

**New Jersey Drug Utilization Review Board
Virtual Platform
July 15, 2026**

<https://nj.gov/humanservices/dmahs/public-advisory/durb/>

AGENDA

- I. Call to order in accordance with New Jersey Open Public Meeting Act
- II. Roll Call
- III. Review of meeting transcript for April 15, 2026, meeting
https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/DURB_Transcript_April_2026_Final.pdf
- IV. Review of draft meeting summary for April 15, 2026, meeting (pages 3-6)
- V. Secretary's report (page 7)
- VI. Old Business
 - A. Utilization Trends of GLP-1/GIP Agonists (pages 8-9)
 - B. Utilization Trends of SGLT-2 Inhibitors (pages 10-11)
- VII. New Business
 - A. Proposed Addendum to Protocol for Gattex[®] (pages 12-13)
 - B. Proposed Addendum to Protocol for Strensiq[®] (pages 14-16)
 - C. Proposed Protocol for C Type Natriuretic Peptide Products (pages 17-18)
 - D. Protocols to be Retired (page 19)

VIII. A. Informational Highlights/Reports

1. Gainwell Technologies/NJ MCO 1st Quarter 2026 Prior Authorization Report
2. (page 20)
3. Summary of DURB Action Items (pages 21-24)
4. 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/documents/boards/durb/agendas/7-2026/FFS_Top_Drugs_Report_\(March-2026\)_ALL.pdf](https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/FFS_Top_Drugs_Report_(March-2026)_ALL.pdf)

MCO top drugs:

[https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/MCO_Top_Drugs_Report_\(March-2026\)_by_Payment.pdf](https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/MCO_Top_Drugs_Report_(March-2026)_by_Payment.pdf)

FFS top drugs by category:

[https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/FFS_Top_Drugs_by_Category_\(March-2026\)_by_Payment.pdf](https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/FFS_Top_Drugs_by_Category_(March-2026)_by_Payment.pdf)

MCO top drugs by category:

[https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/MCO_Top_Drugs_by_Category_\(March-2026\)_by_Payment.pdf](https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/MCO_Top_Drugs_by_Category_(March-2026)_by_Payment.pdf)

FFS antiviral drugs:

[https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/FFS_Antiviral_Drugs_\(March-2026\)_by_Payment.pdf](https://www.nj.gov/humanservices/dmahs/documents/boards/durb/agendas/7-2026/FFS_Antiviral_Drugs_(March-2026)_by_Payment.pdf)

B. Recent Updates

KDIGO 2026 Clinical Practice Guideline for Diabetes and Chronic Kidney Disease (CKD)

<https://kdigo.org/wp-content/uploads/2026/03/KDIGO-2026-Diabetes-and-CKD-Guideline-Update-Public-Review-Draft-March-2026.pdf>

Guidelines of care for the management of atopic dermatitis in pediatric patients

<https://www.jaad.org/action/showPdf?pii=S0190-9622%2826%2900343-9>

Relationship between menopausal hormone therapy and incidence of breast cancer: systemic review and meta-analysis

https://pmc.ncbi.nlm.nih.gov/articles/PMC12981265/pdf/IANN_58_2640244.pdf

American Association of Clinical Endocrinology Consensus Statement: Algorithm for Management of Adults with Type 2 Diabetes – 2026 Update

<https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2826%2900022-4>

April 15, 2026, DURB Meeting Summary (Draft)

Issue	Action	Notes
Roll Call		<u>Present:</u> Dr. Swee, Dr. Gochfeld, Dr. Moynihan, Ms. Olson, Dr. Barberio, and Dr. Lind (ex-officio, Department of Human Services) <u>Unable to attend:</u> Mr. Schafer, Dr. Marcus, Dr. Sahu (ex-officio, Department of Health)
Dr. Swee's pre-meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for Board's meeting: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of filings in the Trenton Times, Star Ledger, Atlantic City Press, Bergen Record, and Courier-Post.
Review of Minutes	Approved	Minutes from January 28, 2026, meeting was reviewed and approved by the Board. The approved meeting summary is posted on the DURB website at: https://nj.gov/humanservices/dmahs/public-advisory/durb/
Secretary's Report		- The Commissioners approved the October 2025 DURB recommended protocols - The January 2026 NJ DURB recommended protocols are in review by the Commissioners - The NJDURB State Fiscal Year 2025 NJDURB Annual Report is in review by the Commissioners - The 2026 NJDURB Meeting dates were announced - o July 15, 2026; October 21, 2026 - There are no further updates on the Board's positions and replacements
Old Business		
(A) & (B) Utilization Trends of GLP-1/GIP Agonists and SGLT-2 Inhibitors	Continue to Monitor	The Board reviewed utilization reports for GLP-1/GIP agonists, and SGLT-2 inhibitors. Dr. Swee requested the FDA approved indications be added for the drugs presented in the utilization graphs. In addition, Dr. Swee requested ongoing reports to monitor utilization of these therapeutic classes.
(C) Updated Protocol for Opzelura®		The protocol was presented highlighting a Board recommended change during the January 2026 meeting. The protocol was updated to allow a specialist who has

Issue	Action	Notes
		appropriate knowledge and experience with managing the conditions to prescribe Opzelura®.
(D) Updated Protocol for Duchenne Muscular Dystrophy Products		The protocol was presented noting the recommended change by the Board to the Elevidys® criteria to state “A current, active infection or infection within the previous 4 weeks.”
New Business		
(A) Proposed Addendum to Protocol for Crysvisa®	Recommended	The Board reviewed a proposed addendum to the Crysvisa® protocol for the treatment of X-linked hypophosphatemia. Dr. Swee requested the incidence or prevalence of these rare conditions be included in the background section of applicable protocols going forward. Dr. Swee also raised a concern regarding the criteria for vitamin D analog and why this is necessary to stop prior to starting the therapy with Crysvisa®. Pinali Agrawal stated she will research and provide the findings to the Board. There were no further questions pertaining to the protocol criteria. The Board recommended approval of the protocol.
(B) Proposed Addendum to Protocol for Cystic Fibrosis Transmembrane Conductance Regulator Products	Recommended	The Board reviewed a proposed addendum to the protocol for Cystic Fibrosis Transmembrane Conductance Regulator products. Dr. Swee questioned if the liver function criteria in the protocol applies to all the drugs or only Alyftrek®. Elena Fernandez, a pharmacist and a health economics and outcomes research representative from Vertex stated it is a boxed warning for both Trikafta® and Alyftrek® and the FDA labeling was updated based on real-world evidence seen in patients taking Trikafta®. The Board recommended approval of the protocol.
(C) Proposed Addendum to Protocol for Spinal Muscular Atrophy Products	Recommended	The Board reviewed a proposed addendum to the protocol for Spinal Muscular Atrophy products. The protocol was updated to include Itvisma®, a new drug approved by the FDA in November 2025. Dr. Swee discussed the Board’s concerns regarding the protocol criteria which is based off of the FDA approved labeling that requires patients receive systemic corticosteroid therapy for at least 30 days for Itvisma® and Zolgensma® requests. The Board’s concern is related to length of systemic corticosteroid treatment required and if the duration can be shortened. Dalia Hanna stated both drugs have black box warnings for serious liver injuries and inflammation, which could be the reason for the steroid therapy. Pinali Agrawal stated based on the prescribing information

Issue	Action	Notes																
		corticosteroids are used prior to the infusion due to increased risk of serious systemic immune response. At the end of 30-day period of systemic corticosteroid treatment, liver status should be assessed. If the liver function tests are abnormal then continuation of systemic corticosteroid treatment is recommended. Dr. Swee stated he agrees on the reason for patients to be on corticosteroids during these infusions. However, the Board would like to know how the recommended days of systemic corticosteroid treatment was determined. Pinali Agrawal stated she will research and provide any additional information to the Board. The Board recommended approval of the protocol.																
Informational Highlights/Reports																		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor	The Board reviewed the 4 th Quarter 2025 prior authorization (PA) denial report for FFS and MCOs. Dr. Swee requested follow-up with the MCOs to obtain additional information to address the denial rates for the antidiabetics (oral and insulin) therapeutic category. Pinali Agrawal stated she will follow up with the MCOs and provide the information to the Board.																
2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of their actions from previous meetings (January 2025 through January 2026). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols.																
3. DHS/DHSS/MCO Programs Top Drugs Report		Top drugs report for January 2026 (FFS) and December 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</th></tr><tr><td>FFS</td><td>January 2026</td><td>\$2,654,083*</td><td>\$2,954,215*</td></tr><tr><td>MCOs</td><td>December 2025</td><td>\$123,912,298</td><td>\$178,856,207</td></tr><tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr></table>	Plan	Month Reported	Top Drugs	Total	FFS	January 2026	\$2,654,083*	\$2,954,215*	MCOs	December 2025	\$123,912,298	\$178,856,207	* Less PAAD, ADDP and Sr. Gold			
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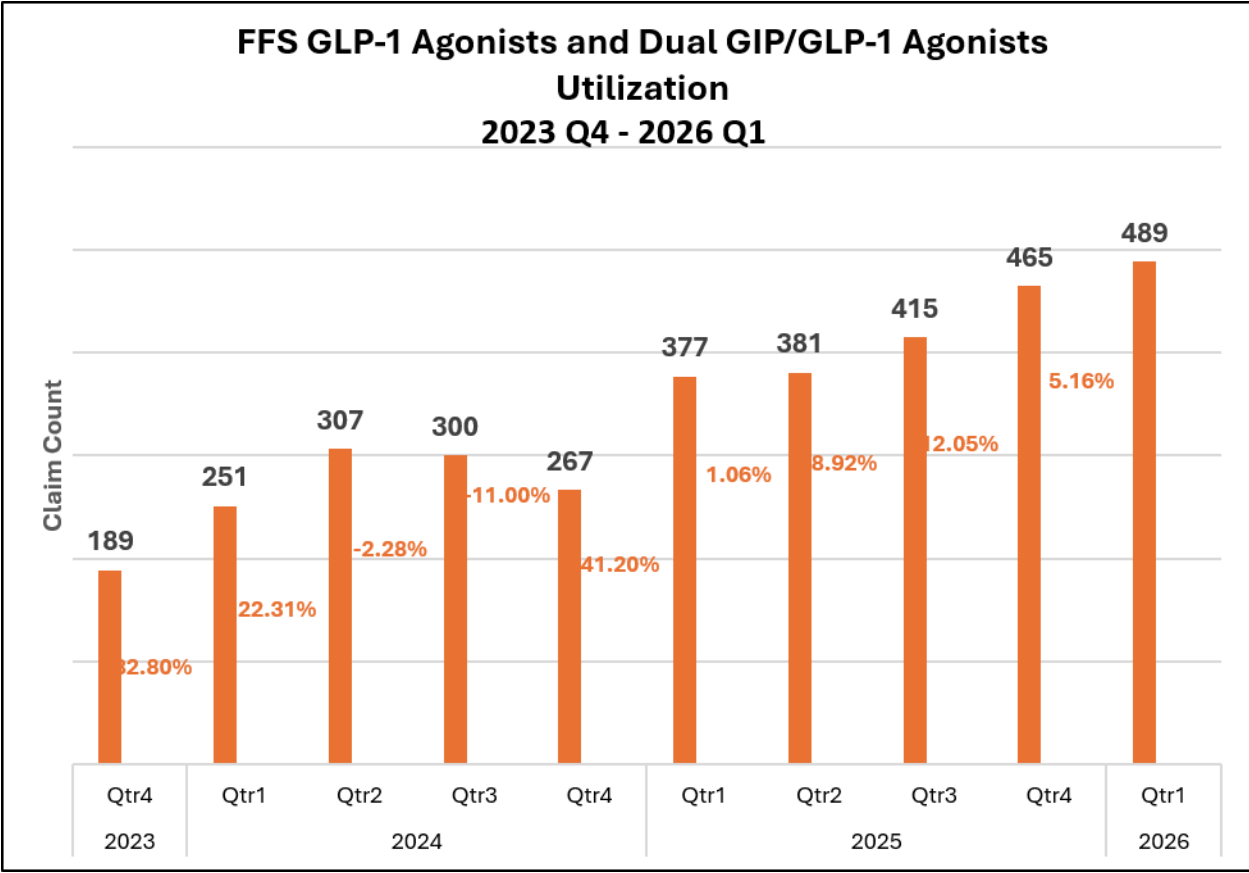
Issue	Action	Notes
4. Medication Information/Clinical Guidelines		Recent Guidelines links provided to the Board for further reading on the topics below: 1. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease 2. Transthyretin Cardiac Amyloidosis Evaluation and Management: 2025 ACC Concise Clinical Guidance 3. KDIGO 2026 Clinical Practice Guideline for the Management of Anemia in Chronic Kidney Disease (CKD) 4. Update on Familial Hypercholesterolemia: An Expert Clinical Consensus from the National Lipid Association
Follow-up items:		1. Provide a breakdown of members new to GLP-1/GIP agonists and SGLT2 inhibitors 2. Include the FDA approved indications for SGLT-2 inhibitors and GLP-1/GIP agonists for the presented utilization charts 3. Provide utilization reports for Lyfgenia® and Casgevy®, as well as monitor if requests go beyond twelve months. 4. Provide explanation for high denial rate in the ADHD/Anti-Narcolepsy/AntiObesity/Anorexiant category for all MCOs based on the 3rd Quarter 2025 PA report 5. Provide additional detail for the high denial rate in the antidiabetic (oral ad insulin) category for all MCOs based on the 4th Quarter 2025 PA report 6. Include disease incidence or prevalence in the protocol's background section for rare disorders.

Secretary's Report

New Jersey Drug Utilization Review Board

July 15, 2026

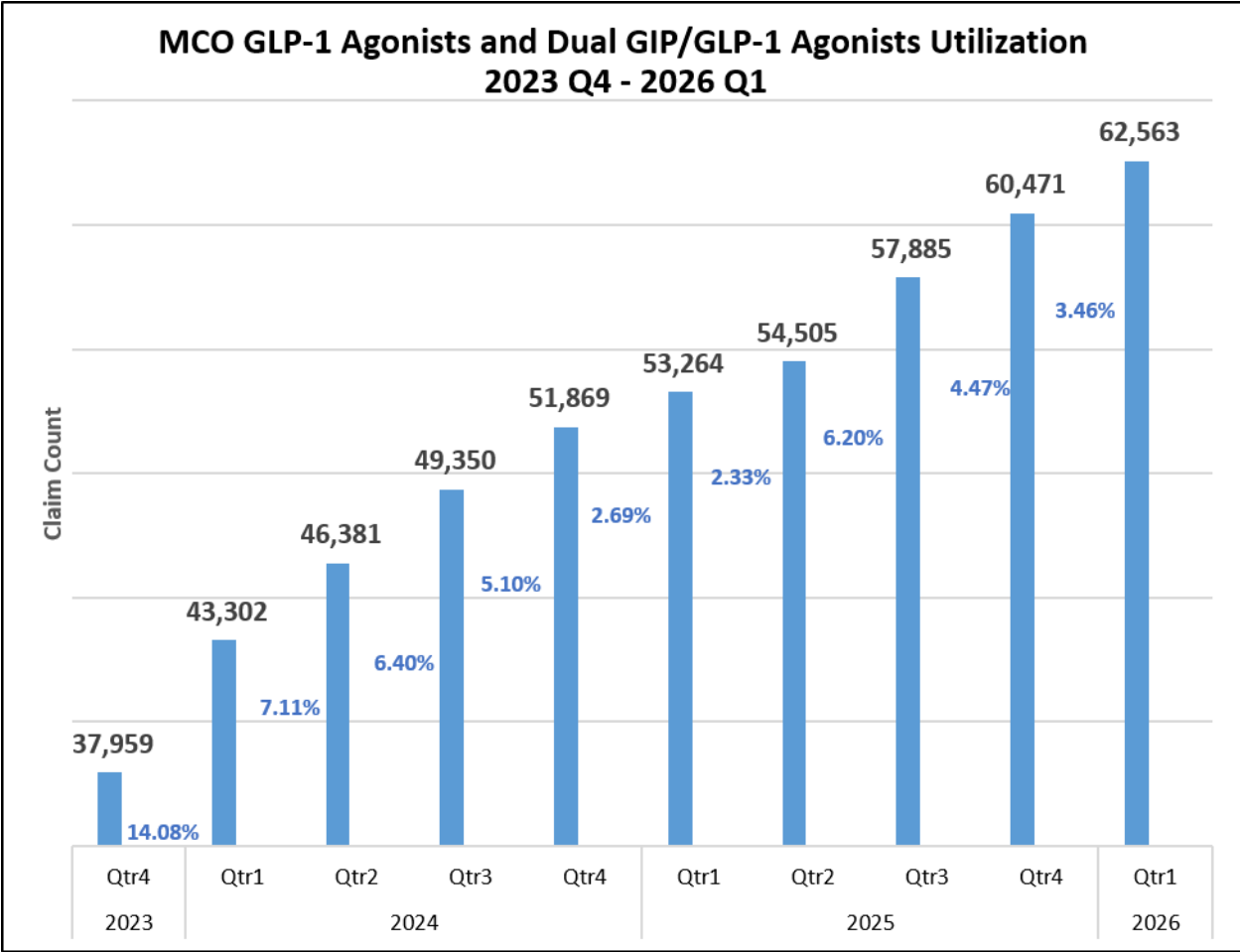
1. The January and April 2026 NJ DURB recommended protocols are approved by the Commissioners
2. Upcoming 2026 NJDURB meeting date is Wednesday, October 21, 2026
3. The Department does not have any new updates for the Board's positions



GLP-1 Agonists and Dual GIP/GLP-1 Agonists

Type 2 Diabetes Mellitus	Cardiovascular Events	Noncirrhotic Metabolic Dysfunction Associated Steatohepatitis	Obstructive Sleep Apnea	Chronic Kidney Disease
Bydureon Bcise Mounjaro Ozempic Rybelsus Soliqua Trulicity Victoza Xultophy	Ozempic Rybelsus Trulicity Victoza Wegovy Injection	Wegovy Injection	Zepbound	Ozempic

Updated June 2026

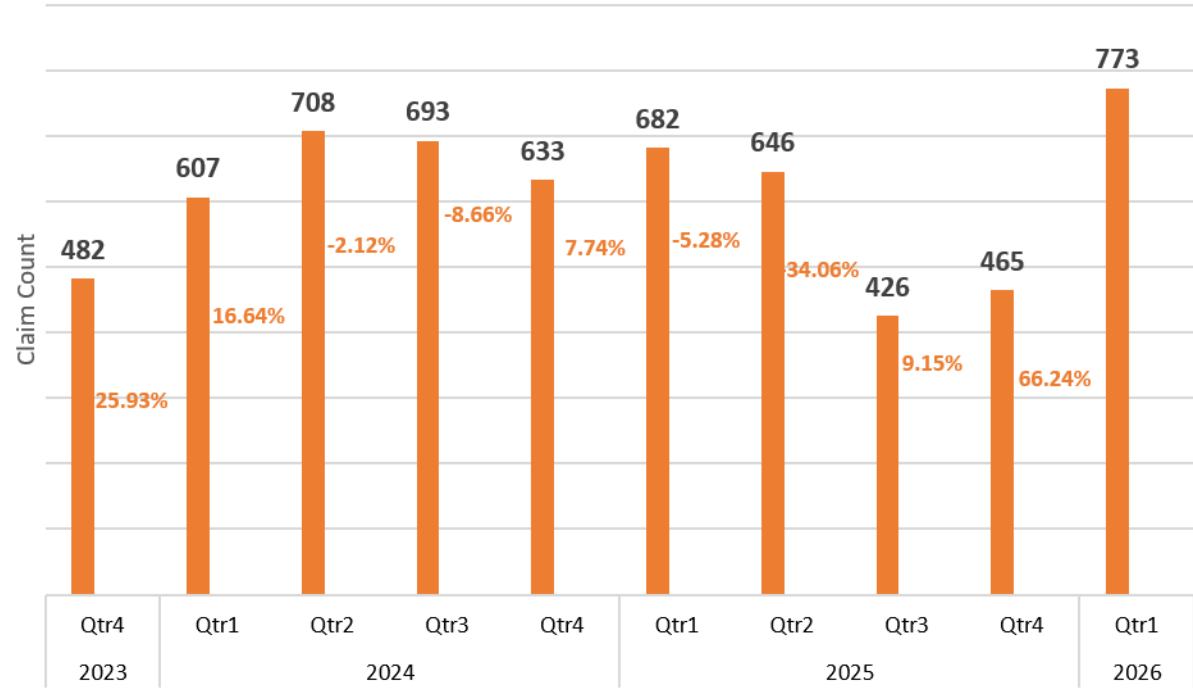


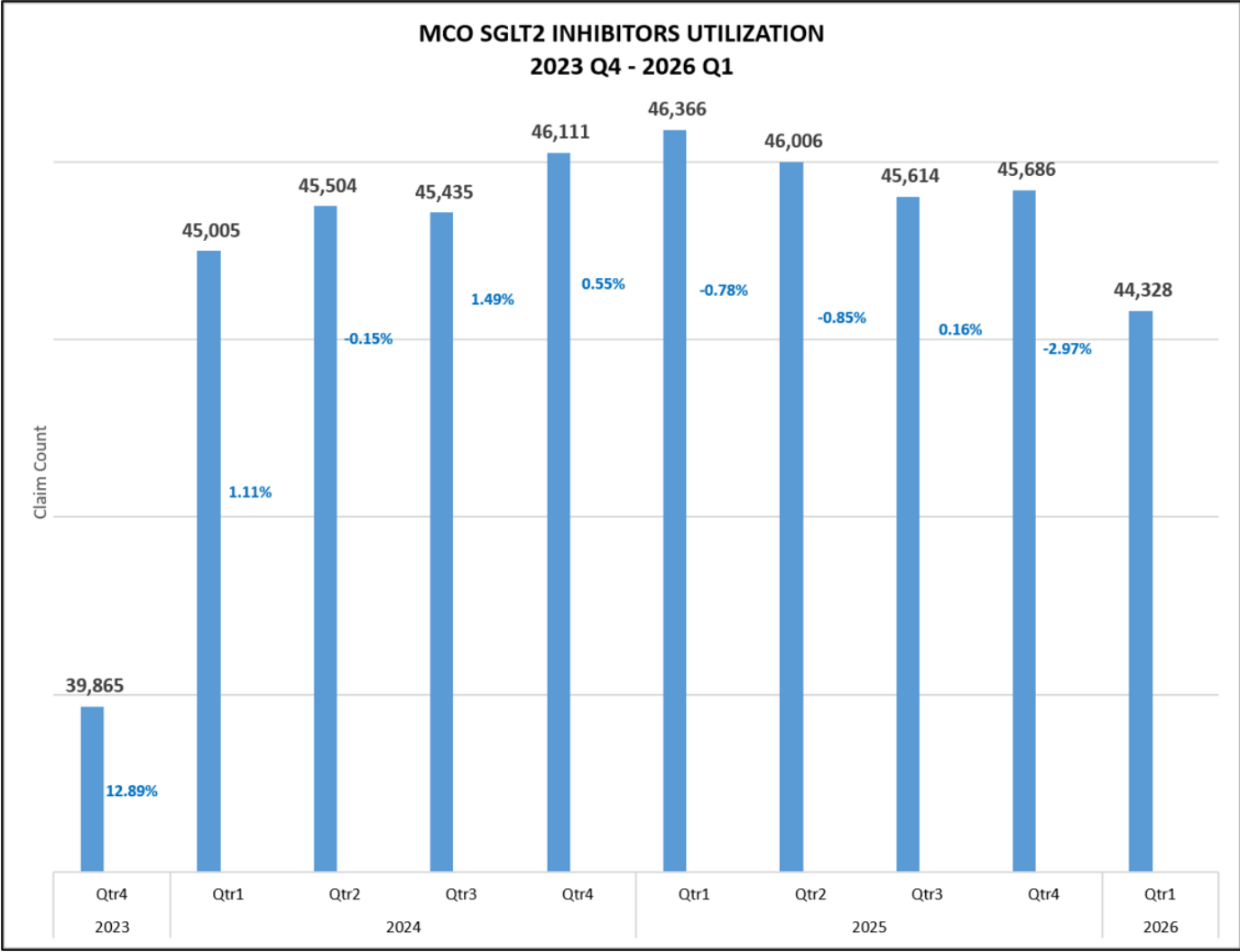
GLP-1 Agonists and Dual GIP/GLP-1 Agonists

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Updated June 2026

**FFS SGLT2 INHIBITORS UTILIZATION
2023 Q4 - 2026 Q1**





**Proposed Addendum to Protocol for Gattex[®] (teduglutide)
July 2026**

DURB Approval Dates	1/2023; 7/2026
Commissioners Approval Dates	2/2024

Addendum:

The initial and continuation of therapy criteria are updated.

Background: Short bowel syndrome (SBS) is a condition **affecting absorption** and results from surgical resection or congenital disease of the small intestine which is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balances when on a conventionally accepted, normal diet. **The global prevalence of SBS is estimated to be 0.12 to 2.74 per 100,000 adults and 0.09 to 1.67 per 100,000 children.** Gattex is as a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of ~~patients~~ **all patients one year of age and older** with SBS who are dependent on parenteral support.

Criteria for initial approval must meet all of the following:

1. **Patient is of the FDA-labeled or compendial approved age**
2. **Patient does not have any contraindications to therapy**
3. **Patient has documented congenital disease of the small intestine or the patient has surgical resection of the small intestine**
4. ~~Patient~~ **For adults has** a documented diagnosis of SBS defined **as small intestine length < 200 cm** ~~of viable small bowel~~
5. **For children <18 years of age a documented diagnosis of SBS defined as small intestine length <25 percent of the normal length of small intestine for the patient's age**
6. ~~Patient is 1 year of age or older and~~ **Patient** is dependent on parenteral nutrition support
7. ~~Patient is (an adult) dependent on parenteral nutrition/intravenous (PN/I.V.) support~~
 - a. ~~For at least 12 months; AND~~
 - b. ~~Requires at least 3 times per week of parenteral nutrition support;~~
 - ~~OR~~
8. The following baseline tests have been completed **within 6 months** before initiation of treatment (**documentation is required**):
 - a. ~~Within 6 months prior to initiating therapy, perform~~ **For all patients: laboratory assessment of** bilirubin, alkaline phosphatase, lipase, and amylase ~~tests~~
 - b. For adult patients: ~~within 6 months prior to initiating therapy,~~ perform a colonoscopy **and an upper gastrointestinal (GI) endoscopy** with removal of polyps if applicable
 - c. For **children** ~~pediatric patients: within 6 months prior to initiating therapy,~~ perform fecal occult blood test; if there is unexplained blood in the stool, ~~perform~~ colonoscopy/sigmoidoscopy and an upper GI endoscopy is

performed

9. Medication is prescribed by or in consultation with a gastroenterologist or a provider specializing in the patient's diagnosis
10. **Patient's current weight is provided** ~~Weight will be monitored~~
11. **The patient does not have a diagnosis of gastrointestinal cancer**
12. The medication ~~is 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 responding to therapy, defined as **meeting at least one of the following:**
 - a. Clinically stable**
 - b. Reduction in parenteral nutrition**
 - c. Increase in oral intake of nutrition**
 - d. Increase in enteral nutrition**
 - ~~e. Achieving at least 20% reduction in weekly PN/I.V. from baseline; OR~~
 - ~~f. Decrease in weekly PN/I.V. volume~~
2. **The patient does not have a diagnosis of gastrointestinal cancer**
3. The medication ~~is 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. Gattex [prescribing information]. Takeda Pharmaceuticals America, Inc. Lexington, MA. **September 2025** ~~October 2022~~
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Cagir, B. (2021, February 16). Short-Bowel Syndrome. Medscape. Accessed November 18, 2022 at: <https://emedicine.medscape.com/article/193391-overview>
4. Guillen G and Atherton NS. ; Nichole S. Atherton. Short Bowel Syndrome. Stat Pearls, July 26, 2022. Accessed November 21, 2022 at: <https://www.ncbi.nlm.nih.gov/books/NBK536935/>
5. **DiBaise, JK. Pathophysiology of short bowel syndrome. In: UpToDate, Inc. Available at www.uptodate.com Updated January 5, 2026. Accessed on May 7, 2026.**
6. **DiBaise, JK. Management of short bowel syndrome in adults. In: UpToDate, Inc. Available at www.uptodate.com Updated March 6, 2026. Accessed on May 11, 2026.**
7. **Iyer K, DiBaise JK, Rubio-Tapia A. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. Clinical Gastroenterology and Hepatology. 2022;20:2185-2194. [https://www.cghjournal.org/article/S1542-3565\(22\)00561-4/fulltext](https://www.cghjournal.org/article/S1542-3565(22)00561-4/fulltext)**

**Proposed Addendum to Protocol for Strensiq[®] (asfotase alfa)
July 2026**

DURB Approval Dates	1/2020; 7/2026
Commissioners Approval Dates	11/2021

Addendum:

The initial and continuation of therapy criteria are updated.

Background:

Strensiq[®] is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP). **Perinatal/infantile- and juvenile-onset hypophosphatasia** HPP is a rare inherited disease **with an occurrence of approximately 1 in 300,000 live births for the severe autosomal recessive forms and up to 1 in 500 for milder forms in adulthood.** HPP is caused by mutations of the *ALPL* gene, which encodes the tissue nonspecific alkaline phosphatase (TNSALP) ~~iso~~enzyme. **The TNSALP enzyme is involved in bone mineralization and transport of vitamin B6 into cells.**

Criteria for approval:

1. **The patient of the FDA-labeled compendial approved age**
2. **The patient does not have any contraindications to therapy**
3. Patient has a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) ~~evidenced by the following:~~
4. For patients with perinatal/infantile-onset HPP or juvenile-onset HPP **the following must be met (documentation is required):**
 - a. Low serum ALP levels compared to laboratory reference range for age and gender **AND**
 - b. Elevated levels of TNSALP substrate (i.e., serum pyridoxal 5'-phosphate (PLP) or urine phosphoethanolamine (PEA) or serum or urine inorganic pyrophosphate (PPi)) levels compared to laboratory reference range *Note for PLP measurement all vitamin B6 supplementation must be discontinued at least one week prior to testing **AND**
 - c. Presents with pathogenic or likely pathogenic ALPL gene variant **OR presents with a combination of major and minor diagnostic criteria for HPP established by clinical practice guidelines or other medically accepted compendia**
- ~~5. Patient has clinical symptoms consistent with hypophosphatasia at the age of onset (e.g. vitamin B6-dependent seizures, skeletal abnormalities such as flawed and frayed metaphysis; AND~~
 - ~~a. Molecular genetic test has confirmed mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP); AND~~

- ~~b. There is reduced activity of unfractionated serum alkaline phosphatase (ALP) [below the age and gender adjusted normal range]; AND~~
- ~~c. Patient has one of the following:~~
 - ~~i. Elevated urine concentration of phosphoethanolamine (PEA)~~
 - ~~ii. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within a week prior to assaying~~
 - ~~iii. Elevated urine inorganic pyrophosphate (PPi)~~
- 6. Prescribed by or in consultation with a physician specialized in the treatment of inherited metabolic disorders
- 7. Baseline ophthalmologic examination and renal ultrasound completed
- 8. **For drugs with weight-based dosing**, the patient's current weight is provided, ~~must be received for drugs that have weight-based dosing. Height and weight must be received for drugs that have dosing based on body surface area~~
- 9. The medication ~~is prescribed~~ **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, or national guidelines

Continuation of therapy:

- 1. Patient has responded to treatment as demonstrated by improvement and/or stabilization **of condition** (e.g. radiographic findings, growth, mobility, **decrease in bone pain**) ~~respiratory status~~, **documentation is required**
- 2. **For drugs with weight-based dosing, the patient's current is provided** ~~For dose increases, height and weight must be received for drugs that have dosing based on body surface area~~
- 3. The medication ~~is prescribed~~ **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, or national guidelines

There is a black box warning for anaphylaxis, hypersensitivity reactions, and initiation of therapy under healthcare provider supervision. See full prescribing information for complete boxed warning.

References:

- 1. Strensiq [prescribing information]. Alexion Pharmaceuticals, Inc. ~~Cheshire, CT.~~ **Boston, MA. July 2024 October 2015**
- 2. Rush ET. Childhood hypophosphatasia: to treat or not to treat. Orphanet Journal of Rare Diseases (2018) 13:116. Access online on 9.20.19
- 3. Mornet E, Nunes ME. Hypophosphatasia. US National Library of Medicine (2007). Updated February 2016.

4. Clinical Pharmacology[®] Gold Standard Series [Internet database]. Tampa, FL. Updated periodically
5. National Institute for Health and Care Excellence (NICE) Guidance. Asfotase alfa for treating paediatric-onset hypophosphatasia. 2017.
<https://www.nice.org.uk/guidance/hst6>.
6. **Pallais JC. Hypophosphatasia: Clinical manifestations and diagnosis. In: UpToDate, Inc. Available at www.uptodate.com Updated April 2026. Accessed on May 11, 2026.**
7. **Pallais JC. Hypophosphatasia: Management. In: UpToDate, Inc. Available at www.uptodate.com Updated April 2026. Access on May 12, 2026.**
8. **Khan AA, Brandi ML, Rush ET, et al. Hypophosphatasia diagnosis: current state of the art and proposed diagnostic criteria for children and adults. Osteoporosis International. March 2024; 35:431-438. <https://pubmed.ncbi.nlm.nih.gov/37982857/>**
9. **Cardenas-Aguilera JG, Gonzalez-Lopez V, Zarante-Bahamon AM, et al. Diagnosis, treatment, and follow-up of patients with hypophosphatasia. Endocrine. 2025;87(2):400-419. <https://link.springer.com/article/10.1007/s12020-024-04054-1>**

Proposed Protocol for C Type Natriuretic Peptide Products
July 2026

DURB Approval Dates	
Commissioners Approval Dates	

Voxzogo® (vosoritide)
Yuviwel® (navepegritide)

Background:

Achondroplasia is an autosomal dominant condition caused by mutations in the fibroblast growth factor receptor 3 (*FGFR3*) gene, which activates the FGFR3 receptor. Activation of the FGFR3 receptor leads to impaired endochondral bone formation, growth restriction, bone shortening, and other skeletal anomalies. The prevalence of achondroplasia is approximately 1 in 20,000.

Voxzogo and Yuviwel are C type natriuretic peptide (CNP) analogs indicated to increase linear growth in pediatric patients with achondroplasia with open epiphyses. C type natriuretic peptide (CNP) counteracts the inhibitory effects of FGFR3 and promotes bone growth in achondroplasia.

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age
2. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
3. Patient does not have any contraindications to therapy
4. The patient is not concomitantly receiving another C Type Natriuretic Peptide
5. The medication is prescribed by or in consultation with a specialist who has appropriate knowledge and experience
6. For products with weight-based dosing, the patient's current weight is provided
7. The documentation of the patient's most current eGFR is provided
8. Documentation is required that the patient's epiphyses are open
9. The prescriber will monitor patient's body weight, growth, and physical development regularly (e.g. every 3 to 6 months)
10. Prescriber confirms other causes (e.g. hypochondroplasia, thanatophoric dysplasia) of skeletal dysplasia have been ruled out
11. Diagnosis of achondroplasia is confirmed by one of the following (a. or b.):
 - a. Documentation is required of genetic testing confirming a pathogenic mutation of the *FGFR3* gene **OR**
 - b. Documentation is required confirming both of the following:
 - i. Clinical features consisting of but not limited to the following: short stature, long-bone shortening affecting upper and lower extremities,

macrocephaly, brachydactyly, kyphoscoliosis, or accentuated lumbar lordosis **AND**

- ii. Radiographic studies of the thorax and pelvis showing skeletal abnormalities

Continuation of therapy:

1. The patient's epiphyses are open, documentation is required
2. The documentation includes the patient's most current eGFR
3. The patient's current weight is provided
4. Documentation is required demonstrating an increase in linear growth
5. The patient is not concomitantly receiving another C Type Natriuretic Peptide

References:

10. Voxzogo [prescribing information]. BioMarin Pharmaceutical Inc. Novato, CA. November 2025.
11. Yuviwel [prescribing information]. Ascendis Pharma Endocrinology, Inc. Princeton, NJ February 2026.
12. Bacino, CA. Achondroplasia: Clinical features, diagnosis and management. In: UpToDate, Inc. Available at www.uptodate.com Updated April 2026. Accessed on May 18, 2026.
13. Savarirayan, R., Ireland, P., Irving, M. *et al.* International Consensus Statement on the diagnosis, multidisciplinary management and lifelong care of individuals with achondroplasia. *Nat Rev Endocrinol* **18**, 173–189 (2022).
<https://www.nature.com/articles/s41574-021-00595-x>

Protocols Recommended for Retirement

Protocol to Retire	Reason
Makena [®]	No longer available on market
Zyvox [®]	Low PA requests
Low Molecular Weight Heparin	High approval Rate

Gainwell Technologies/NJ MCO 1st Quarter 2026 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	86,813	113,962	84,221	974680	345,842	166,969
Total # of Pharmacy Claims Processed	505,643	556,966	318,340	3287822	891,829	948,441
Total # of Members Requesting Prior Authorization*	1,614	3,202	2,735	23269	7,890	5,905
Total Prior Authorizations Requests Received**	4,180 (0.8%)	4,489 (0.8%)	4,736 (1.5%)	34,117 (1%)	10,486 (1.2%)	8,436 (0.9%)
Received Requests Denials	73 (2%)	2,275 (51%)	1,792 (38%)	12,191 (36%)	4,148 (40%)	3,995 (47%)
Without Non-formulary Denials	73 (2%)	903 (20%)	324 (7%)	4,305 (13%)	1,964 (19%)	1,271 (15%)
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	66 (90%)	771 (34%)	313 (17%)	4,220 (35%)	1,740 (42%)	1,091 (27%)
Excluded Benefit	7 (10%)	132 (6%)	11 (1%)	85 (1%)	224 (5%)	180 (5%)
Non-formulary	0 (0%)	1,372 (60%)	1,468 (82%)	7,886 (65%)	2,184 (53%)	2,724 (68%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	8.2%	3.3%	3.6%	3.6%	4.5%	3.1%
Antidepressants	0.0%	0.8%	1.8%	1.8%	0.9%	1.0%
Antihypertensives	0.0%	0.9%	0.7%	0.7%	0.5%	0.5%
Antianxiety	2.7%	0.0%	0.1%	0.1%	0.0%	0.1%
Antidiabetics (oral and insulin)	11.0%	19.3%	17.8%	17.8%	11.9%	15.0%
Anticoagulants	4.1%	0.0%	0.0%	0.0%	0.1%	0.0%
Thyroid agents	0.0%	0.2%	0.1%	0.1%	0.5%	0.2%
Ulcer Drugs/Antispasmodics/Anticholinergics	0.0%	1.9%	1.9%	1.9%	2.2%	1.0%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiant	0.0%	13.8%	8.2%	8.2%	14.2%	12.0%
Antipsychotic/Antimanic agents	0.0%	0.7%	4.1%	4.1%	0.9%	2.3%
Antiasthmatic and Bronchodilator agents	12.3%	5.9%	5.0%	5.0%	8.1%	3.5%
Antivirals (includes both HIV and Hep C)	0.0%	0.4%	0.4%	0.4%	0.4%	0.4%
Digestive Aids (Digestive Enzymes)	1.4%	0.4%	0.1%	0.1%	0.0%	0.1%
Anticonvulsants	1.4%	1.1%	1.6%	1.6%	1.8%	1.2%
Migraine Products	0.0%	6.1%	4.5%	4.5%	5.7%	4.7%
Analgesics Anti-inflammatory	4.1%	1.5%	2.4%	2.4%	2.5%	2.2%
Analgesic Opioids	6.8%	3.6%	1.1%	1.1%	1.7%	3.9%
Endocrine and Metabolic Agents-Misc (Growth Hormone	0.0%	1.3%	1.1%	1.1%	1.8%	2.2%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.9%	0.9%	0.9%	0.5%	0.7%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.0%	0.0%	0.0%	0.2%	0.1%
Dermatologics (Antipsoriatics-Systemic)	0.0%	18.8%	18.5%	18.5%	14.7%	16.0%

* Value represents unduplicated data and will not include a member more than once, even if multiple requests are made.

** Denominator for percentage is Total Number of Pharmacy Claims Processed.

*** See below for explanation of categories:

Clinical Criteria Not Met: includes categories such as Clinical Criteria Not Met, Drug-Drug Interaction, Therapeutic Duplication, Unacceptable Diagnosis

Excluded Benefit: includes categories such as Duration Exceeded, Excessive Dose, Mandatory Generic

Non-Formulary: includes categories such as Non-Formulary

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
April 2026	Proposed Addendum to Protocol for Crysvita Proposed Addendum to Protocol for Cystic Fibrosis Transmembrane Conductance Regulator Products Proposed Addendum to Protocol for Spinal Muscular Atrophy Products	- The Board recommended approval of the addendum to the protocol for Crysvita. The protocol was updated with specific monitoring parameters. The update also included aligning it with standard criteria for all protocols. - The Board recommended approval of the addendum to the protocol for Cystic Fibrosis Transmembrane Conductance Regulator products. The update included addition of Alyftrek which was approved by the FDA in December 2024. - The Board recommended approval of the addendum to the Spinal Muscular Atrophy products. The protocol was updated to include Itmisva, a new drug approved by the FDA in November 2025.	
January 2026	Proposed Protocol for Opzelura Proposed Addendum to Protocol for Duchenne Muscular Dystrophy Products	- The Board recommended approval of the protocol for Opzelura. Opzelura is indicated for the diagnosis of atopic dermatitis and nonsegmental vitiligo. - The Board recommended approval of the addendum to the Duchenne Muscular Dystrophy products. Duvyzat, a new drug, was added to the protocol. Elevidys criteria	

DURB Meeting	Action Items	Status/DURB Recommendations	Impact/Comments
	Proposed Addendum to Protocol for Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modifiers	was updated to allow approval for those who are ambulatory. The Board recommended approval of the addendum to the PCSK9 modifiers protocol. The protocol was updated to include a new FDA approved indication for patients at an increased risk of developing a major cardiovascular event. Additional information from Amgen was received and reviewed by the Board.	Will continue to monitor any guideline updates / recommendations to the use of PCSK9 modifiers versus other cholesterol lowering therapies
October 2025	Proposed Addendum to Protocol for Biologics in Moderate to Severe Asthma Proposed Addendum to Protocol for Dupixent®	- The Board recommended approval of the addendum to the biologics in moderate to severe asthma protocol. Specific criteria were updated based on the Food and Drug Administration (FDA) labeling and Global Initiative for Asthma (GINA) 2024 Guidelines. Dupixent® for the indication of asthma was removed from this protocol and added to the Dupixent® protocol. - The Board recommended approval of the addendum to the Dupixent® protocol. The protocol was updated to include the following FDA approved indications: chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid. The criteria pertaining to asthma as updated based on GINA 2024	

DURB Meeting	Action Items	Status/DURB Recommendations	Impact/Comments
	Proposed Addendum to Protocol for Hereditary Angioedema Proposed Addendum to Protocol for Wegovy®	Guidelines. The criteria for chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis were updated. - The Board recommended approval of the addendum to the Hereditary Angioedema protocol. Andembry®, Dawnzera®, Orladeyo®, and Ekterly® were added to the protocol. - The Board recommended approval of the addendum to the Wegovy® protocol. The protocol was updated to include a new FDA approved indication for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) and relevant criteria for approval.	
July 2025	Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products Proposed addendum to the protocol for Imcivree® (setmelanotide)	- 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. - 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	

DURB Meeting	Action Items	Status/DURB Recommendations	Impact/Comments
	Proposed addendum to the protocol for Paroxysmal 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 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. • The Board recommended approval of the addendum to the CAR T Cell products protocol. • The Board recommended approval of the addendum to the GLP-1RA and GLP-1RA/GIP Agonists for Type 2 Diabetes.	