New Jersey Drug Utilization Review Board
Virtual Platform
January 28, 2026

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 October 22, 2025, meeting https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/DURB_Transcript_October_2025.pdf

IV. Review of draft meeting summary for October 22, 2025, meeting (pages 4-7)

V. Secretary's report (page 8)

VI. Old Business
   - A. Fee-for-Service (FFS) and Managed Care Organization (MCO) Utilization Trends of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors (pages 9-10)
   - B. FFS and MCO Utilization Trends of Glucagon-like peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-dependent Insulinotropic Polypeptide (GIP) Agonists for Diabetes Mellitus (pages 11-12)

VII. New Business
   - A. Proposed Protocol for Opzelura® (pages 13-15)
   - B. Proposed Addendum to Protocol for Duchenne Muscular Dystrophy Products (pages 16-19)
   - C. Proposed Addendum to Protocol for Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modifiers (pages 20-25)

VIII. A. Informational Highlights/Reports
   1. Gainwell Technologies/NJ MCO 3rd Quarter 2025 Prior Authorization Report (page 26-27)
   2. Summary of DURB Action Items (pages 28-34)
   3. DHS/DOH Pharmacy Programs Top Drugs Report/Physicians Administered Drugs Report (by amount paid and by category):

FFS top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/FFS_Top_Drugs_Report_November-2025.pdf

MCO top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/MCO_Top_Drugs_Report_October-2025.pdf

FFS top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/FFS_Top_Drugs_by_Category_November-2025.pdf

MCO top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/MCO_Top_Drugs_by_Category_October-2025.pdf

FFS antiviral drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/FFS_Antiviral_Drugs_November-2025.pdf

B. Medication/Medical information

WHO issues global guideline on the use of GLP-1 medicines in treating obesity
https://www.who.int/news/item/01-12-2025-who-issues-global-guideline-on-the-use-of-glp-1-medicines-in-treating-obesity

One Dose versus Three Doses of Benzathine Penicillin G in Early Syphilis
https://pubmed.ncbi.nlm.nih.gov/40902161/

American Association of Clinical Endocrinology Consensus Statement: Algorithm for the Evaluation and Treatment of Adults with Obesity/Adiposity-Based Chronic Disease – 2025 Update
https://www.sciencedirect.com/science/article/pii/S1530891X25009772?ref=pdf_download&fr=RR-2&rr=9b086d0b5bb6fef2

Use of Risk Assessment to Guide Decision-Making for Blood Pressure Management in the Primary Prevention of Cardiovascular Disease: A Scientific Statement from The American Heart Association and American College of Cardiology
https://www.jacc.org/doi/10.1016/j.jacc.2025.08.001?_gl=1*11a97wk*_ga*MjAyNTIzNzYwMC4xNzU2ODMxNTQx*_ga_2V8VW4Y237*czE3NTY4MzE1NDAkbzEkZzAkdDE3NTY4MzE1NDAkajYwJGwwJGgw

RSV Vaccine Effectiveness Against Hospitalization Among US Adults Aged 60 Years or Older During 2 Seasons
https://pubmed.ncbi.nlm.nih.gov/40884491/

HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy
https://www.hhs.gov/press-room/hhs-advances-womens-health-removes-misleading-fda-warnings-hormone-replacement-therapy.html

FDA asks for removal of suicide warnings on GLP-1 drugs
https://www.axios.com/2026/01/13/fda-wegovy-zepbound-suicide-warnings

October 22, 2025, DURB Meeting Summary (Draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Moynihan, Ms. Olson, Dr. Barberio, Dr. Lind (ex-officio, Department of Human Services) and Dr. Sahu (ex-officio, Department of Health) Unable to attend: Dr. Marcus and Mr. Schafer
Dr. Swee's pre-meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the Board's meeting: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the filings in the Trenton Times, Star Ledger, and Atlantic City Press.
Review of Minutes	Approved	Ms. Olson and Dr. Barberio requested an update to the minutes from July 16, 2025, regarding the naloxone discussion in the DHS/DHSS/MCO Programs Top Drugs Report Section. The statement was updated to "Addressing naloxone on the top drugs report, Dr. Barberio stated it is dispensed in certain situations where there is an increase in the risk of an opioid overdose such as, but not limited to, the following: receiving opioid doses ≥90 MME/day or taking opioids with benzodiazepines." The approved meeting summary with the update is posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		- The Department is working with the Commissioners to review and sign off on the July 2025 DURB recommended protocols - The Department is working with the Commissioners to review and sign off on the State Fiscal Year (SFY) 2024 Annual Report - The 2026 NJDURB Meeting dates were announced o January 28, 2026; April 15, 2026; July 15, 2026; October 21, 2026 - The SFY 2025 NJDURB Annual Report is drafted and will be sent to the Board for review and comments
Old Business		

Issue	Action	Notes
(A) 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 ongoing reports to monitor utilization of these therapeutic classes. Dr. Swee commented on the increase in utilization from 4Q2024 to 1Q2025 of the GLP-1/GIP agonist category. The Board noted these drugs are not covered for the diagnosis of obesity alone.
(B) Updated Protocol for Imcivree®		The Board reviewed an updated version of the Imcivree® protocol with the recommended addition of noting a reduction in body mass index at one year from baseline for the continuation of therapy section. There was no further discussion.
(C) Updated Protocol for Chimeric Antigen Receptor (CAR) T Cell Products		The Board reviewed an updated version of the Chimeric Antigen Receptor (CAR) T Cell products protocol with the recommended change for Abecma® to include trial of at least two prior lines of therapy. There was no further discussion.
(D) Updated Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products		The Board reviewed an updated version of the Paroxysmal Nocturnal Hemoglobinuria (PNH) products protocol with the recommended deletion of the word normalization from the continuation of therapy criteria pertaining to reticulocyte counts. There was no further discussion.
New Business		
(A) Proposed Addendum to Protocol for Biologics in Moderate to Severe Asthma	Recommended	The Board reviewed a proposed addendum to the protocol for biologic drugs used in the treatment of moderate to severe asthma. Dr. Swee stated Dupixent® for the diagnosis of asthma is no longer included in this protocol, however it is still available as a covered drug in a separate protocol. Discussion took place regarding the age-related criteria for the requested drugs. Pinali Agrawal stated the patient must meet the FDA approved age for the requested drug. In addition, if there is support in the compendia for use of the requested drug in non-FDA approved ages, approval is considered. The Board recommended approval of the protocol.
(B) Proposed Addendum to Protocol for Dupixent®	Recommended	The Board reviewed a proposed addendum to the Dupixent® protocol. Dr. Swee stated the Board's concern regarding prolonged use of high potency steroids, including topical steroids, to treat many of the conditions noted in the protocol. He stated the newer drugs are an alternative with their respective pros and cons. Dr. Swee asked if laser treatment for nasal polyps would be considered as trial of surgery. Pinali Agrawal stated she will

Issue	Action	Notes
		follow-up and confirm if laser procedures would be an effective alternative for the treatment of nasal polyps and if it can be added to the nasal polyp criteria for approval. The Board recommended approval of the protocol with follow-up information on laser treatment for nasal polyps.
(C) Proposed Addendum to Protocol for Hereditary Angioedema	Recommended	The Board reviewed a proposed addendum to the protocol for Hereditary Angioedema. Dr. Swee expressed the importance of monitoring patients receiving these medications, especially when the drugs are administered in a health care setting. The Board recommended approval of the protocol.
(D) Proposed Addendum to Protocol for Wegovy®	Recommended	The Board reviewed a proposed addendum to the protocol for Wegovy®. Dr. Swee discussed the black box warning pertaining to thyroid c-cell tumors and the warning and precaution of acute pancreatitis associated with this drug. Dr. Gochfeld asked if there were any associations between this drug and suicide risks. Ashmita Jadubans, a medical science liaison with Novo Nordisk stated there is no official link between suicide and suicidal ideation and GLP use. There is some data regarding suicide and GLP utilization, however it has not been correlated with one another. She stated there is research studying the use of GLPs in those with addiction. 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 2nd Quarter 2025 prior authorization (PA) denial report for FFS and MCOs. Dr. Swee stated Aetna's denial rate for the ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants category is an outlier in comparison to the other managed care plans. He requested an explanation for the high denial percentage. Pinali Agrawal stated Aetna provided feedback pertaining to the types of denials. But with respect to what is causing the high denial rate, the State will follow up with Aetna and provide the information to the Board.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (July 2024 through July 2025). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2025 (FFS) and June 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>July 2025</td><td>$ 2,180,975*</td><td>$ 2,406,614*</td></tr>
<tr><td>MCOs</td><td>June 2025</td><td>$ 119,081,572</td><td>$170,089,981</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
</table>
</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:
1. American Association of Clinical Endocrinology Clinical Practice Guidelines on the Pharmacologic Management of Adults with Dyslipidemia 2025
2. American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines - 2025 Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults
Dr. Swee expressed his concern with the potential conflict of interest of the clinicians and practitioners who make the recommendations in the published guidelines. He also stated how he looks forward to recommendations made by the U.S. Preventive Services Task Force.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Provide utilization reports for GLP-1/GIP agonists and SGLT2 inhibitors.
2. Provide utilization reports for Lyfgenia® and Casgevy®, as well as monitor if requests go beyond twelve months.
3. Laser surgery for nasal polyps, confirm if this meets criteria for approval</td></tr>
</table>

Secretary's Report

New Jersey Drug Utilization Review Board
January 28, 2026

1. The Commissioners approved the July 2025 DURB recommended protocols

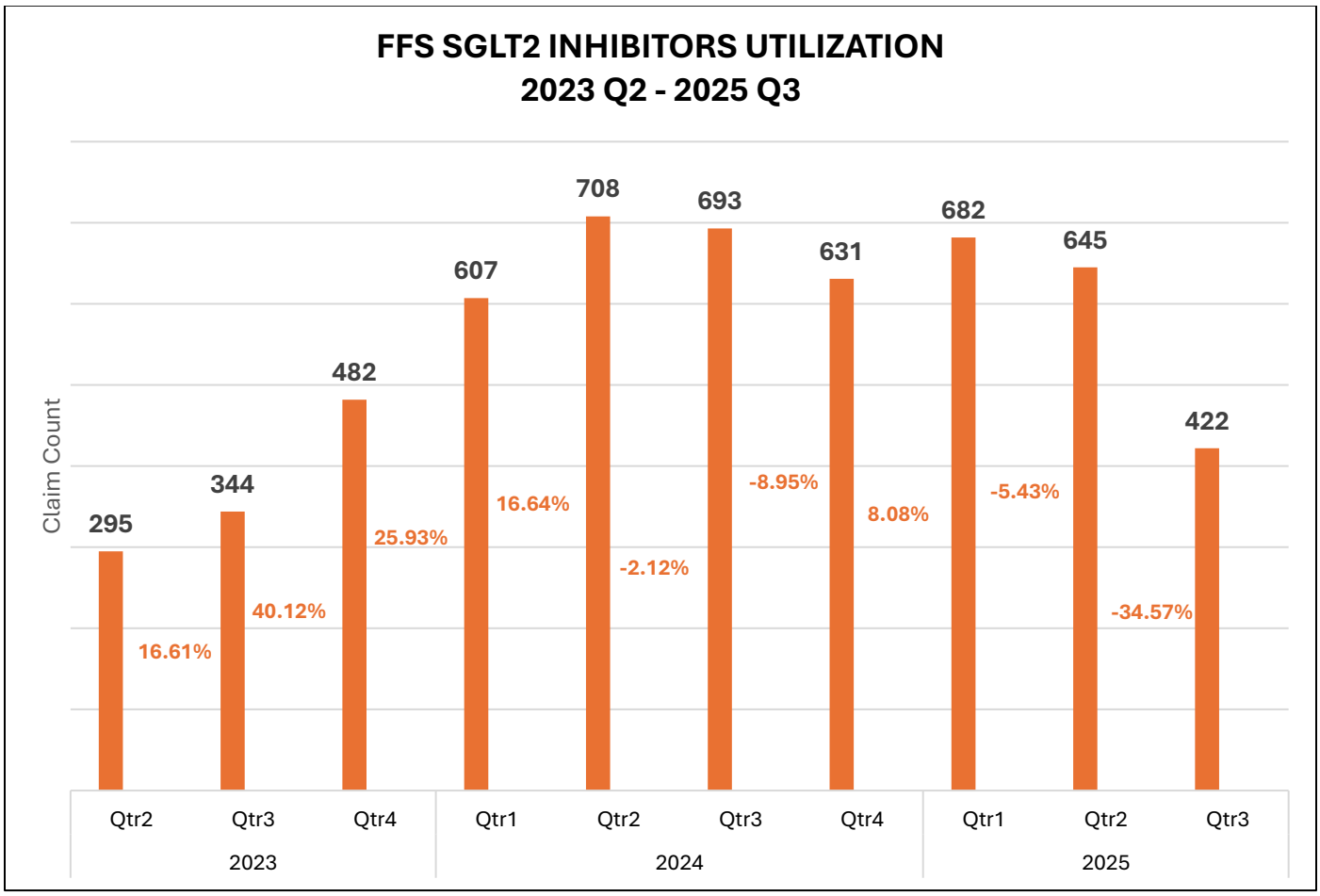
2. NJDURB State Fiscal Year 2025 Annual Report is under review by the Commissioners

3. Follow-up to the Protocol for Dupixent® presented during the October 2025 meeting, nasal laser therapy for the treatment of chronic rhinosinusitis with nasal polyposis meets criteria for approval. The Protocol was updated and is currently under review by the Commissioners.

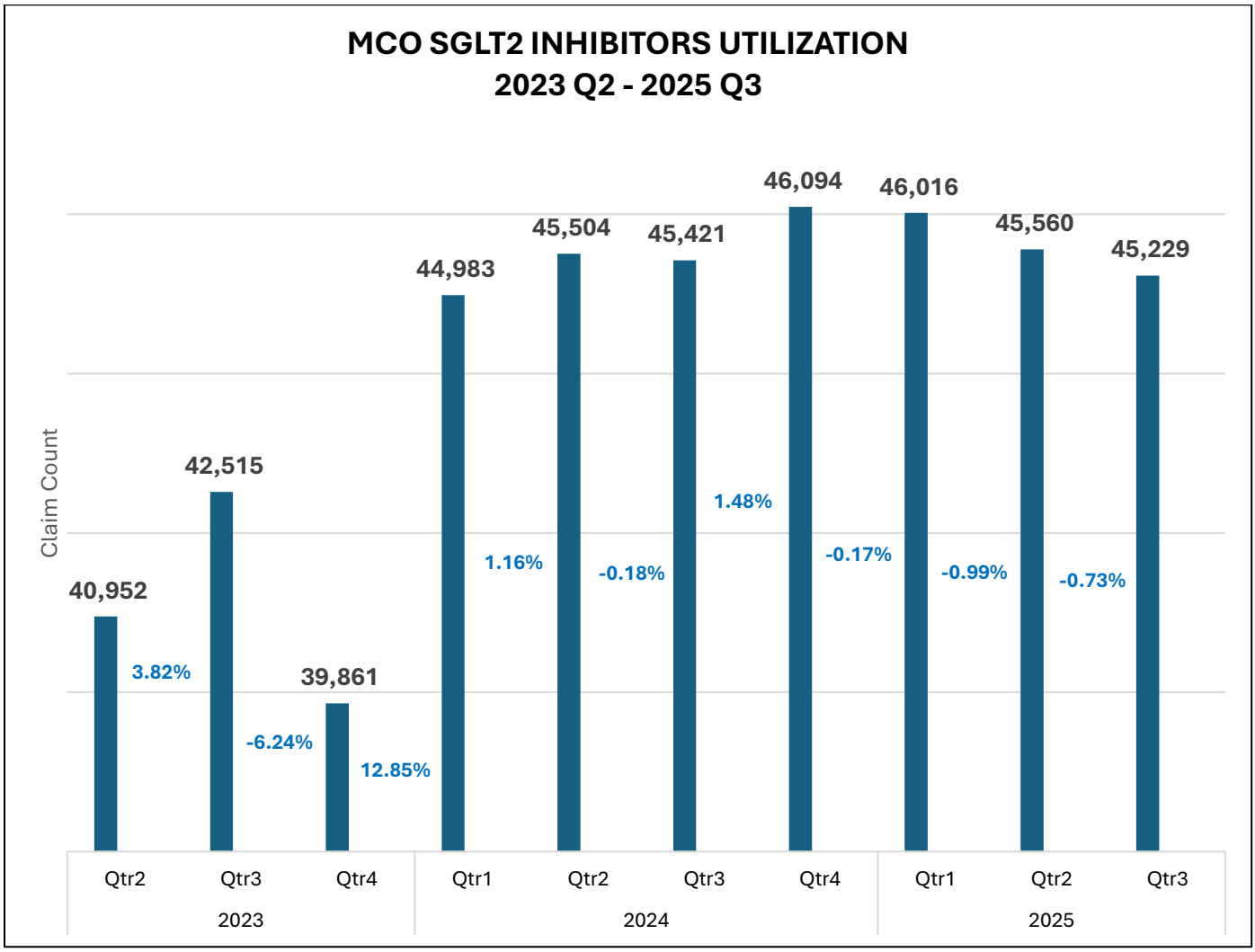
4. Upcoming 2026 NJDURB Meeting Dates:
   Wednesday, April 15, 2026
   Wednesday, July 15, 2026
   Wednesday, October 21, 2026

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

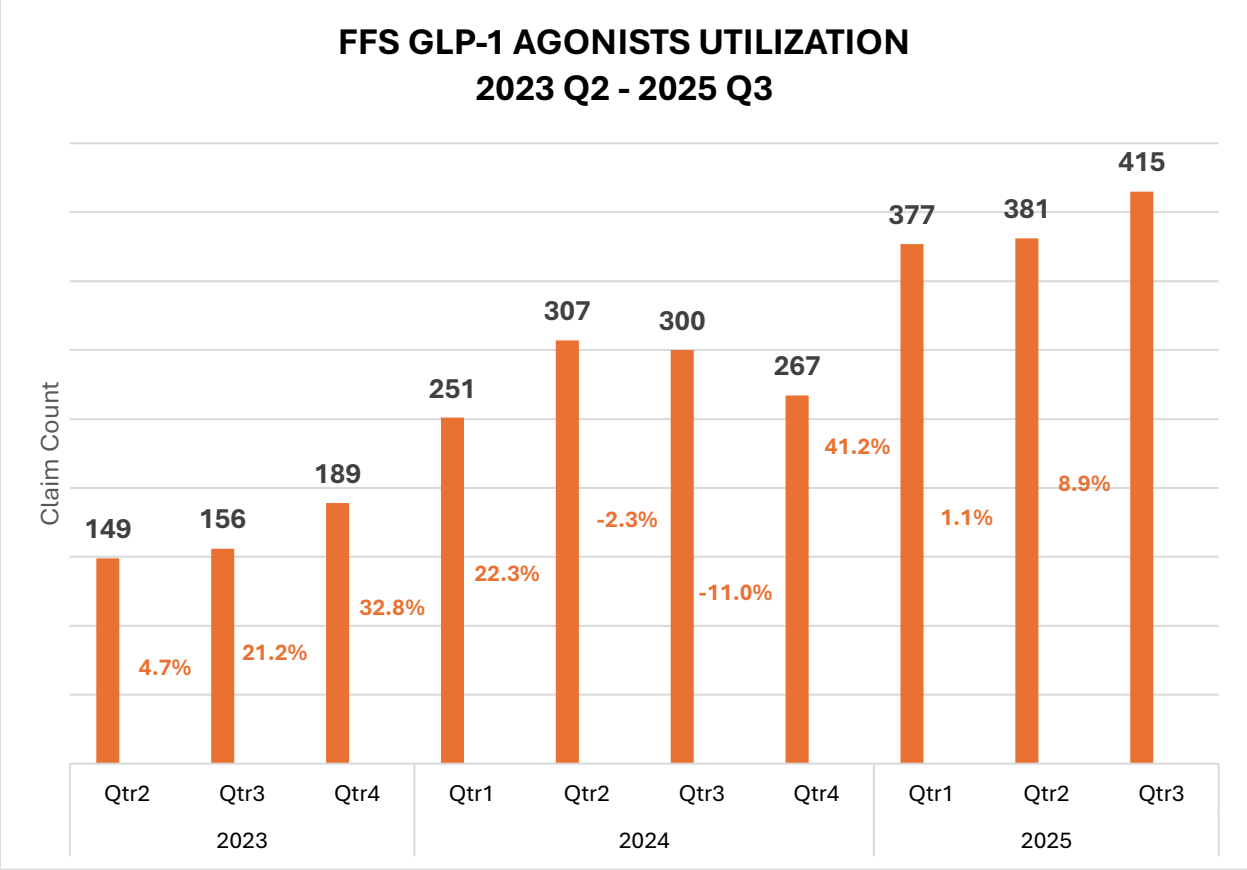
Utilization Trends
FFS Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors Utilization



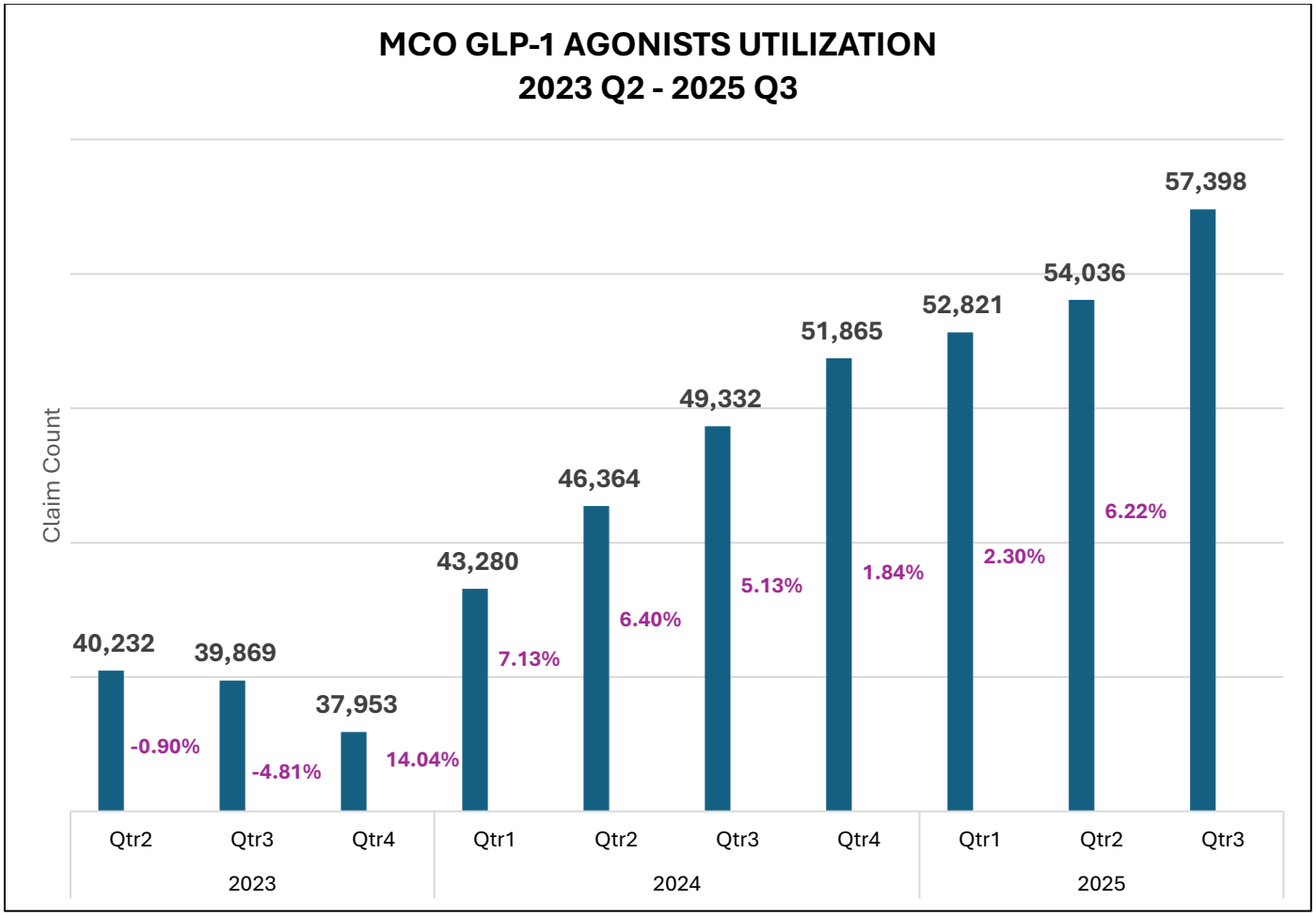
MCO SGLT-2 Inhibitors Utilization



FFS Utilization of Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonist for Diabetes Mellitus



MCO Utilization of Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonist for Diabetes Mellitus



Proposed Protocol for Opzelura® (ruxolitinib)
January 2026

Opzelura® (ruxolitinib)
Protocol applies to FDA approved biosimilars and related indications and dosages

Background:
Opzelura® is a janus kinase (JAK) inhibitor approved for the treatment of mild to moderate atopic dermatitis and nonsegmental vitiligo.

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

1. Patient is of the FDA-labeled or compendial approved age
2. The medication will not be used concomitantly with biologic immunomodulators, JAK inhibitors or potent immunosuppressants
3. The medication is prescribed by or in consultation with a specialist in the appropriate field
4. Patient is not immunocompromised
5. Patient does not have any contraindications to therapy
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 mild to moderate atopic dermatitis
    b. Opzelura will not be used on more than 20% of the patient's body surface area
    c. Patient has tried and failed topical corticosteroids for at least 2 weeks or has an intolerance or contraindication to topical steroids (for example the affected area is on the face, groin or skin folds)
    d. Patient has tried and failed topical calcineurin inhibitors (e.g., Elidel®, Protopic®) or phosphodiesterase 4 (PDE4) inhibitor (Eucrisa®) for at least 4 weeks or has an intolerance or contraindication to one of these products
    e. Topical emollients are concomitantly used in the affected areas to help prevent flares

2. **Nonsegmental Vitiligo** (must meet all of the following):
    a. Patient has a diagnosis of nonsegmental vitiligo
    b. Opzelura will not be used on more than 10% of the patient's body surface area
    c. Initial approval is limited to 24 weeks
    d. Patient has tried and failed each of the following or has a contraindication or intolerance to all:
        i. Topical corticosteroid, unless the affected area is on the face, groin or skin folds
        ii. Topical tacrolimus or topical pimecrolimus

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

1. The medication will not be used concomitantly with biologic immunomodulators, JAK inhibitors or potent immunosuppressants
2. Patient is not immunocompromised
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. Patients with atopic dermatitis must meet all of the following:
    a. Opzelura will not be used on more than 20% of the patient's body surface area
    b. Documentation of a positive clinical response from baseline is received
    c. Topical emollients are concomitantly used in the affected areas to help prevent flares
5. Patients with nonsegmental vitiligo must meet all of the following
    a. Opzelura will not be used on more than 10% of the patient's body surface area
    b. Documentation of a positive clinical response with stable disease and/or re-pigmentation compared to baseline is received

There is a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events and thrombosis. See full prescribing information for complete boxed warning.

References:

1. Opzelura (ruxolitinib). Prescribing Information. Incyte Corp. Wilmington, DE. 9/2025.
2. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE – and Institute of Medicine – based recommendations. Ann Allergy Asthma Immunol 132 (2024) 274-312. https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Allergist%20Resources/Statements%20and%20Practice%20Parameters/JTF-Atopic-Dermatitis-Guideline-2023-07-31-2026.pdf
3. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. February 2024. Vol 90 (2) e43-e56 https://www.jaad.org/article/S0190-9622(23)02878-5/fulltext
4. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. July 2023. Volume 89 (1) e1-e20 https://www.jaad.org/article/S0190-9622(23)00004-X/fulltext
5. Schoch JJ, Anderson KR, Jones AE. Atopic Dermatitis: Update on Skin-Directed Management: Clinical Report. Pediatrics. June 2025. Volume 155 (6) https://publications.aap.org/pediatrics/article/155/6/e2025071812/201952/Atopic-Dermatitis-Update-on-Skin-Directed?autologincheck=redirected
6. van Geel N, Speeckaert R, Taieb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task Force Part 1: towards a new management algorithm. J Eur Acad Dermatol Venereol. 2023 Nov;37(11):2173-2184. https://pubmed.ncbi.nlm.nih.gov/37746876/
7. Seneschal J, Speeckaert R, Taieb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the international Vitiligo Task Force-Part 2: Specific treatment recommendations. J Eur Acad Dermatol Venereol. 2023 Nov;37(11):2185-2195. https://pubmed.ncbi.nlm.nih.gov/37715487/

8. Renert-Yuval Y, Ezzedine K, Grimes P, et al. Expert Recommendations on Use of Topical Therapeutics for Vitiligo in Pediatric, Adolescent, and Young Adult Patients. JAMA Dermatol. 2024;160(4):453–461. https://jamanetwork.com/journals/jamadermatology/article-abstract/2815807
9. V. Eleftheriadou, R. Atkar, J. Batchelor, B. McDonald, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021, British Journal of Dermatology, Volume 186, Issue 1, 1 January 2022, Pages 18–29. https://academic.oup.com/bjd/article/186/1/18/6593593?login=false#google_vignette
10. Davis, D MR, Frazer-Green L, Alikhan A. et al. Focused update: Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. September 2025. Vol 93 (3) e1-745–e7 – 745. https://www.jaad.org/article/S0190-9622(25)02125-5/fulltext

Proposed Addendum to Protocol for Duchenne Muscular Dystrophy Products
January 2026

DURB Approval Dates	4/2017, 7/2020, 7/2021, 10/2021, 10/2023, 7/2024
Commissioners Approval Dates	10/2017, 5/2021 5/2022, 7/2024, 1/2025

Exondys 51® (eteplirsen)
Vyondys 53® (golodirsen)
Viltepso® (viltolarsen)
Amondys 45® (casimersen)
Elevidys® (delandistrogene moxeparvovec-rokl)
Agamree® (vamorolone)
Emflaza® (deflazacort)
Duvyzat® (givinostat)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
Duvyzat, a new drug approved for Duchenne Muscular Dystrophy (DMD), is included in this update. Monitoring parameters to assess kidney function and toxicity are updated for the antisense oligonucleotides. Elevidys is only indicated for use in ambulatory patients with DMD.

Background:
Duchenne muscular dystrophy (DMD) is a progressive X-linked recessive neuromuscular disorder. The mutations in the DMD gene affects the dystrophin protein production. In patients with DMD, dystrophin is either absent or dysfunctional, which leads to progressive muscle degeneration. Dystrophin helps to keep the muscle cells intact and thereby preventing muscle breakdown. Exondys 51, Vyondys 53, Viltepso and Amondys 45 are antisense oligonucleotides that work by skipping the mutated section of the DMD gene. These drugs produce a truncated but functional dystrophin protein. Elevidys is the first gene therapy approved for DMD. It is an adeno-associated virus (AAV) based gene therapy indicated for the treatment of ambulatory patients with DMD. Agamree and Emflaza are corticosteroids indicated for the treatment of DMD. Duvyzat is a histone deacetylase (HDAC) enzyme inhibitor approved for use in patients 6 years of age and older. Inhibition of HDAC leads to a decrease in muscle inflammation and fibrosis.

Criteria for initial approval must meet the following:

1. Patient is of the FDA-labeled or compendial approved age
2. Patient does not have any contraindications to 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

4. The medication is prescribed by or in consultation with a neurologist or another specialist who is an expert in the treatment of DMD and other neuromuscular disorders
5. Patient has a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD)
6. Patient was stable on a systemic corticosteroid regimen for at least 12 weeks, unless contraindicated, or had experienced significant adverse effects (documentation required)
7. For products with weight-based dosing, the patient's most current weight is provided

For Antisense Oligonucleotides (Exondys 51, Vyondys 53, Viltepso, Amondys 45) the patient meets all of the following criteria (1. through 4.):

1. ~~Patient must have a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD)~~
2. Submission of documentation (e.g. medical records and labs) includes the following:
    a. For Exondys 51: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 51 skipping
    b. For Vyondys 53 and Viltepso: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 53 skipping
    c. For Amondys 45: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 45 skipping
3. Prescriber plans to continue steroid treatment unless there are contraindications, intolerance or hypersensitivity
4. Prescriber ~~understands~~ acknowledges that continued approval for this indication may be contingent upon confirmatory trials
5. Patient is not using the requested medication concomitantly ~~in combination~~ with another antisense oligonucleotide

Request for Vyondys 53, Viltepso, or Amondys 45, the patient will be monitored for kidney toxicity during treatment with the patient's urine sample measured prior to infusion or at least 48 hours after the most recent infusion

For Oral Glucocorticoids (Agamree, Emflaza) requests the patient meets all of the following:

1. Prescriber confirms the patient is up to date on immunizations
2. Prescriber attests any live or live-attenuated vaccines are administered at least 4 to 6 weeks prior to the first dose of requested medication

For Gene Therapy (Elevidys) requests the patient meets all of the following:

1. Genetic testing confirms that the patient has a mutation in the DMD gene
2. Documentation is received showing the patient does ~~but~~ not have a deletion ~~mutation~~ in exon 8 and/or exon 9
3. Patient has baseline anti-AAVrh74 antibody titers <1:400 as determined by a total binding antibody titers
4. Patient is ambulatory
5. The patient does not have any of the following:
    a. Gamma-glutamyl transferase [GGT] >2 times the upper limit of normal
    b. Total bilirubin > the upper limit of normal not due to Gilbert's syndrome
    c. Active hepatic viral infection

d. Recent vaccination, within 4 weeks of Elevidys treatment
e. Active or recent, within 4 weeks of infections

6. Post-Elevidys infusion the prescriber attests to monitoring all of the following:
   a. Weekly platelets count for the first two weeks, continue monitoring if clinically necessary
   b. Weekly liver function assessment (clinical exam, GGT, ALT, AST, aPTT, INR and total bilirubin) for the first 3 months and thereafter as clinically necessary ~~Liver function tests, and troponin-I levels are obtained prior to initiating treatment~~
   c. Weekly troponin-1 measurements for the first month, continue monitoring if clinically necessary
7. Elevidys is not used in combination with any ~~at the same time as the~~ exon-skipping therapies (casimersen, eteplirsen, golodirsen, viltolarsen); however, it can be used after discontinuation of these treatment options
8. Treatment is one-time only
9. The prescriber has informed the patient to stay in close proximity to an appropriate healthcare facility for at least 2 months after receiving Elevidys infusion

For Histone Deacetylase (HDAC) Inhibitor (Duvyzat) the patient meets all of the following:

1. Documentation is received confirming the patient has baseline platelet counts ≥150 x 10^9/L
2. Platelets are monitored every 2 weeks for the first 2 months, then monthly for the first 3 months and every 3 months thereafter post treatment
3. The prescriber is monitoring the following:
   a. Patient's triglyceride levels at 1 month, 3 months, 6 months then every 6 months thereafter
   b. ECGs if the patient has cardiac disease or is taking medications that causes QT prolongation
   c. Presence of moderate or severe diarrhea

Elevidys has a black box warning for acute serious liver injury, including life-threatening and fatal acute liver failure. See full prescribing information for complete boxed warning.

Continuation of therapy for all drugs except Elevidys (delandistrogene moxeparvovec-rokl):

1. Updated chart notes demonstrate positive clinical response to therapy (such as improvement and/or stabilization compared to baseline)
~~2. The medication is prescribed by or in consultation with a pediatric or adult neurologist or another specialist who is an expert in the treatment of DMD and other neuromuscular disorders~~
~~3. Patient is monitored for the potential development of infections and liver function~~
4. The medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer (Lexicomp) ~~Drugs~~, national guidelines, or other peer-reviewed evidence
5. Patient will not use golodirsen (Vyondys 53) together with viltolarsen (Viltepso)

References:

1. Exondys 51 [package insert]. Sarepta Therapeutics, Inc. Cambridge, MA. 11/2025
2. Vyondys 53 [package insert]. Sarepta Therapeutics, Inc. Cambridge, MA. 6/2024
3. Viltepso [package insert]. NS Pharma, Inc. Paramus, NJ. 3/2021
4. Amondys 45 [package insert]. Sarepta Therapeutics, Inc. Cambridge MA. 7/2024
5. Elevidys [package insert]. Sarepta Therapeutics, Inc. Cambridge MA. 8/2024
6. Agamree [package insert]. Catalyst Pharmaceuticals, Inc. Coral Gables, FL. 6/2024
7. Emflaza[package insert]. PTC Therapeutics, Inc. Warren, NJ. 6/2024
8. Duvyzat [package insert]. ITF Therapeutics, LLC. Concord, MA. 3/2024
9. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically
10. Mendell JR, et al; Eteplirsen Study Group. Eteplirsen for the treatment of Duchenne muscular dystrophy. Ann Neurol. 2013;74(5):637-647
11. Lee JJA, Saito T et al. Direct Reprogramming of Human DMD Fibroblasts into Myotubes for In Vitro Evaluation of Antisense-Mediated Exon Skipping and Exons 45-55 Skipping Accomplished by Rescue of Dystrophin Expression. Methods Mol Biol. 2018; 1828: 141-150
12. Bushby K, Finkel R, Birnkrant DJ, Case LE, Clemens PR, Cripe L, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol; 2010 Jan; 9(1):77-93
13. Mah JK, Clemens PR, Guglieri M, et al. Efficacy and Safety of Vamorolone in Duchenne Muscular Dystrophy: A 30-Month Nonrandomized Controlled Open-Label Extension Trial. JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178
14. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
15. 14. Bushby K, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. The Lancet Neurol 2018; 17,3; 251-267
16. Griggs RC et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131
17. Duchenne Muscular Dystrophy (DMD). https://www.mda.org/disease/duchenne-muscular-dystrophy Muscular Dystrophy Association. July 25, 2025. Accessed August 13, 2025
18. FDA Recommends Removal of Voluntary Hold for Elevidys for Ambulatory Patients. FDA News Release. https://www.fda.gov/news-events/press-announcements/fda-recommends-removal-voluntary-hold-elevidys-ambulatory-patients July 28, 2025. Accessed August 13, 2025

Proposed Addendum to Protocol for ~~the Safe and Efficient Use of~~ Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modifiers
January 2026

DURB Approval Dates	**1/2016, 7/2020, 1/2022, 1/2024**
Commissioner Approval Dates	**7/2016, 5/2021, 11/2022, 8/2024**

Praluent® (evolocumab)
Repatha® (alirocumab)
Leqvio® (inclisiran)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
Update the clinical criteria based on recent updates to the FDA labeled indications and current guidelines/literature.

Background:
Praluent and Repatha are human monoclonal antibodies that bind to proprotein convertase subtilisin kexin type 9 (PCSK9) allowing for an increase in the low-density lipoprotein (LDL) receptors (LDLR). The LDLRs are then available to bind to the circulating LDL, leading to a lowering of LDL-C levels.

Leqvio is a double-stranded small interfering ribonucleic acid (siRNA) that causes a catalytic breakdown of mRNA for PCSK9, ultimately increasing the LDLRs which leads to an increase in binding to LDL, leading to a lowering of LDL-C levels.

Criteria for Initial Approval (must meet 1-8):

1. The patient is of the FDA-labeled or compendial approved age
2. The patient does not have any contraindications to the requested drug
3. The patient is not receiving another PCSK9 modifier
4. ~~Consider the benefit versus risk for pregnant or nursing patients~~
5. Leqvio is administered by a healthcare professional
6. Unless the patient has documented contraindication or intolerance to ezetimibe therapy **BOTH** of the following (a. and b.) must be met:
    a. The prescriber must plan to continue prescribing ezetimibe together with the requested PCSK-9 inhibitor
    b. The patient is currently on ezetimibe **AND** has documented adherence to ezetimibe for at least the past 90 continuous days (dates and length of therapy must be provided)

7. Unless the patient has documented contraindication or intolerance to statins **ONE** of the following (a. or b.) must be met:
    a. The patient is currently on statin therapy **AND** has documented adherence to maximally tolerated statins for a combined total of at least the past 90 continuous days (dates and length of therapy must be provided) **OR**
    b. Documentation that the patient has statin intolerance, defined as intolerance to at least two statins, including at least one statin at the lowest approved daily dose ~~was not able to tolerate a high-intensity statin~~, ~~but used a high-intensity statin and decreased the daily dose of statin OR trial of two lower intensity statins~~
8. The medication is requested ~~prescribed~~ in accordance with a 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
9. The patient meets **ONE** of the following (A. B. C. or D.):
    A. Patients at an increased risk of developing a major cardiovascular event(s) must meet **ALL** of the following criteria (a. b. and c.):
        a. Must meet **ONE** of the following criteria (i. ii. iii. or iv.):
            i. LDL-C ≥ 190 mg/dL
            ii. Patients 40 to 75 years of age with diabetes mellitus
            iii. Patients 40 to 75 years of age with documentation provided stating patient's specific risk factor(s) including 10-year Clinical atherosclerotic cardiovascular disease (ASCVD) risk percent based on a risk assessment tool recommended by a national professional organization showing **ONE** of the following criteria (a. or b.):
                a. ≥5% risk with at least **ONE** ASCVD risk enhancing factor listed in the 2019 American College of Cardiology/A Heart Association Guideline on the Primary Prevention of Cardiovascular Disease
                b. ≥20% risk
            iv. Patient is over 75 years of age
        b. Documentation of lab results from within the past 90 days is received showing LDL-C ≥ 70 mg/dL
        c. Documentation of current or past interventions(s) is provided to treat patient specific ASCVD related-risk/condition(s)

    B. Patients with established ASCVD must meet **BOTH** of the following criteria (a. and b.):
        a. Documentation of lab results from within the past 90 days is received showing **ONE** of the following (i. or ii.):
            i. LDL-C ≥ 70 mg/dL ~~for documented ASCVD~~

ii. LDL-C ≥ 55 mg/dL for patient with diabetes or patient hospitalized with acute coronary syndrome

~~iii. LDL-C ≥ 100 mg/dL for familial hypercholesterolemia without documented ASCVD~~

b. Clinical ASCVD or a cardiovascular event, documentation is received (medical records, patient's chart) of at least **ONE** of the following condition/events (i. through ix.):

i. Acute coronary syndrome
ii. History of myocardial infarction (MI)
iii. History of stable or unstable angina
iv. History of coronary or other arterial revascularization (e.g., PTCA, CABG)
v. History of ~~ischemic~~ stroke
vi. History of transient ischemic attack (TIA)
vii. Peripheral arterial disease presumed to be of atherosclerotic origin
viii. Findings from CT angiogram or catheterization are consistent with clinical ASCVD; OR
ix. Other documented atherosclerotic diseases such as:
    a. coronary atherosclerosis
    b. renal atherosclerosis
    c. aortic aneurysm secondary to atherosclerosis
    d. carotid plaque (≥ 50% stenosis)

C. Patients with homozygous familial hypercholesterolemia (HoFH) or heterozygous familial hypercholesterolemia (HeFH) must meet **ALL** of the following criteria (a. b. and c.):

~~a. Patient is 18 years of age or older for Praluent or 10 years of age or older for Repatha **AND**~~

a. The patient is using the requested medication with diet and exercise regimen designed to reduce the LDL-C

b. For HoFH requests, the patient must not be receiving lomitapide (Juxtapid®) or other biologics indicated for treatment of HoFH concomitantly unless otherwise recommended by the FDA or guidelines for concomitant use ~~mipomersen (Kynamro®)~~

c. Diagnosis of HoFH or HeFH is confirmed by **ONE** of the following (i. or ii.), documentation (medical records, patient's chart) is received:

i. Genetic confirmation of **ONE** (for HeFH patients) or **TWO** (for HoFH patients) LDLR, Apo-B, PCSK9, or LDLR adaptor protein 1 gene locus mutations **OR**

ii. Patient has definite familial hypercholesterolemia as determined by using one of the following: Dutch Lipid Clinical Network Criteria, Simon Broome Criteria, or the Make Early Diagnosis to Prevent Early Death Criteria

D. Patients with Primary Hypercholesterolemia (excluding HoFH and HeFH) must meet **BOTH** of the following criteria (a. and b.):
   a. The patient is using the requested medication with diet and exercise regimen designed to reduce the LDL-C
   b. Documentation of lab results from within the past 90 days is received showing LDL- C ≥ 130 mg/dL

Initial Approval Length: 6 months

Criteria for Continuation of Therapy:

~~1. The patient is of the FDA-labeled or compendial approved age~~
~~2. The patient does not have any contraindications to the requested drug~~
3. The patient is not receiving more than one PCSK-9 modifier
4. Leqvio is administered by a healthcare professional
5. The medication is requested ~~prescribed~~ in accordance with a 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
6. For the diagnosis of HoFH, the patient must not be concurrently receiving lomitapide (Juxtapid®) or other biologics indicated for HoFH ~~mipomersen (Kynamro).~~
~~7. Consider the benefit versus risk for pregnant or nursing patients.~~
8. The patient has been adherent to and must plan to continue using PCSK-9 inhibitor, maximally tolerated statin, and ezetimibe therapy (unless patient has a contraindication or an intolerance to statin and/or ezetimibe therapy) for the past 90 continuous days and documentation is provided
9. Documentation of lab results from within the past 90 days is received showing the patient is responding to treatment based on reduction in LDL-C levels compared to baseline

Subsequent Approval Length: 1 year

References:

1. Praluent. Prescribing Information. Sanofi-Aventis. Bridgewater, NJ. 10/2025.
2. Repatha. Prescribing Information. Amgen. Thousand Oaks, CA. 8/2025.

3. Leqvio. Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. 7/2025.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
5. Alirocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
6. Evolocumab. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: http://www.clinical pharmacology.com. Updated 8/2018
7. Wong ND, Shapiro, MD. Interpreting the Findings From the Recent PCSK9 Monoclonal Antibody Cardiovascular Outcomes Trials. Front Cardiovasc Med. 2019; 6: 14. Accessed online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6414420/
8. Schwartz GG, Steg PG, Szarek M, et al. Alirocumab and cardiovascular outcomes after acute coronary syndrome. N Engl J Med 2018; 379:2097-2107.
9. Szarek M, White HD, Schwartz GG, et al. Alirocumab Reduces Total Nonfatal Cardiovascular and Fatal Events: The ODYSSEY OUTCOMES Trial. J Am Coll Cardiol 2019;73:387-96.
10. Murphy SA, Pedersen TR, Gaciong ZA, et al. Effect of the PCSK9 Inhibitor Evolocumab on Total Cardiovascular Events in Patients With Cardiovascular Disease: A Prespecified Analysis From the FOURIER Trial. JAMA Cardiol. 2019;4(7):613-619. doi:10.1001/jamacardio.2019.
11. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically
12. Frampton JE. Inclisiran: A Review in Hypercholesterolemia. Am J Cardiovasc Drugs. 2023 Mar;23(2):219-230. doi:10.1007/s40256-023-00568-7. Epub 2023 Mar 4. PMID: 36869996.
13. Ray KK, Troquay RP, et al. Long-term efficacy and safety of inclisiran in patients with high cardiovascular risk and elevated LDL cholesterol (ORION-3): results from the 4-year open-label extension of the ORION-1 trial. Lancet Diabetes & Endocrinology. 2023; 11:109-119.
14. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al.; Writing Committee. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2022;80:1366-418.
15. Roe MT, Li QH, Bhatt, DL, et al. Categorization Using New American College of Cardiology/American Heart Association Guidelines for Cholesterol Management and Its Relation to Alirocumab Treatment Following Acute Coronary Syndromes. Circulation Volume 140, Issue 19, 5 November 2019; 1578-1589.
16. Patel, SB, Wyne, KL, Afreen, S, et al. American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults with Dyslipidemia. Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2025;31(2): 236–262. https://doi.org/10.1016/j.eprac.2024.09.016
17. McGowan, MP, Hosseini Dehkordi SH, Moriarty PM, et al. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. J Am Heart Assoc. 2019;8(24):e013225. https://pubmed.ncbi.nlm.nih.gov/31838973/

18. German, C. Homozygous Familial Hypercholesterolemia: Diagnosis and Emerging Therapies. American College of Cardiology. 2022. https://www.acc.org/latest-in-cardiology/articles/2022/02/18/18/04/homozygous-familial-hypercholesterolemia
19. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;140(11):e596-e646. https://pubmed.ncbi.nlm.nih.gov/30879355/
20. Khan SS, Coresh J, Pencina MJ, et al. Novel Prediction Equations for Absolute Risk Assessment of Total Cardiovascular Disease Incorporating Cardiovascular-Kidney-Metabolic Health: A Scientific Statement From the American Heart Association. *Circulation*. 2023;148(24):1982-2004. https://pubmed.ncbi.nlm.nih.gov/37947094/
21. Arnold J, Acharya D, Boricha H, et al. Real-world prescribing in accordance to ACC/AHA guidelines for lipid-lowering therapy in high-risk primary and secondary prevention of ASCVD: Real-World Prescribing for Lipid-Lowering Therapy. Am J Prev Cardiol. 2025;23:101067. Published 2025 Jul 23. https://pubmed.ncbi.nlm.nih.gov/40894319/
22. Mach F, Baigent C, Catapano AL, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. Eur Heart J. 2020;41(1):111–88. https://eas-society.org/wp-content/uploads/2022/11/2019_dyslipidaemias_guidelin.pdf
23. Austin MA, Hutter CM, Zimmern RL, Humphries SE. Genetic Causes of Monogenic Heterozygous Familial Hypercholesterolemia: A Huge Prevalence Review. American Journal of Epidemiology. 2004;160:407-420
24. Goldberg AC, Hopkins PN, Toth PP, et al. Familial Hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients: Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipidol. 2011;5:S1-S8.
25. American Diabetes Association Professional Practice Committee for Diabetes*; 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes—2026. Diabetes Care 1 January 2026; 49 (Supplement_1): S216–S245. https://doi.org/10.2337/dc26-S010
26. Jackson EJ, Willard KE, Ballantyne CM. LDL cholesterol management simplified in adults-Lower for longer is better: Guidance from the National Lipid Association. *J Clin Lipidol*. Published online June 18, 2025. https://pubmed.ncbi.nlm.nih.gov/40713232/

Gainwell Technologies/NJ MCO 3rd Quarter 2025 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**73,491**	**114,120**	**84,563**	**987,244**	**349,640**	**171,483**
Total # of Pharmacy Claims Processed	**426,999**	**538,176**	**333,630**	**3,258,562**	**877,637**	**960,964**
Total # of Members Requesting Prior Authorization*	**1,543**	**3,471**	**2,504**	**22,737**	**7,899**	**5,793**
Total Prior Authorizations Requests Received**	**4,712 (1.1%)**	**4,998 (0.9%)**	**4,254 (1.3%)**	**34,140 (1%)**	**10,539 (1.2%)**	**8,277 (0.9%)**
Percentage of Claims Requiring Prior Authorization	**1.1%**	**0.9%**	**1.3%**	**1.0%**	**1.2%**	**0.9%**
Received Requests Denials	**84 (2%)**	**2,604 (52%)**	**1,874 (44%)**	**11,145 (33%)**	**4,366 (41%)**	**3,799 (46%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	75 (89%)	892 (34%)	320 (17%)	4,109 (37%)	1,688 (39%)	1,087 (29%)
Excluded Benefit	9 (11%)	98 (4%)	6 (0%)	91 (1%)	238 (5%)	188 (5%)
Non-formulary	0 (0%)	1,614 (62%)	1,548 (83%)	6,945 (62%)	2,440 (56%)	2,524 (66%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	7.1%	2.3%	2.8%	3.7%	8.0%	2.5%
Antidepressants	0.0%	1.5%	0.4%	1.8%	2.0%	1.0%
Antihypertensives	2.4%	0.7%	0.5%	0.5%	0.7%	0.6%
Antianxiety	0.0%	0.1%	0.1%	0.2%	0.1%	0.0%
Antidiabetics (oral and insulin)	7.1%	18.0%	22.5%	23.5%	17.9%	15.3%
Anticoagulants	0.0%	0.1%	0.3%	0.1%	0.7%	0.1%
Thyroid agents	0.0%	0.3%	0.2%	0.2%	0.7%	0.2%
Ulcer Drugs/Antispasmodics/Anticholinergics	2.4%	2.0%	0.8%	2.2%	3.4%	0.8%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	16.1%	11.9%	5.2%	13.8%	11.5%
Antipsychotic/Antimanic agents	0.0%	0.7%	1.3%	3.2%	1.3%	1.6%
Antiasthmatic and Bronchodilator agents	20.2%	5.4%	3.1%	5.0%	12.0%	3.7%
Antivirals (includes both HIV and Hep C)	0.0%	0.4%	0.5%	0.3%	0.3%	0.3%
Digestive Aids (Digestive Enzymes)	0.0%	0.1%	0.3%	0.1%	0.1%	0.2%
Anticonvulsants	0.0%	1.1%	2.9%	1.6%	2.8%	1.1%
Migraine Products	2.4%	5.7%	4.7%	4.9%	6.5%	4.7%
Analgesics Anti-inflammatory	4.8%	1.1%	3.0%	3.0%	3.9%	1.7%

Analgesic Opioids	9.5%	3.8%	0.8%	1.1%	2.4%	3.7%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	0.9%	1.6%	1.2%	1.9%	1.6%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.8%	0.5%	0.8%	0.8%	0.8%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.0%	0.1%	0.0%	0.1%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	14.4%	15.4%	16.2%	20.6%	15.9%

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

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

*** See below for explanation of categories:

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

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

Non-Formulary: includes categories such as Non-Formulary

Other: includes categories such as Directed Intervention, Multiple Pharmacies, Multiple Prescribers, Other DUR related rejections

Summary of DURB Recommendations

DURB Meeting	Action Items	Status/DURB Recommendations	Impact/Comments
October 2025	Proposed Addendum to Protocol for Biologics in Moderate to Severe Asthma	• 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.	
	Proposed Addendum to Protocol for Dupixent®	• 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 Guidelines. The criteria for chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis were updated.	
	Proposed Addendum to Protocol for Hereditary Angioedema	• The Board recommended approval of the addendum to the Hereditary Angioedema protocol. Andembry®, Dawnzera®,	

		Orladeyo®, and Ekterly® were added to the protocol.	
	Proposed Addendum to Protocol for Wegovy®	• 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	• 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	Updated information was presented at the October 2025 meeting

		percentage decrease in body mass index (BMI) to evaluate efficacy.	
	Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products	• 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.	Updated information was presented at the October 2025 meeting
	Proposed Addendum to the protocol for Chimeric Antigen Receptor (CAR) T Cell Products	• The Board recommended approval of the addendum to the CAR T Cell products protocol.	
	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	• The Board recommended approval of the protocol with the suggested change to add “significant” prior to side effects to the continuation of therapy criteria #1	

	Proposed protocol for Zepbound® Proposed protocol for Spravato®	• 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-	• The Board recommended the addendum to the protocol	

	mediated Amyloidosis (ATTR) products Proposed protocol for ileal bile acid transporter (IBAT) inhibitor products Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products Proposed Protocol for Winrevair® (sotatercept-csrk)	• The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol pending further clarification 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	• The Board recommended the addendum to the protocol • The Board recommended the addendum to the protocol	

	Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec) Proposed addendum to the protocol for Duchenne Muscular Dystrophy products Proposed protocol for Qelbree (viloxazine) Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)	• 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 - 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	These changes were presented at the October 2024 meeting This change was presented at the October 2024 meeting