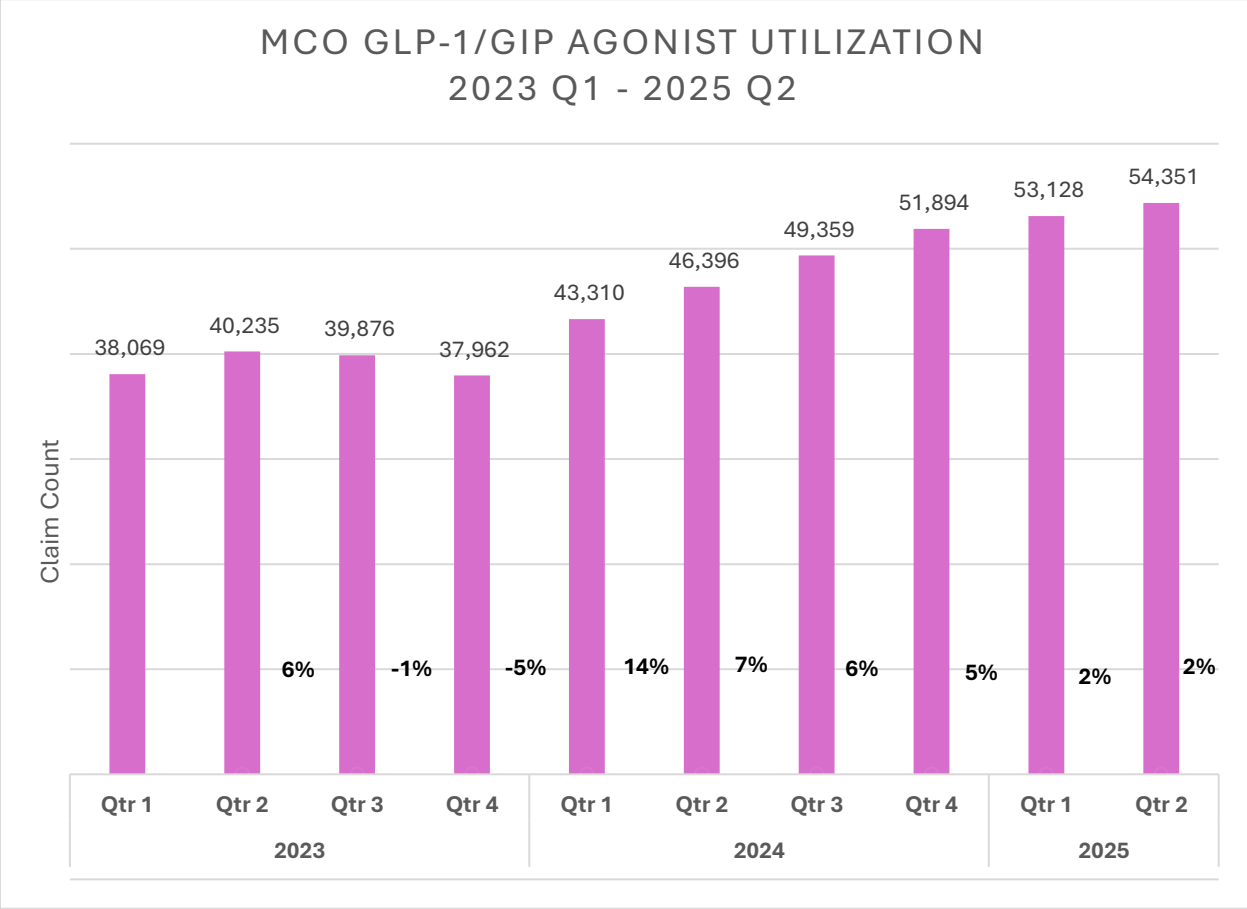
MCO SGLT2 Inhibitors Utilization



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



MCO GLP-1 Receptor Agonist and GLP-1/GIP Agonist for Diabetes Mellitus



Addendum to the Protocol for Imcivree® (setmelanotide)

July 2025

DURB Approval Dates	**10/2021, 1/2023, 7/2025**
Commissioners Approval Dates	**5/2022, 2/2024**

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. Patients 20 years or older with BMI $\geq$ 30 kg/m^2
    b. Patients less than 20 years of age with BMI $\geq$ 95th percentile

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)

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 a reduction in BMI at 1 year from baseline
    b. Bardet-Biedl Syndrome there is a documented positive response to therapy as evidenced by a reduction in BMI at 1 year from 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

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.
4. Wabitsch M, Flück CE, et all. Natural History of Obesity Due to POMC, PCSK1, and LEPR Deficiency and the Impact of Setmelanotide. J Endocr Soc. 2022 Apr 15;6(6).
5. Forsythe, E., Beales, P. Bardet–Biedl syndrome. Eur J Hum Genet 21, 8–13 (2013)
6. Beales PL, Elcioglu N, Woolf AS, et al. New criteria for improved diagnosis of Bardet-Biedl syndrome: results of a population survey. J Med Genet. 1999;36:437-446.
7. Centers for Disease Control and Prevention. (2024, June 28). Child and Teen BMI Categories. Retrieved June 12, 2025, from https://www.cdc.gov/bmi/child-teen-calculator/index.html
8. Centers for Disease Control and Prevention. (2024, June 28). Adult BMI Categories. Retrieved June 12, 2025, from https://www.cdc.gov/bmi/adult-calculator/bmi-categories.html#cdc_generic_section_3-adult-bmi-calculator

Addendum to Protocol for Chimeric Antigen Receptor (CAR) T Cell Products

July 2025

DURB Approval Dates	**7/2023, 7/2025**
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 (FDA). In addition, 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. Treatment is one time

9. 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

10. 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 two prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody

11. 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

12. 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 one prior line of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
    iii. Documentation is received patient is refractory to lenalidomide treatment

13. 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

14. 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

15. 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

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.
2. Carvykti [package insert]. Janssen Biotech, Inc. Horsham, PA. June 2025.
3. Kymriah [package insert]. Novartis Pharmaceuticals Corp. East Hanover, NJ. June 2025.
4. Tecartus [package insert]. Kite Pharma, Inc. Santa Monica, CA. June 2025.
5. Yescarta [package insert]. Kite Pharma, Inc. Santa Monica, CA. June 2024.
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
8. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Multiple Myeloma. Version 1.2026. Last accessed 7/7/2025.

9. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. Version 2.2025. Last accessed 7/7/2025.
10. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 2.2025. Last accessed 7/72025.
11. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 3.2025. Last accessed 7/7/2025.
12. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Pediatric Acute Lymphoblastic Leukemia. Version 3.2025. Last accessed 7/7/2025.
13. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Pediatric Aggressive Mature B-Cell Lymphomas. Version 2.2025. Last accessed 7/7/2025.
14. Hayden PJ, Roddie C, Bader P., et al. Management of adults and children receiving CAR T cell therapy: 2021 best practice recommendations of the European Society for Blood and Marrow Transplantation (EBMT) and the Joint Accreditation Committee of ISCT and EBMT (JACIE) and the European Haematology Association (EHA). Annals of Oncology. March 2022. Vol 33 (3) p259-27.
15. US Food and Drug Administration. FDA Eliminated Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T cell Immunotherapies. FDA News Release. June 27, 2025. 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

Addendum to the Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products

July 2025

DURB Approval Dates	**7/2022, 10/2024, 7/2025**
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

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. Decrease in reticulocyte count from pre-treatment level

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

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4. Fabhalta® [prescribing information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. March 2025.
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Proposed Addendum to Protocol for Biologics in Moderate to Severe Asthma
October 2025

DURB Approval Date	**10/2022**
Commissioners Approval Date	**7/2023**

Cinqair® (reslizumab)
~~**Dupixent** (dupilumab)~~
Fasenra® (benralizumab)
Nucala® (mepolizumab)
Tezspire® (tezepelumab-ekko)
Xolair® (omalizumab)
Protocol applies to FDA approved biosimilars and related indications and dosages
For Dupixent® requests please refer to the Dupixent Protocol

Addendum:
Specific criteria for biologic drugs were updated to reflect the Food and Drug Administration (FDA) labeling and GINA (Global Initiative for Asthma) 2024 guidelines. Additional examples for poor asthma control added to protocol. Dupixent has been removed from this protocol. Dupixent for asthma treatment is addressed in another protocol specifically for Dupixent.

Background:
Severe asthma is present, by definition, when adequate control of asthma cannot be achieved by high-dose treatment with inhaled corticosteroids and additional controllers (long-acting inhaled beta 2 agonists, montelukast, and/or theophylline) or by oral corticosteroid treatment (for at least six months per year) or is lost when the treatment is reduced.

General Criteria for Approval (must meet all of the following):

1. Confirmed diagnosis of one of the following (a. or b.):

    a. Severe asthma with eosinophilic phenotype (blood eosinophil counts ≥ 150 cells/microliter) ~~while on high-dose inhaled corticosteroids (ICS) or oral corticosteroids~~ (**Fasenra, Cinqair, Nucala)** or severe asthma (**Tezspire**)
    ~~b. Moderate to severe asthma with eosinophilic phenotype (blood eosinophil counts ≥150 cells/microliter or with oral corticosteroid dependence (**Dupixent**)~~
    c. Moderate to severe persistent allergic asthma not adequately controlled with inhaled corticosteroids documented by one of the following (**Xolair**):
        i. A positive skin test
        ii. In-vitro reactivity to a perennial aeroallergen

~~2. Medication is used as add-on therapy in patients receiving conventional asthma treatment for the past 3 months (e.g., inhaled corticosteroid (ICS), long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline~~

2. The patient is currently being treated with one of the following maximally tolerated conventional regimens for at least the past 3 months (must meet a. or b.)
    a. Patients 12 years and older must receive one of the following:
        i. An inhaled corticosteroid (ICS) plus formoterol (or another long-acting beta agonist (LABA) with an as-needed short-acting beta agonist (SABA)) plus long-acting

muscarinic antagonist (LAMA)
ii. ICS plus LABA plus leukotriene receptor antagonist (LTRA)
iii. ICS plus LABA plus theophylline

b. Patients 6 to 11 years of age must receive an ICS plus formoterol (or another LABA with an as needed SABA) or ICS plus LABA plus LTRA or ICS plus LABA plus tiotropium

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

4. Medication is prescribed by or in consultation with a pulmonologist, allergist, or immunologist

5. The patient is continuing to utilize maximally tolerated conventional asthma treatment with the requested medication, where indicated

6. Patient has experienced one of the following despite regular use of conventional therapies within the past 12 months (must meet a. b. or c.):
   a. Two or more exacerbations requiring systemic corticosteroids (steroid bursts)
   b. At least one asthma exacerbation requiring hospitalization or emergency medical care visits
   c. Poor symptom control defined by one of the following:
      i. Frequent asthma symptoms
      ii. Frequent rescue medication use
      iii. Limited activity due to asthma
      iv. Night waking due to asthma

~~despite meeting all of the following (exacerbation is defined as requiring the use of oral/systemic corticosteroids, urgent care/hospital admission, or intubation):~~
~~a. Adherence to a maximally tolerated inhaled corticosteroid for the past 3 months or has intolerance, contraindication, or hypersensitivity to all inhaled corticosteroids; **AND**~~

~~b. Adherence to at least ONE of the aforementioned therapies (LABA, LTRA, or LAMA) for 90 consecutive days unless there is documented intolerance, contraindication, or hypersensitivity~~

7. The patient will not concomitantly be using another biologic immunomodulator for the same diagnosis ~~[e.g., omalizumab (Xolair), reslizumab (Cinqair), mepolizumab (Nucala), or benralizumab (Fasenra)].~~

8. Weight will be monitored and provided for drugs that have weight-based dosing

9. Tezspire vial and Cinqair are administered by a healthcare provider

10. 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

11. Patient does not have any contraindications to therapy

Criteria for Continuation of Therapy:

1. Documentation of positive clinical response to therapy by at least one of the following:
    a. Decreased asthma symptoms and frequency of exacerbations from baseline
    b. Improved lung function, defined as FEV1 increase from baseline
    c. Reduction in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to asthma exacerbations
    d. Reduction in the dose of inhaled/oral corticosteroids required to control the patient's asthma
    e. Decreased utilization of rescue medications
2. The patient will not concomitantly be using another biologic immunomodulator for the same diagnosis
3. The patient is continuing to utilize maximally tolerated conventional asthma treatment with the requested medication, where indicated

~~2. For Xolair requests the medication is administered by a healthcare provider unless the patient has already received at least 3 doses under the guidance of a healthcare provider with no hypersensitivity reactions~~

References:

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Proposed Addendum to Protocol for Dupixent® (dupilumab)
October 2025

DURB Approval Date	**4/2019, 7/2020, 7/2021, 1/2023, 7/2024**
Commissioners Approval Date	**10/2019, 5/2021, 5/2022, 2/2024, 1/2025**

Dupixent® (dupilumab)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
The protocol has been updated to include chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid. The criteria for use of Dupixent in asthma was updated to ensure patients are utilizing at least 3 months of conventional asthma treatment and continue to present with symptomatic asthma. Nasal irrigation was added to the criteria for Chronic Rhinosinusitis with Nasal Polyposis. Eosinophilic Esophagitis criteria updated to include a trial of a high dose proton pump inhibitor and a swallowed topical corticosteroid. References are updated.

Background:
Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of atopic dermatitis, asthma, eosinophilic esophagitis, prurigo nodularis, chronic rhinosinusitis with nasal polyposis, chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid.

General Criteria for Approval (must meet all of the following):

1. Patient is of the FDA-labeled or compendial approved age
2. Medication is not concomitantly used with another biologic immunomodulator or JAK inhibitor for the same diagnosis
3. Medication is prescribed by or in consultation with a specialist in the appropriate field
4. Patient does not have any contraindications to therapy
5. Patient's current weight is provided for indications utilizing weight-based dosing
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

Approval Criteria for Specific Diagnoses:

1. **Atopic Dermatitis** (must meet all of the following):
    a. Patient has a diagnosis of moderate to severe atopic dermatitis
    b. Patient has a minimum of 10% body surface area involvement OR has clinically difficult to treat areas (e.g., face, neck, genital) that interfere with quality of life
    c. Patient has tried and failed or has an intolerance or has contraindications to ALL of the following:
        i. One medium to very high potency topical prescription corticosteroid for a trial of ≥ 2 weeks
        ii. One topical calcineurin inhibitor (e.g., Elidel®, Protopic®) for a trial of ≥ 4 weeks
    d. Topical emollients are concomitantly used in problem areas (e.g., face, neck, genitals) to help prevent flares

e. ~~Success of treatment will be assessed regularly~~

2. **Asthma** (must meet all of the following):
   a. The patient has moderate to severe asthma and meets one of the following (i. or ii.):
      i. Patient has an eosinophilic phenotype and blood eosinophil counts ≥150 cells/microliter on current laboratory assessment
      ii. Patient has oral corticosteroid-dependent asthma and is adherent to an oral corticosteroid regimen
   b. The patient is currently being treated with one of the following maximally tolerated conventional regimens for at least the past 3 months (must meet i. or ii.)
      i. Patients 12 years of age and older must receive one of the following:
         a. An inhaled corticosteroid (ICS) plus formoterol (or another long-acting beta agonist (LABA) with an as-needed short-acting beta agonist (SABA)) plus long-acting muscarinic antagonist (LAMA)
         b. ICS plus LABA plus leukotriene receptor antagonist (LTRA)
         c. ICS plus LABA plus theophylline ~~regimen in the past 12 months~~
      ii. Patients 6 to 11 years of age must receive an ICS plus formoterol (or another LABA with an as needed SABA) or ICS plus LABA plus LTRA or ICS plus LABA plus tiotropium ~~A regimen containing an ICS regimen **AND** one of the following:~~
         ~~a. Long-acting beta agonist (LABA) plus as-needed short-acting beta agonist (SABA)~~
         ~~b. LABA plus long-acting muscarinic antagonist (LAMA)~~
         ~~c. Leukotriene receptor antagonist (LTRA) theophylline, or zileuton for the last 6 months~~
      ~~iii. Patient has documented intolerance, contraindication, or hypersensitivity to all the therapies listed in 6.b.i.~~
   c. The patient is continuing to utilize maximally tolerated conventional asthma treatment with requested medication
   d. The patient has experienced one of the following events despite regular use of conventional therapies within the past 12 months (must meet i. ii. or iii.) ~~(see section 6.b.i.)~~:
      i. Two or more exacerbations requiring systemic corticosteroids (steroid bursts)
      ii. At least one asthma exacerbation requiring hospitalization or emergency medical care visits ~~intubation/mechanical ventilation~~
      iii. Poor symptom control defined by one of the following:
         1. Frequent asthma symptoms
         2. Frequent rescue medication use
         3. Limited activity due to asthma
         4. Night waking due to asthma

3. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)** (must meet all of the following):
   a. Patient has a confirmed diagnosis of CRSwNP
   b. The patient **meets at least one** of the following:
      i. The patient had an inadequate response to oral systemic corticosteroids or has an intolerance or contraindication to

all oral systemic corticosteroids
ii. The patient is not a candidate for sinonasal surgery
iii. The patient had an inadequate response to sinonasal surgery

c. The patient had an inadequate response to a 3-month trial of at least one intranasal corticosteroid (INCS) and an 8-week trial of nasal saline irrigation or has an intolerance or contraindication to all intranasal corticosteroids and nasal saline irrigation
d. The patient has ongoing symptoms of nasal congestion, blockage, or obstruction with moderate to severe symptom severity along with another CRSwNP related symptom
e. Medication is being used as add-on therapy for CRSwNP, unless all other therapies are contraindicated

4. **Eosinophilic Esophagitis** (must meet all of the following):
   a. Patient has a diagnosis of eosinophilic esophagitis (EoE) and has an eosinophil count of ≥15 intraepithelial eosinophils per high power field on esophageal biopsy ~~light microscopy following a treatment course of a proton pump inhibitor (PPI)~~
   b. Patient has signs or symptoms of esophageal dysfunction ~~regurgitation, dysphagia, or food impaction~~
   c. Patient had an inadequate response to at least an ~~90-day~~ 8-week trial of a swallowed topical steroid (e.g. budesonide respules) and/or a high dose proton pump inhibitor ~~one appropriate corticosteroid~~ or has an intolerance or contraindication to corticosteroids and proton pump inhibitors ~~to the therapies listed in 8.c~~.

5. **Prurigo Nodularis** (must meet all of the following):
   a. Patient has a diagnosis of prurigo nodularis (PN)
   b. Patient has widespread or recalcitrant ≥20 nodular lesions
   c. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score ≥7 on a scale of 0 to 10
   d. Patient had an inadequate response to at least one previous PN treatment
   e. Patient has an intolerance or contraindication to all other PN treatments

6. **Chronic Obstructive Pulmonary Disease** (must meet all of the following):
   a. Patient has a confirmed diagnosis of chronic obstructive pulmonary disease (COPD)
   b. Patient has confirmed eosinophilic phenotype as shown by an eosinophilic count ≥300 cell/µL despite trial of conventional therapy
   c. Medication is used as an add-on maintenance treatment to conventional therapy that includes a LABA plus LAMA with or without an inhaled corticosteroid trial and has continued to experience ≥2 moderate exacerbations or ≥1 exacerbation leading to hospitalization

7. **Chronic Spontaneous Urticaria** (must meet all of the following):
   a. Patient has a confirmed diagnosis of chronic spontaneous urticaria
   b. Unless patient has an intolerance or contraindication must try both of the following:
      i. Two different second-generation H1-antihistamine at maximally tolerated dose
      ii. One second-generation H1-antihistamine together with a LTRA

8. **Bullous Pemphigoid** (must meet all of the following):
   a. Patient has a confirmed diagnosis of bullous pemphigoid

b. Unless there is an intolerance or contraindication patient has tried a high-dose glucocorticoid plus at least one of the following:
   i. High potency topical corticosteroid
   ii. Antibiotic
   iii. Immunosuppressant

Criteria for Continuation of therapy:

1. Documentation of a positive clinical response
2. Medication is not used concomitantly with another biologic immunomodulator or JAK inhibitor for the same diagnosis
3. The patient is continuing to utilize maximally tolerated conventional asthma treatment with requested medication, where indicated

References:

1. Dupixent® (package insert). Regeneron Pharmaceuticals, Inc. Tarrytown, NY. June 2025.
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Proposed Addendum to Protocol for Hereditary Angioedema (HAE) Drug Products
October 2025

DURB Approval Dates	**July 2019**
Commissioners Approval Dates	**2019**

Drugs indicated for prophylaxis treatment
Cinryze® (human c1-esterase inhibitor)
Haegarda® (human c1-esterase inhibitor)
Takhzyro® (lanadelumab-flyo)
Andembry® (garadacimab-gxii)
Dawnzera™ (donidalorsen)
Orladeyo® (berotralstat)

Drugs indicated for acute treatment
Firazyr® (icatibant)
Kalbitor® (ecallantide)
Berinert® (human c1-esterase inhibitor)
Ruconest® (recombinant c1-esterase inhibitor)
Ekterly® (sebetralstat)

Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum
The protocol was updated to include the following drugs: Andembry, Dawnzera Ekterly, and Orladeyo.

Background
Hereditary angioedema (HAE) is a rare autosomal dominant genetic disorder. In patients with HAE a mutation to the C1-esterase-inhibitor (C1-INH) located on Chromosome 11q results in low levels of C1-INH activity and low levels of C4. C1-INH regulates activation of the complement and intrinsic coagulation (contact system pathway) and is a major inhibitor of plasma kallikrein. Kallikrein-kinin system is involved in the inflammatory and coagulation pathways. Kallikrein converts high molecular weight (HMW) kininogen to bradykinin. Bradykinin is a vasodilator that leads to swelling, inflammation and pain in patients with HAE.

General Criteria for Approval (must meet all of the following):

1. Patient is of the FDA-labeled or compendial approved age
2. Patient has a confirmed diagnosis of Hereditary Angioedema and documentation is received
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. Patient does not have any contraindications to therapy
5. Patient's current weight is provided
6. Medication is prescribed by or in consultation with an allergist, immunologist, or a physician that specializes in the treatment of HAE or related disorders
7. Medications known to cause angioedema ~~(e.g., angiotensin-converting enzyme inhibitors, estrogen containing medications, angiotensin II receptor blockers, pregabalin)~~ have been evaluated and discontinued when appropriate
8. The patient will not use the requested medication concurrently with another drug ~~with the same mechanism of action or~~ within the same treatment category (i.e. prophylaxis or acute attack)
~~9. For Ekterly requests only the prescriber must confirm the following:~~
    ~~a. The patient is not on any strong CYP3A4 inhibitors and/or strong and moderate CYP3A4 inducers~~
    ~~b. The patient's Ekterly dose is reduced if taking moderate CYP3A4 inhibitors~~
    ~~c. The patient does not have severe hepatic impairment (Child-Pugh Class C), documentation is provided~~
    d. ~~The patient's Ekterly dose is reduced if moderate hepatic impairment (Child-Pugh Class B) is present, documentation is provided~~

Criteria for Continuation of Therapy:

1. Patient meets initial criteria for approval
2. Patient has documented improvement or does not have clinical worsening of HAE

Note: Kalbitor – Anaphylaxis reported post administration. Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and HAE. Healthcare professional should be aware of the similarity between hypersensitivity reactions and HAE and should monitor patients closely.

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4. Firazyr [package insert]. Takeda Pharmaceuticals America, Inc. Lexington, MA. 1/2024
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Addendum to Protocol for Wegovy (semaiglutide)® ~~for Reduction of Major Adverse Cardiovascular Events (MACE)~~
October 2025

DURB Approval Date	**7/2024**
Commissioners Approval Date	**1/2025**

Addendum:
Added new Food and Drug Administration (FDA) for metabolic dysfunction-associated steatohepatitis (MASH). The indication for MASH is approved under accelerated approval based on MASH and fibrosis improvement. Continued approval may be contingent on clinical benefit in a confirmatory trial.

Background:
Wegovy® approved by the Food and Drug Administration in June 2021 is a glucagon-like peptide-1 (GLP-1) receptor agonist. Wegovy is available for patients to reduce the risk of major adverse cardiovascular (CV) events in adults with established CV disease who are obese or overweight and for the treatment of noncirrhotic MASH who have moderate to advanced liver fibrosis.

General Criteria for Approval:

1. Patient is of the FDA labeled or compendial age; **AND**
2. Patient does not have any contraindications to therapy; **AND**
3. Patient is not utilizing another GLP-1 receptor agonist concomitantly; **AND**
4. Documentation that the member has received individualized healthy lifestyle counseling and will use Wegovy together with a reduced caloric diet and increased physical activity

Approval Criteria Specific Diagnoses:

1. **Major Adverse Cardiovascular Event**
    a. Patient has established cardiovascular disease as evidenced by at least one of the following:
        i. Prior myocardial infarction
        ii. Prior ischemic or hemorrhagic stroke or **transient ischemic attack**
        iii. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation
        iv. Positive nuclear stress test
        v. Ischemic cardiomyopathy
        vi. History of revascularization (coronary artery bypass grafting, percutaneous coronary intervention, or angioplasty)**; AND**
    b. Documentation that the patient has a body mass index (BMI) ≥27 kg/m^2; **AND**
    c. Medication is prescribed by or in consultation with a cardiologist, vascular specialist or **endocrinologist**; **AND**
    ~~d. Medication will be used with caution in patients with type 1 diabetes mellitus.~~
    e. Prescriber will maintain the patient on appropriate cardiovascular pharmacotherapy for their cardiovascular disease; **AND**
    f. Patient's target dose will be in the range of manufacturer dosing shown to reduce major cardiovascular events as tolerated

2. **Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis**

    a. Patient has documented or confirmed moderate to advanced liver fibrosis; **AND**
    b. Patient has a liver fibrosis stage of F2 or F3 and documentation is received; **AND**
    c. The patient does not have evidence of cirrhosis as documented by clinical notes or laboratory values; **AND**
    d. Medication is prescribed by or in consultation with a hepatologist, gastroenterologist or endocrinologist; **AND**
    e. Patient's target dose is in the range of manufacturer dosing for treatment of MASH

Criteria for Continuation of Therapy:

1. There is no evidence of disease progression (documentation received)**; AND**
2. The patient continues to follow lifestyle modifications**; AND** ~~Patient has attained and is tolerating the maintenance dose of 2.4mg weekly, or documentation is provided justifying the use of a different dose~~
3. For MACE requests patient remains on appropriate CV pharmacotherapy for their CV disease; **AND**
4. Patient is not utilizing another GLP-1 receptor agonist concomitantly

NOTE: Wegovy has a black box warning regarding thyroid C-cell tumors. Please see full prescribing information for details.

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Gainwell Technologies/NJ MCO 2nd Quarter 2025 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**81,760**	**115,836**	**87,355**	**999,666**	**350,815**	**180,641**
Total # of Pharmacy Claims Processed	**471,975**	**535,864**	**346,752**	**3,400,533**	**914,152**	**1,025,137**
Total # of Members Requesting Prior Authorization*	**1,671**	**3,850**	**2,618**	**23,345**	**7,984**	**6,394**
Total Prior Authorizations Requests Received**	**4,326**	**5,348**	**4,128**	**35,316**	**10,924**	**9,285**
Percentage of Claims Requiring Prior Authorization	**0.90%**	**0.99%**	**1.19%**	**1.00%**	**1.20%**	**0.90%**
Received Requests Denials**	**76 (2%)**	**2,898 (54%)**	**1,837 (45%)**	**11,359 (32%)**	**4,599 (42%)**	**4,215 (45%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	62 (82%)	1,004 (34%)	416 (23%)	3,840 (34%)	1,835 (40%)	1,230 (29%)
Excluded Benefit	14 (18%)	65 (2%)	5 (0%)	71 (1%)	227 (5%)	236 (6%)
Non-formulary	0 (0%)	1,829 (63%)	1,416 (77%)	7,448 (66%)	2,537 (55%)	2,749 (65%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	7.9%	2.4%	1.6%	2.9%	5.0%	2.7%
Antidepressants	2.6%	1.2%	0.6%	1.4%	1.3%	1.1%
Antihypertensives	1.3%	0.9%	0.2%	0.4%	0.3%	0.5%
Antianxiety	3.9%	0.1%	0.1%	0.1%	0.0%	0.1%
Antidiabetics (oral and insulin)	3.9%	20.9%	26.4%	23.5%	14.0%	20.5%
Anticoagulants	0.0%	0.0%	0.4%	0.1%	0.4%	0.1%
Thyroid agents	0.0%	0.4%	0.0%	0.2%	0.4%	0.1%
Ulcer Drugs/Antispasmodics/Anticholinergics	2.6%	1.5%	0.9%	2.2%	1.8%	0.8%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	17.9%	11.5%	5.2%	8.8%	10.1%
Antipsychotic/Antimanic agents	0.0%	1.3%	1.3%	3.2%	0.8%	1.8%
Antiasthmatic and Bronchodilator agents	11.8%	4.5%	3.9%	5.0%	7.7%	3.3%
Antivirals (includes both HIV and Hep C)	0.0%	0.3%	0.5%	0.3%	0.2%	0.2%
Digestive Aids (Digestive Enzymes)	1.3%	0.4%	0.3%	0.1%	0.0%	0.1%
Anticonvulsants	0.0%	1.6%	3.2%	1.6%	2.4%	1.1%
Migraine Products	1.3%	5.3%	3.7%	4.9%	4.8%	3.5%
Analgesics Anti-inflammatory	6.6%	1.4%	3.3%	3.0%	2.9%	1.8%
Analgesic Opioids	9.2%	3.1%	1.5%	1.1%	1.6%	4.3%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	0.6%	1.3%	1.2%	1.7%	2.1%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.0%	1.0%	0.8%	0.4%	0.4%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.2%	0.0%	0.0%	0.0%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	12.9%	14.2%	16.2%	13.5%	14.8%

* 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

DURB Meeting	Action Items	Status/DURB Recommendations	Impact/Comments
July 2025	Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products	• The Board recommended approval of the addendum to the ATTR products protocol. Attruby a new drug approved by the FDA in November 2024 was added to the protocol. In addition, the protocol was updated to include a new indication approved by the FDA on March 2025 for Amvuttra.	
	Proposed addendum to the protocol for Imcivree® (setmelanotide)	• The Board recommended approval of the addendum to the Imcivree protocol. The protocol was updated to allow Imcivree for patients 2 years of age and older based on the recent FDA approval. Initial criteria was updated to include the Centers for Disease Control and Prevention (CDC) parameters for obesity. The Board recommended the continuation of therapy criteria be updated to remove the requirement for a specific percentage decrease in body mass index (BMI) to evaluate efficacy.	
		• The Board recommended approval of the addendum to the PNH products protocol. The continuation of therapy criteria was updated to include an additional parameter to assess efficacy.	
	Proposed addendum to the protocol for Paroxysmal	• The Board recommended approval of the addendum to the CAR T Cell products protocol.	

	Nocturnal Hemoglobinuria (PNH) products Proposed Addendum to the protocol for Chimeric Antigen Receptor (CAR) T Cell Products 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	• The Board recommended approval of the addendum to the GLP-1RA and GLP-1RA/GIP Agonists for Type 2 Diabetes.	
April 2025	Proposed protocol for Attention Deficit Hyperactivity Disorder (ADHD) for children <6 years of old Proposed protocol for Zepbound® Proposed protocol for Spravato®	• 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 • The Board recommended approval of the protocol • 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) Proposed protocol for Alopecia Areata products Proposed protocol for Lyfgenia™ Proposed protocol for Casgevy®	• The Board recommended the addendum to the protocol • The Board recommended approval of the protocol with a suggested change to add "syphilis" to examples in criterion #3 • The Board recommended approval of the protocol with suggested addition of the black box warning • The Board recommended approval of the protocol with the additional criteria for the product to be administered at a Qualified Treatment Center.	Updated information was presented at the April 2025 meeting Updated information was presented at the April 2025 meeting Updated information was presented at the April 2025 meeting
October 2024	Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products Proposed protocol for ileal bile acid transporter (IBAT) inhibitor products Proposed addendum to the protocol for Paroxysmal	• The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol pending further clarification	

	Nocturnal Hemoglobinuria (PNH) products Proposed Protocol for Winrevair® (sotatercept-csrk)	from the manufacturer, Genentech regarding age of eligibility • The Board recommended the addendum to the protocol pending more information from specialists in the disease state	Information was provided at the January 2025 meeting Will monitor and revisit any potential hindering criteria
July 2024	Proposed addendum to the protocol for Dupixent (dupilumab) Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec) Proposed addendum to the protocol for Duchenne Muscular Dystrophy products	• The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol • 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	These changes were presented at the October 2024 meeting

	Proposed protocol for Qelbree (viloxazine) Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)	- Delete criterion #4 in the continuation of therapy section which referred to making patient's weight available • The Board recommended the protocol with suggested change to delete criterion #3 which required treatment failure with atomoxetine, clonidine, or guanfacine • The Board recommended the protocol	This change was presented at the October 2024 meeting