New Jersey Drug Utilization Review Board
Virtual Platform
April 15, 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 January 28, 2026, meeting https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2026/DURB_Transcript_January_2026.pdf

IV. Review of draft meeting summary for January 28, 2026, meeting (pages 4-8)

V. Secretary's report (page 9)

VI. Old Business
   - A. Utilization Trends of GLP-1/GIP Agonists (pages 10-11)
   - B. Utilization Trends of SGLT-2 Inhibitors (pages 12-13)
   - C. Updated Protocol for Opzelura® (pages 14-16)
   - D. Updated Protocol for Duchenne Muscular Dystrophy Products (pages 17-20)

VII. New Business
   - A. Proposed Addendum to Protocol for Crysvita® (pages 21-23)
   - B. Proposed Addendum to Protocol for Cystic Fibrosis Transmembrane Conductance Regulator Products (pages 24-26)
   - C. Proposed Addendum to Protocol for Spinal Muscular Atrophy Products (pages 27-30)

VIII. A. Informational Highlights/Reports

1. Gainwell Technologies/NJ MCO 4th Quarter 2025 Prior Authorization Report
2. (page 31)
3. Summary of DURB Action Items (pages 32-36)
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/boards/durb/agendas/4-2026/FFS_Top_Drugs_Report_by_Payment_%20January-2026.pdf

MCO top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2026/MCO_Top_Drugs_Report_by_Payment_%20December-2025.pdf

FFS top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2026/FFS_Top_Drugs_by_Category_by_Payment_%20January-2026.pdf

MCO top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2026/MCO_Top_Drugs_by_Category_by_Payment_%20December-2025.pdf

FFS antiviral drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/4-2026/FFS_Antiviral_Drugs_by_Payment_%20January-2026.pdf

B. Recent Guidelines

AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease
https://www.sciencedirect.com/science/article/pii/S0016508525060913?via%3Dihub

Transthyretin Cardiac Amyloidosis Evaluation and Management:2025 ACC Concise Clinical Guidance
https://www.jacc.org/doi/epdf/10.1016/j.jacc.2025.09.004

KDIGO 2026 Clinical Practice Guideline for the Management of Anemia in Chronic Kidney Disease (CKD)
https://www.kidney-international.org/article/S0085-2538(25)00495-8/fulltext

Update on familial hypercholesterolemia: An expert clinical consensus from the National Lipid Association
https://www.lipidjournal.com/article/S1933-2874(26)00010-3/fulltext

January 28, 2026, DURB Meeting Summary (Draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Moynihan, Ms. Olson, Dr. Barberio, Dr. Marcus, Dr. Lind (ex-officio, Department of Human Services) and Dr. Sahu (ex-officio, Department of Health) Unable to attend: Mr. Schafer
Dr. Swee's pre-meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the first annual meeting of the Board: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the filings: • On January 5, 2026, it was published in the issue of the NJ Register at 58 N.J.R 172(s) • On December 11, 2025, it was posted on the DHS/DMAHS website • On December 30, 2025, it was published either online or print in the following newspapers: the Atlantic City Press, the Bergen Record, the Trenton Times, the Star Ledger, and the Courier-Post • On January 6, 2026, it was emailed to the DMAHS email list including the local Medical Assistance Customer Centers, County Social Service Agencies and Statehouse Press Office, where the notice is to be posted in an area accessible to both employees and the general public Dr. Swee also stated an overview of the DURB's responsibilities and duties.
Review of Minutes	Approved	Minutes from October 22, 2025, meeting was reviewed and approved by the Board. The approved meeting summary is posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		- The Commissioners approved the July 2025 DURB recommended protocols - The NJDURB State Fiscal Year 2025 NJDURB Annual Report is in review by the Commissioners

Issue	Action	Notes
		- The Dupixent® protocol, presented during the October 2025 meeting, was updated to include nasal laser therapy for the treatment of chronic rhinosinusitis with nasal polyposis. The Dupixent® protocol with this update is under review by the Commissioners. - The 2026 NJDURB Meeting dates were announced o April 15, 2026; July 15, 2026; October 21, 2026 - There are no further updates on the Board's positions and replacements
Old Business		
(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 discussed the decrease in FFS SGLT-2 inhibitors utilization from 645 claims in 2025Q2 to 422 claims in 2025Q3 could potentially be attributed to FFS membership. Dr. Marcus requested a report be provided that can identify new utilizers of SGLT-2 inhibitors and GLP-1/GIP agonists. Dr. Swee requested ongoing reports to monitor utilization of these therapeutic classes.
New Business		
(A) Proposed Protocol for Opzelura®	Recommended	The Board reviewed the proposed Opzelura® protocol for the treatment of atopic dermatitis and nonsegmental vitiligo. The Board recommended updating the following general initial criteria to state "The medication is prescribed by or in consultation with a specialist who has appropriate knowledge and experience." Dr. Swee stated the Board will update criteria in the future if new guidelines become available allowing for safe concomitant use of Opzelura® and Dupixent® for atopic dermatitis. The Board recommended approval of the protocol with the proposed update.
(B) Proposed Addendum to Protocol for Duchenne Muscular Dystrophy Products	Recommended	The Board reviewed a proposed addendum to the protocol for Duchenne Muscular Dystrophy products. Ms. Olson recommended the following criteria for Elevidys® be updated to "A current, active infection or infection within the previous 4 weeks." The Board recommended approval of the protocol with the proposed update.

Issue	Action	Notes
(C) Proposed Addendum to Protocol for Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modifiers	Recommended	The Board reviewed a proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) modifiers. The protocol was updated to include an additional FDA approved indication for use in patients at an increased risk of developing a major cardiovascular event. Two speakers, Jeffrey Baldwin and Dawn Howard-Mistry representatives from Amgen provided information on Repatha® and proposed to eliminate the ezetimibe trial criteria from the protocol. Dr. Angel Lazo, spoke in support to remove the ezetimibe criteria as well. Pinali Agrawal stated the protocol would allow for exceptions to not require ezetimibe trial on a case-by-case basis. Dr. Marcus stated he would like to see the vascular data the Amgen speakers referred to and would move to accept the protocol as presented but review it again at a later meeting after having reviewed the materials. Dr. Barberio similarly requested more information referred to by Amgen. Dr. Swee stated the Board will review additional information provided by Amgen and if needed revisit the protocol with amendments. The Board recommended approval of the protocol and requested additional information from Amgen for review.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor	The Board reviewed the 3rd Quarter 2025 prior authorization (PA) denial report for FFS and MCOs. Aetna identified and corrected an issue based on Dr. Swee highlighting their high denial rate on the 2nd Quarter 2025 PA denial report compared to the other MCOs in the ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants category. Dr. Swee stated denial rates in the 3rd Quarter 2025 PA report for the ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants category is high in other MCOs as well. He requested follow-up with the MCOs to obtain additional information to address the denial rates. Pinali Agrawal stated the State 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 (July 2024 through October 2025). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for November 2025 (FFS) and October 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>November 2025</td><td>$ 2,424,950*</td><td>$ 2,681,932*</td></tr><tr><td>MCOs</td><td>October 2025</td><td>$ 118,719,517</td><td>$171,477,482</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. WHO issues global guideline on the use of GLP-1 medicines in treating obesity
2. One Dose versus Three Doses of Benzathine Penicillin G in Early Syphllis
3. American Association of Clinical Endocrinology Consensus Statement: Algorithm for the Evaluation and Treatment of Adults with Obesity/Adiposity-Based Chronic Disease – 2025 Update
4. 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
5. RSV Vaccine Effectiveness Against Hospitalization Among US Adults Aged 60 Years or Older During 2 Seasons
6. HHS Advances Women’s Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy
7. FDA asks for removal of suicide warnings on GLP-1 drugs

Nikki Patel, a pharmacist with Novo Nordisk, reiterated that on 1/13/26, the FDA requested the removal of suicidal behavior and ideation from the labeling of GLP-1 drugs.</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 a breakdown of members new to GLP-1/GIP agonists and SGLT2 inhibitors</td></tr>
</table>

Issue	Action	Notes
		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/Anorexiants category for all MCOs based on the 3rd Quarter 2025 PA report

Secretary's Report

New Jersey Drug Utilization Review Board
April 15, 2026

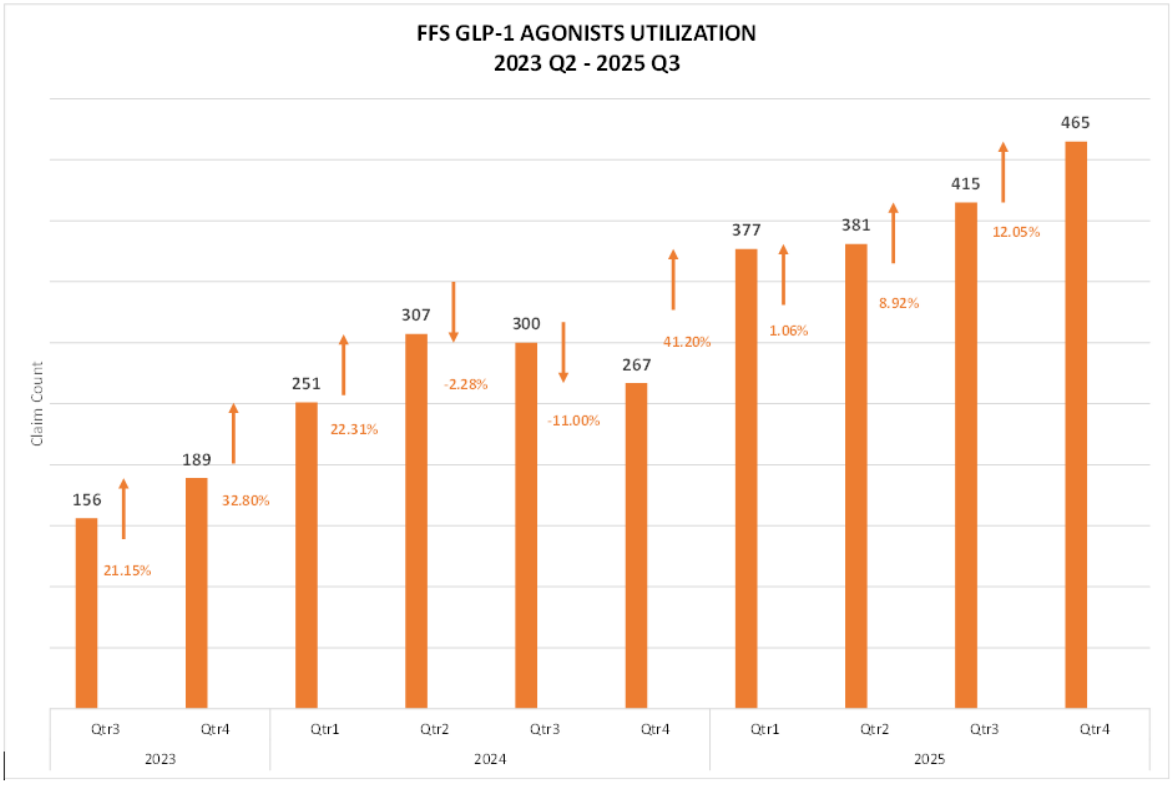
1. The Commissioners approved the October 2025 NJ DURB recommended protocols

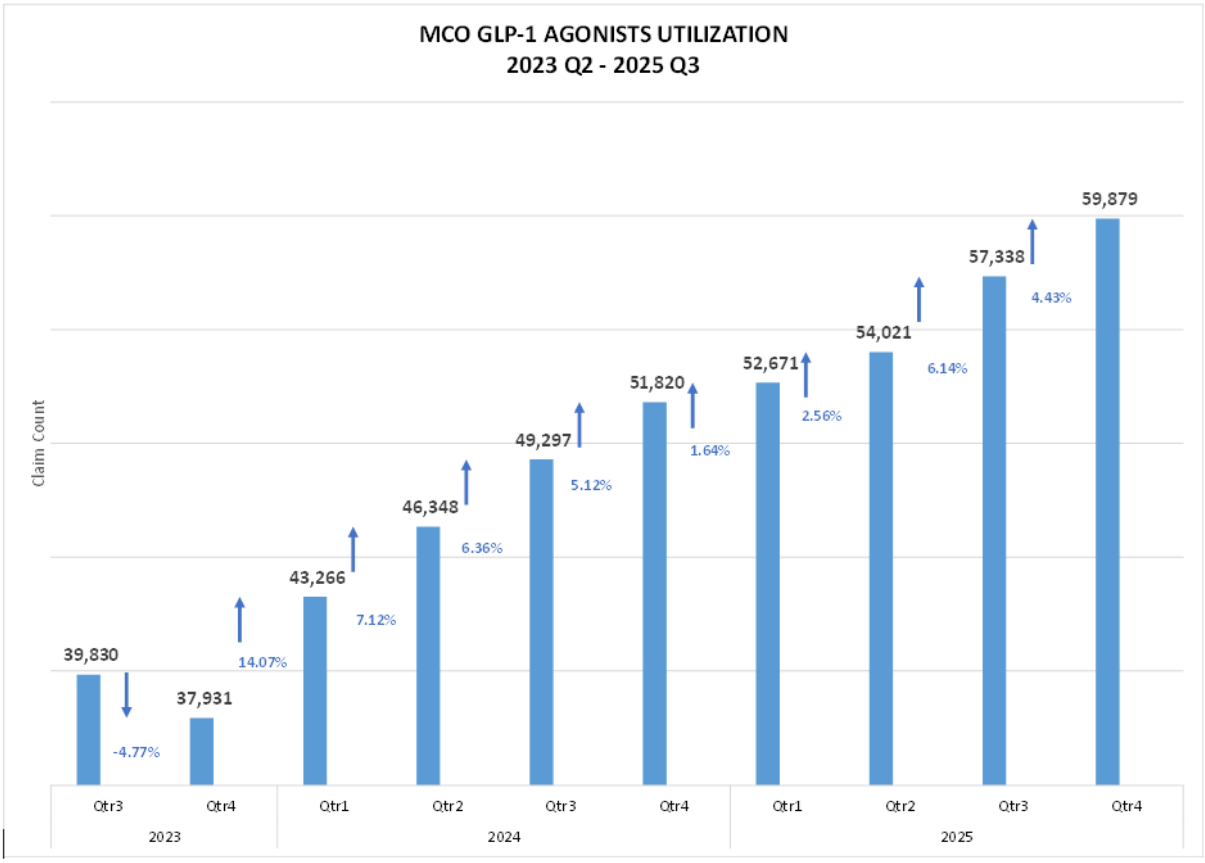
2. January 2026 NJ DURB recommended protocols are submitted for Commissioners approvals

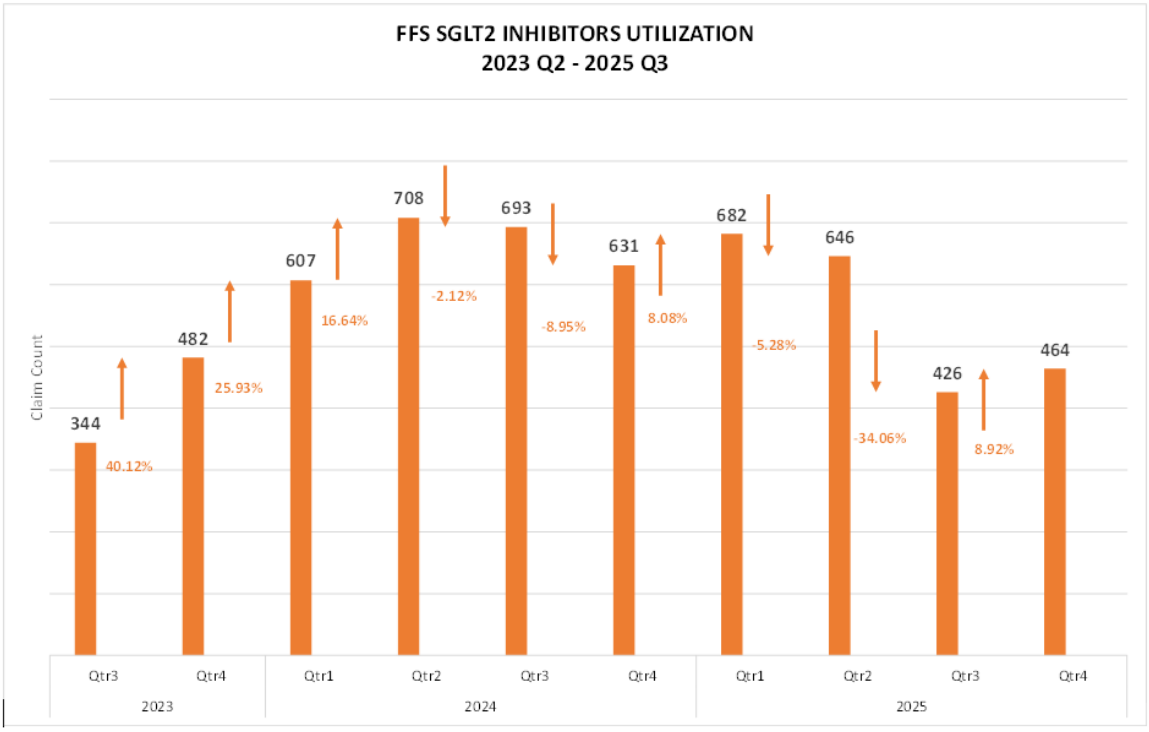
3. NJDURB State Fiscal Year 2025 Annual Report is under review by the Commissioners

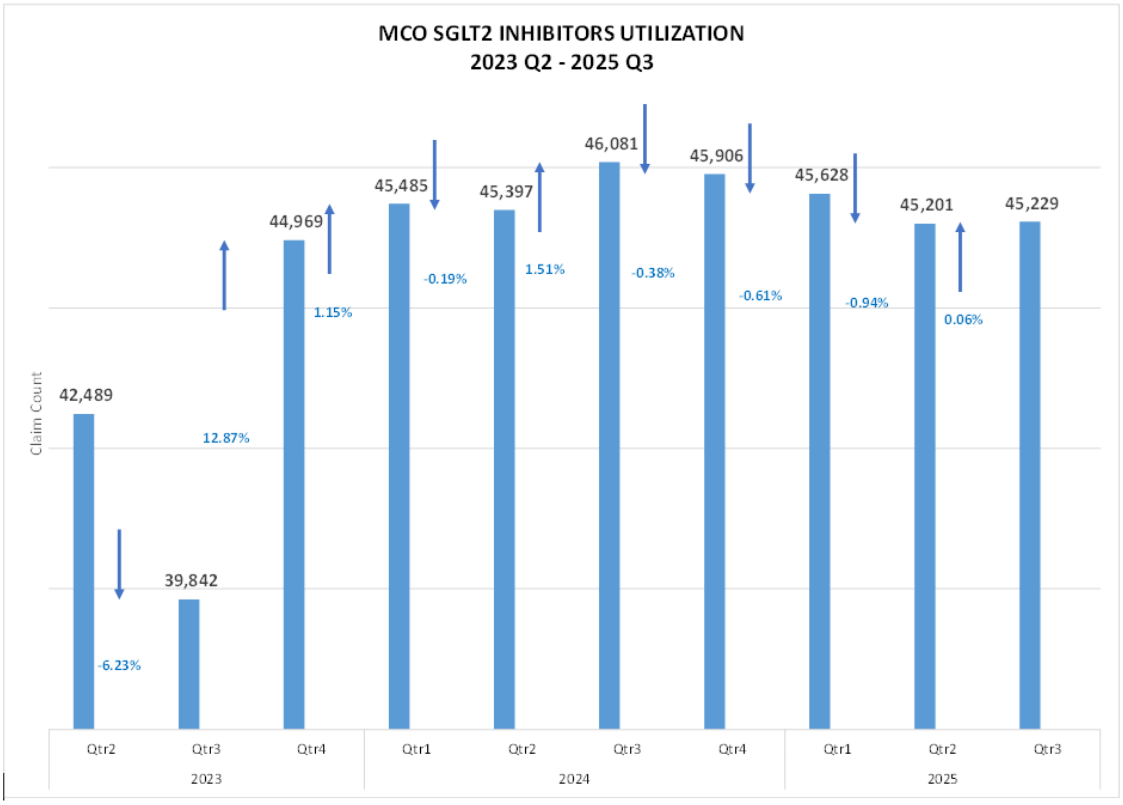
4. Upcoming 2026 NJDURB Meeting Dates:
   Wednesday, July 15, 2026
   Wednesday, October 21, 2026

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


FFS GLP-1 AGONISTS UTILIZATION
2023 Q2 - 2025 Q3
Claim Count
156
189
251
307
300
267
377
381
415
465
21.15%
32.80%
22.31%
-2.28%
-11.00%
41.20%
1.06%
8.92%
12.05%
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
2023
2024
2025


MCO GLP-1 AGONISTS UTILIZATION
2023 Q2 - 2025 Q3
Claim Count
39,830
-4.77%
37,931
14.07%
43,266
7.12%
46,348
6.36%
49,297
5.12%
51,820
1.64%
52,671
2.56%
54,021
6.14%
57,338
4.43%
59,879
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
2023
2024
2025


FFS SGLT2 INHIBITORS UTILIZATION
2023 Q2 - 2025 Q3
Claim Count
344
40.12%
482
25.93%
607
16.64%
708
-2.12%
693
-8.95%
631
8.08%
682
-5.28%
646
-34.06%
426
8.92%
464
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
2023
2024
2025


MCO SGLT2 INHIBITORS UTILIZATION
2023 Q2 - 2025 Q3
Claim Count
42,489
39,842
44,969
45,485
45,397
46,081
45,906
45,628
45,201
45,229
-6.23%
12.87%
1.15%
-0.19%
1.51%
-0.38%
-0.61%
-0.94%
0.06%
Qtr2
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
Qtr4
Qtr1
Qtr2
Qtr3
2023
2024
2025

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 who has appropriate knowledge and experience
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 recent 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. 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
2. Prescriber plans to continue steroid treatment unless there are contraindications, intolerance or hypersensitivity
3. Prescriber acknowledges that continued approval for this indication may be contingent upon confirmatory trials
4. Patient is not using the requested medication concomitantly 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 not have a deletion 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. A current, active infection or infection within the previous 4 weeks
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
    c. Weekly troponin-1 measurements for the first month, continue monitoring if clinically necessary
7. Elevidys is not used in combination with any 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 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), national guidelines, or other peer-reviewed evidence
3. Patient will not use golodirsen (Vyondys 53) together with viltolarsen (Viltepso)

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Addendum to Protocol for Crysvita® (burosumab-twza)
~~**Approved October 2022**~~ **April 2026**

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

Crysvita® (burosumab-twza)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
Reviewed current clinical literature and updated criteria to include additional laboratory parameters used to aid in the diagnosis of both X-linked hypophosphatemia and FGF23-related hypophosphatemia in tumor-induced osteomalacia.

Background:
Crysvita is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in patients 6 months and older and for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in patients 2 years of age and older.

- ~~*The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.*~~
- ~~*The treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.*~~

Criteria for initial approval must meet all of the following:
1. 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
2. **The patient is of the FDA-labeled or compendial approved age**
3. **The patient's most recent weight is provided**
4. The Medication is prescribed by or in consultation with a geneticist, nephrologist, endocrinologist **or a specialist who has appropriate knowledge or experience**
5. The patient does not have any contraindications to therapy:
    a. Concomitant use with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol)
    b. Serum phosphorus within or above the normal range for age
    c. Severe renal impairment or end stage renal disease~~, defined as an estimated glomerular filtration rate (GFR) of <30 mL/min in children or creatinine clearance (CrCl) < 30mL/min in adults~~
6. **Prescriber attests oral phosphate and/or active vitamin D analogs have been discontinued one week prior to starting Crysvita**
7. **Crysvita is administered by a healthcare provider**

For X-linked Hypophosphatemia (XLH) must meet 1 through 4:
1. **Patient has evidence of rickets or another bone disease**

2. ~~Patient has a diagnosis of X-linked hypophosphatemia (XLH)~~ **The diagnosis is** confirmed by one of the following (**documentation is provided**):
    a. **Patient's** genetic test **confirms mutation of the PHEX gene** OR
    b. **Genetic test results confirming a PHEX gene mutation in a directly related family member (first-degree relative) OR**
    c. ~~Elevated levels of~~ **S**erum fibroblast growth factor 23 (FGF23) **level above the upper limit of normal or abnormal for laboratory reference range**
~~3. Patient is 6 months of age or older~~
4. **Documentation is provided confirming the patient has low serum phosphate levels compared to age-appropriate normal range or laboratory defined normal range**
5. ~~Pediatric patients must have had an inadequate response from~~ Patient tried and failed or **has an intolerance or contraindication to treatment with** oral phosphate and active vitamin D analogs

For Tumor-induced Osteomalacia (TIO) (must meet 1 through 3):

1. **The diagnosis is** ~~Patient has a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors~~ confirmed by **ALL** ~~one~~ of the following (**documentation is provided**):
    a. ~~Genetic testing; OR~~
    b. ~~Elevated levels of~~ **S**erum FGF23 **level above the upper limit of normal or abnormal for laboratory reference range**
    c. **Fasting Serum phosphorus levels below lower limit of normal or abnormal for laboratory reference range**
    d. **Tubular maximum reabsorption of phosphate per glomerular filtration rate (TmP/GFR) ratio is below lower limit of normal or abnormal for laboratory reference range, documentation is received ensuring concomitant administration of phosphate supplementation is avoided**
~~2. The patient is 2 years of age or older~~
3. The tumor cannot be curatively resected or localized (located)
4. **Patient tried and failed or has an intolerance or contraindication to treatment with oral phosphate and active vitamin D analogs**

Continuation of therapy (must meet 1 through 3):

1. ~~Increase in~~ **Documentation is provided of** serum phosphorus levels, **alkaline phosphatase (ALP) levels, or TmP/GFR ratio trending towards or at laboratory normal range**
2. **Patient has** improvement in symptoms (e.g., skeletal pain, linear growth, etc.), ~~and/or~~ improvement in radiographic imaging and/or **no evidence of clinical worsening**
3. The medication **requested** is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

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Addendum to Protocol for Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Products ~~Approved April 2021~~ April 2026

DURB Approval Dates	**4/2021**
Commissioners Approval Dates	**6/2022**

Kalydeco® (ivacaftor)
Orkambi®
(lumacaftor/ivacaftor)
Symdeko®
(tezacaftor/ivacaftor)
Trikafta® (elexacaftor/tezacaftor/ivacaftor)
Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor)

Addendum:
Alyftrek was approved in December 2024 for the treatment of cystic fibrosis in patients 6 years of age and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductase regulator (CFTR) gene.

Background:
Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are a class of drugs that act by improving production, intracellular processing, and/or function of the defective CFTR protein. These drugs represent an important advance in management of cystic fibrosis (CF) because they target the production or function of the mutant CFTR protein rather than its downstream consequences. Their indications and efficacy depend upon the CFTR gene mutations in an individual patient.

~~***Kalydeco*** *– Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.*~~

~~***Orkambi*** *- Orkambi is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene.*~~

~~***Symdeko*** *– Symdeko is a combination of tezacaftor and ivacaftor, indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.*~~

~~***Trikafta*** *~~ TRIKAFTA is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data~~*

Criteria for initial approval must meet all of the following:

1. Patient **is of the FDA-labeled or compendial approved age** ~~meets the FDA-approved age for the product requested (see above)~~
2. **The** medication **requested** is 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
3. **Patient does not have any contraindications to therapy**
4. **Documentation is provided confirming diagnosis** ~~Patient has a diagnosis~~ of cystic fibrosis
5. Documentation is provided that indicates the patient has a CFTR gene mutation(s), confirmed by an FDA-cleared CF mutation test for which the requested drug is indicated. ~~(see above). If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use~~
6. Prescriber is a specialist in CF, a pulmonologist, or in consultation with one
7. The patient is not receiving ~~currently being treated with~~ another CFTR agent ~~OR Prescriber will discontinue current CFTR prior to initiating another~~
8. **Documentation of the patient's liver function is provided** ~~Baseline liver function tests (e.g., ALT, AST) are done prior to initiating treatment~~
9. **For drugs with weight-based dosing**, the patient's most recent weight is provided ~~Weight must be received for drugs that have weight-based dosing~~
10. ~~For pediatric patients, an eye examination is required at baseline and periodically during therapy~~
11. **For patient's receiving moderate and/or strong CYP3A4 inhibitors the CFTR dosing is adjusted based on the prescribing information for the requested drug** ~~Dose of CFTR product is reduced in patients taking CYP3A inhibitors such as fluconazole, erythromycin, ketoconazole, etc~~

Trikafta and Alyftrek have a black box warning for drug-induced liver injury and liver failure. See full prescribing information for complete boxed warning.

Continuation of therapy:

1. The patient has demonstrated **at least one of the following** ~~a~~ clinical improvement or stabilization with the product being requested **(documentation must be received)**
    a. Improvement in FEV1 from baseline
    b. Increase in weight or body mass index (BMI)
    c. Improvement in quality of life as demonstrated by CF Questionnaire-Revised (CFQ-R) Respiratory Domain Score

d. Improvement in respiratory symptoms related to patients with CF (cough, sputum production, and difficulty breathing)
e. Reduced number of pulmonary exacerbation

2. The patient is not ~~concurrently~~ receiving another CFTR agent
~~3. The prescriber is a specialist in CF, a pulmonologist or in consultation with one~~
4. Documentation **of recent ALT and AST levels** is provided ~~Monitoring of ALT and AST levels is done annually~~
~~5. Monitoring of pediatric patients for possible development of cataracts~~
6. For dose increase requests, **the patient's** recent weight **is provided** ~~must be received for drugs that have weight-based dosing~~
7. **The** medication **requested** is 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

References:

1. Kalydeco® [package insert]. Vertex Pharmaceuticals In. Boston, MA. September 2025.
2. Orkambi® [package insert]. Vertex Pharmaceuticals In. Boston, MA. September 2025.
3. Symdeko® [package insert]. Vertex Pharmaceuticals In. Boston, MA. September 2025.
4. Trikafta® [packet insert]. Vertex Pharmaceuticals In. Boston, MA. September 2025.
5. **Alyftrek® [package insert]. Vertex Pharmaceuticals Inc. Boston, MA. September 2025.**
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Addendum to Protocol for Spinal Muscular Atrophy (SMA) Products

~~Updated April 2024~~ April 2026

DURB Approval Dates	**8/2017; 7/2019; 1/2023 4/2024**
Commissioners Approval Dates	**2/2024; 8/2024; 10/2024**

Evrysdi® (risdiplam)
Spinraza® (nusinersen)
Zolgensma® (onasemnogene abeparvovec-xioi)
Itvisma® (onasemnogene abeparvovec-brve)
Protocol applies to FDA approved biosimilars and related indications and dosages

Addendum:
Itvisma was approved November 2025 and is indicated for the treatment of spinal muscular atrophy in adults and pediatric patients 2 years of age and older who have a confirmed mutation in survival motor neuron 1 (SMN1) gene. Itvisma is an adeno-associated virus (AAV) vector-based therapy indicated for single dose injection. It is not indicated for those patients who have previously been treated with Zolgensma.

Background:
Spinal muscular atrophy (SMA) is characterized by degeneration of the anterior horn cells in the spinal cord and motor nuclei in the lower brainstem, which results in progressive muscle weakness and atrophy.
~~***Evrysdi*** *is a small molecule SMN2 splicing modifier that binds two sites in SMN2 pre-messenger RNA, thereby correcting the splicing deficit of SMN2, leading to increased levels of full-length SMN protein.*~~
~~***Spinraza*** *is an antisense oligonucleotide (ASO) that modifies splicing of the SMN2 gene to increase production of normal, full-length survival motor neuron protein, which is deficient in SMA*~~
~~***Zolgensma*** *is a recombinant adeno-associated viral vector containing complementary DNA encoding the normal human survival motor neuron protein (SMN1).*~~

Criteria for initial approval must meet all of the following:

1. ~~Patient has a diagnosis of spinal muscular atrophy (SMA)~~
2. **The patient is of the FDA-labeled or compendial approved age**
3. The medication **requested** is 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
4. **For Spinraza and Evrysdi documentation is provided of patient's baseline disease status, for example Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND), Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score, Revised Hammersmith Scale (RHS), or Upper Limb Module (ULM)**
5. **The patient does not have any contraindications to therapy**
6. Diagnosis is confirmed by one of the following:

a. Molecular genetic testing showing homozygous deletions of exon 7 of the SMN1 gene
b. Compound heterozygous mutation of SMN1 gene

7. Prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of SMA
8. **For drugs with weight-based dosing,** the patient's **most recent** weight **is provided** ~~will be monitored~~
9. **The requested medication is not used concomitantly with another drug approved for SMA**

~~**Evrysdi:**~~

~~1. Patient will not receive concomitant surviving motor neuron modifying therapy (e.g., Spinraza or Zolgensma)~~

Spinraza (must meet all of the following):

~~1. The patient will not receive concomitant surviving motor neuron modifying therapy (e.g., Evrysdi or Zolgensma)~~
2. **Documentation is provided at baseline and prescriber attests to performing the following laboratory tests prior to each Spinraza dose**:
   a. ~~Testing of~~ Platelet count ~~to be done at baseline and prior to each dose~~
   b. Prothrombin time; activated partial thromboplastin time
   c. Quantitative spot urine protein concentration
3. **Spinraza is administered by a healthcare professional experienced in performing lumbar punctures**

Zolgensma (must meet all of the following):

~~1. Patient is less than 2 years of age~~
~~2. Patient has bi-allelic mutations in the survival motor neuron (SMN1) gene~~
3. The patient does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator-dependence)
~~4. Baseline anti-AAV9 antibody testing is done, and titers is ≤ 1:50~~
5. Patient will not receive concomitant surviving motor neuron (SMN) modifying therapy (e.g., Spinraza or Evrysdi)
6. **Documentation is provided for the following prior to Zolgensma infusion:**
   a. The patient does not have any signs or symptoms of infection
   b. Liver function (clinical exam, AST, ALT, total bilirubin, albumin, prothrombin time, partial thromboplastin (PTT), and INR)
   c. Creatinine and complete blood count counts (platelet count)
   d. Baseline testing for presence of anti-AAV9 antibodies
   e. Vaccination status is up-to-date
7. Prescriber attests the patient will receive systemic corticosteroid therapy equivalent to oral prednisolone 1mg/kg/day at least 1 day prior to Zolgensma infusion and will continue to receive corticosteroid therapy for at least a total of 30 days ~~*(patient's weight information must be received/documented prior to treatment)*~~
8. Prescriber attests the patient has not received Zolgensma **or Itvisma** in their lifetime
~~9. One dose only will be approved for the treatment of SMA~~
~~10. Patient's liver function is assessed prior to administration of Zolgensma and for at least 3 months after infusion~~

11. **Prescriber attests request for Zolgensma is for single-dose administration per patient's lifetime**

Itvisma (must meet all of the following):

1. **Documentation is provided for the following prior to Itvisma infusion:**
    a. **The patient does not have any signs or symptoms of infection**
    b. **Liver function (clinical exam, AST, ALT, total bilirubin, albumin, prothrombin time, partial thromboplastin (PTT), and INR)**
    c. **Creatinine and complete blood count counts (hemoglobin and platelet count)**
    d. **Baseline testing for presence of anti-AAV9 antibodies**
    e. **Vaccination status is up-to-date**
2. **The patient does not have advanced SMA (e.g., complete paralysis of limbs, permanent ventilator-dependence)**
3. **Prescriber attests the patient will receive systemic corticosteroid therapy equivalent to oral prednisolone 1mg/kg/day at least 1 day prior to Itvisma infusion and will continue to receive corticosteroid therapy for at least a total of 30 days**
4. **Prescriber attests the patient has not received Itvisma or Zolgensma in their lifetime**
5. **Prescriber attests request for Itvisma is for single-dose administration per patient's lifetime**
6. **Itvisma is being administered by a healthcare professional experienced in performing lumbar punctures**

Itvisma has a black box warning for serious liver injury. Zolgensma has a black box warning for serious liver injury and acute liver failure. See full prescribing information for complete boxed warning.

Continuation of therapy (For Evrysdi and Spinraza Requests):

1. **Documentation is provided of clinical improvement and/or disease stabilization while on requested drug**
2. **The patient's most recent weight is provided**
3. **The requested medication is not used concomitantly with another drug approved for SMA**
4. **The medication requested is 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**
5. **For Spinraza requests:**
    a. **The medication is administered by a healthcare professional experienced in performing lumbar punctures**
    b. **Documentation is provided of the following laboratory tests**:
        i. **Platelet count**
        ii. **Prothrombin time; activated partial thromboplastin time**
        iii. **Quantitative spot urine protein concentration**

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NJ DURB Prior Authorization Denial Report - 4th Quarter 2025 (October - December)

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**87,135**	**113,789**	**84,467**	**977,181**	**346,239**	**173,602**
Total # of Pharmacy Claims Processed	**439,239**	**544,601**	**336,366**	**3,397,492**	**902,605**	**968,502**
Total # of Members Requesting Prior Authorization	**1,608**	**3,212**	**2,569**	**22,110**	**7,293**	**5,847**
Total Prior Authorizations Requests Received	**4,533**	**4,475**	**4,267**	**32,756**	**9,666**	**8,345**
Percentage of Claims Requiring Prior Authorization	**1.03%**	**0.82%**	**1.27%**	**0.96%**	**1.07%**	**1.20%**
Received Requests Denials* **	**81 (1.79%)**	**739 (16.51%)**	**368 (8.62%)**	**4,096 (12.50%)**	**1,857 (19.21%)**	**1,258 (15.07%)**
Percentage Breakdown of Denials* **						
Clinical Criteria Not Met	67 (83%)	618 (30%)	355 (20%)	4,023 (36%)	1,649 (41%)	1,063 (28%)
Excluded Benefit	14 (17%)	121 (6%)	13 (1%)	73 (1%)	208 (5%)	195 (5%)
Non-formulary	0 (0%)	1,312 (64%)	1399 (79%)	7,183 (64%)	2,125 (53%)	2,587 (67%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification**						
Antihyperlipidemics	11.1%	3.1%	2.0%	3.5%	7.5%	3.5%
Antidepressants	0.0%	0.8%	0.5%	1.7%	1.1%	0.9%
Antihypertensives	1.2%	0.8%	0.6%	0.6%	0.6%	0.7%
Antianxiety	1.2%	0.0%	0.0%	0.3%	0.1%	0.1%
Antidiabetics (oral and insulin)	7.4%	19.5%	18.7%	18.1%	16.6%	12.9%
Anticoagulants	1.2%	0.0%	0.0%	0.1%	0.3%	0.1%
Thyroid agents	0.0%	0.1%	0.0%	0.1%	0.6%	0.1%
Ulcer Drugs/Antispasmodics/Anticholinergics	0.0%	1.6%	0.9%	2.1%	3.2%	1.1%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	1.2%	14.8%	12.7%	7.7%	17.3%	12.0%
Antipsychotic/Antimanic agents	1.2%	1.3%	1.3%	4.3%	1.6%	2.4%
Antiasthmatic and Bronchodilator agents	8.6%	4.4%	4.0%	5.6%	12.1%	4.4%
Antivirals (includes both HIV and Hep C)	0.0%	0.3%	0.5%	0.4%	1.1%	0.1%
Digestive Aids (Digestive Enzymes)	0.0%	0.4%	0.2%	0.1%	0.1%	0.2%
Anticonvulsants	2.5%	0.8%	1.9%	1.4%	3.0%	0.8%
Migraine Products	1.2%	5.5%	3.9%	4.6%	7.9%	4.4%
Analgesics Anti-inflammatory	7.4%	1.4%	3.3%	3.2%	3.9%	1.8%
Analgesic Opioids	7.4%	3.7%	1.5%	1.0%	2.0%	3.9%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.4%	1.6%	1.0%	2.5%	1.9%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.9%	1.0%	0.9%	0.6%	0.6%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.1%	0.1%	0.0%	0.1%	0.2%
Dermatologics (Antipsoriatics-Systemic)	0.0%	17.0%	15.8%	16.1%	17.7%	16.2%

* 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
January 2026	Proposed Protocol for Opzelura	• The Board recommended approval of the protocol for Opzelura. Opzelura is indicated for the diagnosis of atopic dermatitis and nonsegmental vitiligo.	
	Proposed Addendum to Protocol for Duchenne Muscular Dystrophy Products	• The Board recommended approval of the addendum to the Duchenne Muscular Dystrophy products. Duvyzat, a new drug, was added to the protocol. Elevidys criteria was updated to allow approval for those who are ambulatory.	
	Proposed Addendum to Protocol for Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modifiers	• 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	• 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 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 the recent FDA approval. Initial criteria was updated to include the Centers for Disease Control and Prevention (CDC) parameters for obesity. The Board recommended the continuation of therapy criteria be updated to remove the requirement for a specific percentage decrease in body mass index (BMI) to evaluate efficacy. • The Board recommended approval of the addendum to the PNH products protocol. The continuation of therapy criteria was updated to include an additional parameter to assess efficacy.	

	Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products Proposed Addendum to the protocol for Chimeric Antigen Receptor (CAR) T Cell Products Proposed addendum to the protocol for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) and Glucagon-Like Peptide-1 Receptor Agonist (GLP-1RA)/Glucose-Dependent-Insulinotropic-Polypeptide (GIP) Agonist for Type 2 Diabetes	• The Board recommended approval of the addendum to the 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.	
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.	