NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

January 15, 2025

http://www.state.nj.us/humanservices/dmahs/boards/durb/

AGENDA

I. Call to order in accordance with New Jersey Open Public Meeting Act

II. Roll Call

III. Review of meeting transcript for October 16, 2024, meeting https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/DURB_October_2024_meeting_transcript.pdf

IV. Review of draft meeting summary for October 16, 2024, meeting (pages 4-10)

V. Secretary's report (page 11)

VI. Old Business
- A. Utilization Trends of Bupropion, SGLT-2 inhibitors, GLP-1/GIP Agonists, and CGRP Inhibitors (pages 12-14)
- B. Expansion of Antidiabetic Denials (page 15)
- C. Examples of clinical criteria not met denials for antidiabetic products (page 16)

VII. New Business
- A. Proposed addendum to the protocol for Ingrezza® (valbenazine) [pages 17-18]
- B. Proposed protocol for Alopecia Areata products (pages 19-20)
- C. Proposed protocol for Lyfgenia™ (lovotibeglogene autotemcel) [page 21]
- D. Proposed protocol for Casgevy® (exagamglogene autotemcel) [page 22]

VIII. DURB Annual Report for SFY 2024

IX. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 3rd Quarter 2024 Prior Authorization Report (page 23)
2. Summary of DURB Action Items (pages 24-27)
3. DHS, DHSS and MCO Programs Top Drugs Report/Physicians Administered Drugs (by amount paid and by category)

FFS top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/FFS_Top_Drugs_Report_Nov-2024.pdf

MCO top drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/MCO_Top_Drugs_Report_Oct-2024.pdf

FFS top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/FFS_Top_Drugs_by_Category_Nov-2024.pdf

MCO top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/MCO_Top_Drugs_by_Category_Oct-2024.pdf

FFS antiviral drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2025/FFS_Antiviral_Drugs_Nov-2024.pdf

B. Medication/Medical information

1. Scripts for GLP-1, SGLT2 Drugs on the Rise in Type 1 Diabetes Patients
https://www.medpagetoday.com/endocrinology/type1diabetes/112547?xid=nl_mpt_DHE_2024-10-23&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Evening%20-%20Randomized%202024-10-23&utm_term=NL_Daily_DHE_dual-gmail-definition

2. Old Drugs, New Tricks: The Power of Medication Repurposing

https://www.medpagetoday.com/opinion/secondopinions/112651?xid=nl_secondopinion_2024-11-03&mh=b5c7476e39e5ae230cf10fdcb18e1131

3. Real-World Study Confirms RSV Vaccine's, Arexvy and Abrysvo, Protective Power for Seniors

https://www.drugs.com/news/real-world-study-confirms-rsv-vaccine-s-arexvy-abrysvo-protective-power-seniors-121911.html?utm_source=ddc&utm_medium=email&utm_campaign=Daily+Mednews+++October+19++2024&utm_content=Real+World+Study+Confirms+RSV+Vaccine+s++Arexvy+and+Abrysvo++Protective+Power+for+Seniors&hash2=2f2d27208920fb433cf3207028cab550

4. Shorter Course of Antibiotics Works for Bloodstream Infections
https://www.medpagetoday.com/meetingcoverage/idweek/112481?xid=nl_mpt_morningbreak2024-10-21&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=MorningBreak_102124&utm_term=NL_Gen_Int_Daily_News_Update_active

5. Study: OUD Patients More Likely to Stay on Methadone Than Buprenorphine/Naloxone
https://www.medpagetoday.com/psychiatry/addictions/112477?xid=nl_mpt_morningbreak2024-10-21&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=MorningBreak_102124&utm_term=NL_Gen_Int_Daily_News_Update_active

6. Oral Cephalosporin May Hold Potential for Early Syphilis
https://www.medpagetoday.com/meetingcoverage/idweek/112533?xid=nl_mpt_morningbreak2024-10-23&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=MorningBreak_102324&utm_term=NL_Gen_Int_Daily_News_Update_active

October 16, 2024, DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Barberio, Dr. Moynihan, Ms. Olson, Dr. Lind (ex-officio), Dr. Slim (ex-officio). Unable to attend: Mr. Schafer
Dr. Swee's pre meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the Board's meeting: In compliance with chapter 231 of the public laws of 1975, notice of this meeting was given by way of filings in the Trenton Times, Star Ledger, and Atlantic City Press.
Review of Minutes	Approved	Minutes from July 17, 2024, meeting was reviewed and approved. The approved meeting summary will also be posted on the DURB website at: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report		• The Commissioners have signed off on DURB-recommended protocols for January 2024, and April 2024 meetings. • The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that we've lost. • Proposed dates for 2025 DURB meetings was presented for review and approval by board members. The dates are as follows: Wednesday, January 15 Wednesday, April 23 Wednesday, July 16 Wednesday, October 22 Please review these dates and let me or Dr. Swee know if you would like to make changes. If no changes, these dates will be forwarded to the DHS commissioner for approval and publication. Dr. Swee expressed his gratitude to Dr. Lind and the staff who made it possible to have the protocols signed and also for the work they are doing towards the replacement of board members lost by retirement or resignation.

Issue	Action	Notes
Old Business		
(A) MCO antidiabetic drugs denial trend (2023-2024 YTD)	Continue to monitor	The Board reviewed a Medicaid MCOs antidiabetic drugs denials report for the first quarter of (Jan-March 2024). The Board had requested this report to address the overall denials of antidiabetic products. Dr. Marcus wanted an explanation for 60% denial of GLP-1 agonists. Dr. Swee expressed concern that most of this was due to formularies maintained by the plans. Dr. Elizabeth Bailey, with the State's pharmacy unit explained that over half of the denials were formulary related. She went on to explain that for most of the plans, over half of the products in the antidiabetics category were GLP-agonists and given the popularity of these products for weight loss, it was not surprising to have the observed rate of denials since weight loss products are not part of NJ Medicaid covered benefits. She also told the Board that the denials for non-GLP-1 agonists denials is much smaller than appears in the PA denials report. Twenty-five percent of denials in this category were eventually reversed or approved. Dr. Swee emphasized that the Board would like to keep an eye on the formulary component and inclusion of the eventual approval rate in the report would also be welcome.
(B) CGRP inhibitors report (4th quarter 2022 vs. 2023)	Continue to monitor	The Board reviewed a calcitonin gene-related peptide (CGRP) inhibitors utilization report comparing the 4th quarter of 2022 with the same quarter in 2023. There was a 33% overall increase in utilization in 2023 versus 2022. Dr. Swee expressed satisfaction in the trend and requested review of this report in the next couple of meetings.
(C) Updated addendum to protocol for DMD products	Recommended	The Board reviewed an updated version of the protocol for Duchenne Muscular Dystrophy products with the changes they recommended at the last meeting. There was no further discussion.
(D) Updated Qelbree® protocol	Recommended	The Board reviewed an updated version of the protocol Qelbree® with the changes they recommended at the last meeting. There was no further discussion.

Issue	Action	Notes
New Business		
(A) Proposed addendum to the protocol for ATTR products	Recommended	The Board reviewed a proposed addendum to the protocol for transthyretin-mediated amyloidosis (ATTR) products. The major update was the addition of two products, Anvuttra® (vutrisiran) and Wainua® (eplontersen). Dr. Emenike addressed a panel member's question: if a patient is already on Amvuttra®, could also use it for cardiomyopathy? He explained that the packet insert for Amvuttra® is specific for polyneuropathy, but a prescriber has the discretion to use any medication he/she sees fit under specific circumstances. The Board recommended approval of the protocol.
(B) Proposed protocol for IBAT inhibitor products	Recommended	The Board reviewed a proposed protocol for ileal bile acid transporter (IBAT) inhibitor products. The purpose of the protocol was to combine individual protocols that were previously approved by the Board: Bylvay® (odevixibat), 2022, and Livmarli® (maralixibat), 2023. The Board recommended approval of the protocol.
(C) Proposed addendum to the protocol for PNH products	Recommended	The Board reviewed a proposed addendum for the protocol for paroxysmal nocturnal hemoglobinuria (PNH) products. Dr. Emenike addressed a panel member's offline question about the use of these products for neuromyelitis optica. He informed the Board that Soliris® (eculizumab) is considered a first line treatment for this disease and therefore will be covered by the state. Dr. Swee expressed concern about the minimum age for use of PiaSky® (crovalimab) is 13. Dr. Emenike explained that the information in the protocol represented what is in the drug's label. The Board requested more information from the manufacturer regarding the basis for that age choice. The Board recommended approval of the protocol pending further clarification from the manufacturer, Genentech.
(D) Proposed protocol Winrevair®	Recommended	The Board reviewed a proposed protocol for Winrevair™ (sotatercept-csrk), a product indicated for the treatment of pulmonary arterial hypertension (PAH).

Issue	Action	Notes
		Dr. Emenike addressed a panel member's offline question about criterion number 5: could a patient fulfill the requirement by using 2 medications from the same category? He explained that it would be more efficient to use one from two different categories to explore the different mechanisms of action. Dr. Swee requested Dr. Moynihan's input regarding Medicare's approach to this step therapy options. Dr. Moynihan responded that they would only do that only on review. Dr. Swee further requested consultation with a cardiologist or pulmonologist, or a specialist in this disease state to help the Board understand the rationale behind the step therapy. Ms. Olson informed the Board that from her research, the product will be an add-on for patients at higher risk of hospitalization/death, or not responding to therapy but would not require discontinuation of other conventional therapies. The Board recommended approval of the protocol pending more information from specialists.
(E) Summary of protocols to be retired	Continue to monitor	The Board reviewed a list of protocols (28) recommended by the State to be retired. The protocols were in the following categories: • Protocols that have been updated since first introduced (16) • Protocols that were only applicable to the General Assistance (GA) population, which no longer exists (3) • Protocols that no longer require prior authorization (5) • Protocols that have low PA requests and high approval rates (4) Dr. Swee expressed appreciation for the State considering this approach to the protocols and hoped that this will be an ongoing process.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>Informational Highlights/ Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor</td><td>The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 2nd quarter 2024 are shown below.
<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td><td>% w/o NF*</td></tr>
<tr><td>FFS</td><td>0.9</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>1.0</td><td>46</td><td>15</td></tr>
<tr><td>Fidelis</td><td>1.1</td><td>35</td><td>7</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>1.2</td><td>41</td><td>14</td></tr>
<tr><td>Wellpoint</td><td>0.9</td><td>41</td><td>16</td></tr>
</table>
NF = Non formulary
Note: WellCare is now Fidelis. Amerigroup is now Wellpoint.

• Dr. Swee expressed concern about the disparity of denials among the MCOs. He mentioned formularies to be a major factor and probably monoclonal antibodies. He said that this is not good for physicians and PAs.
• Dr. Marcus raised concern about the clinical criteria not met (CCNM) category.
• Dr. Emenike explained that for FFS, the high percentage could be related to the lower denominator of the patient population in comparison to the MCOs.
• Dr. Lind also explained that the number is high because FFS does not have non-formulary denials.
• Dr. Reut Ghodsi, with the State’s pharmacy unit explained that the high FFS denial rates is related to not receiving requested information from the providers therefore prompting closing of the claim as a denial. She suggested creating another bucket for that category.
• Dr. Swee suggested a category called “information not available”. It is worth noting here that that a category called “incomplete information” already exists but does not have enough claims to make the reporting threshold.

The Board requested more details on the CCNM category.</td></tr>
</table>

<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 (October 2023 through July 2024).
There was no discussion on this section.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2024 (FFS) and June 2024 (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 2024</td><td>$4,216,990 *</td><td>$4,628,767 *</td></tr>
<tr><td>MCOs</td><td>June 2024</td><td>$107,949,726</td><td>$152,594,619</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
</table>

Dr. Marcus had a question why Vivitrol® was injected by the physician but appeared on the top drugs list. Dr. Reut Ghodsi responded that it is typically dispensed from a pharmacy to the provider’s office therefore making it a pharmacy claim.</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. Legit Ozempic® Sales Soar While Counterfeits Put Patients in Danger

2. Medicare Unveils First 10 Negotiated Drug Price

3. FDA Approves First Emergency Allergy Nasal Spray

Dr. Swee wanted to know if the new nasal spray was on the market. Ms. Desai, the State’s pharmacy chief responded that it is loaded on the State’s drug system and will be a covered benefit, but pricing information is not available yet.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Provide a more detailed information on the denials of antidiabetics, including eventual approval data

2. Provide follow up utilization report for calcitonin gene-related peptide (CGRP) inhibitors to show trend</td></tr>
</table>

Issue	Action	Notes
Follow-up items:		3. Approach Genentech, the manufacturer of PiaSky® for clarification on the minimum age of use at 13 4. Consult a cardiologist, pulmonologist or specialist in PAH to provide clarity on the State's step therapy approach in the protocols 5. Provide examples of CCNM denials 6. Consider an educational newsletter for providers on the CCNM category

Secretary's Report

New Jersey Drug Utilization Review Board
January 15, 2025

1. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for **July 2024** and **October 2024**

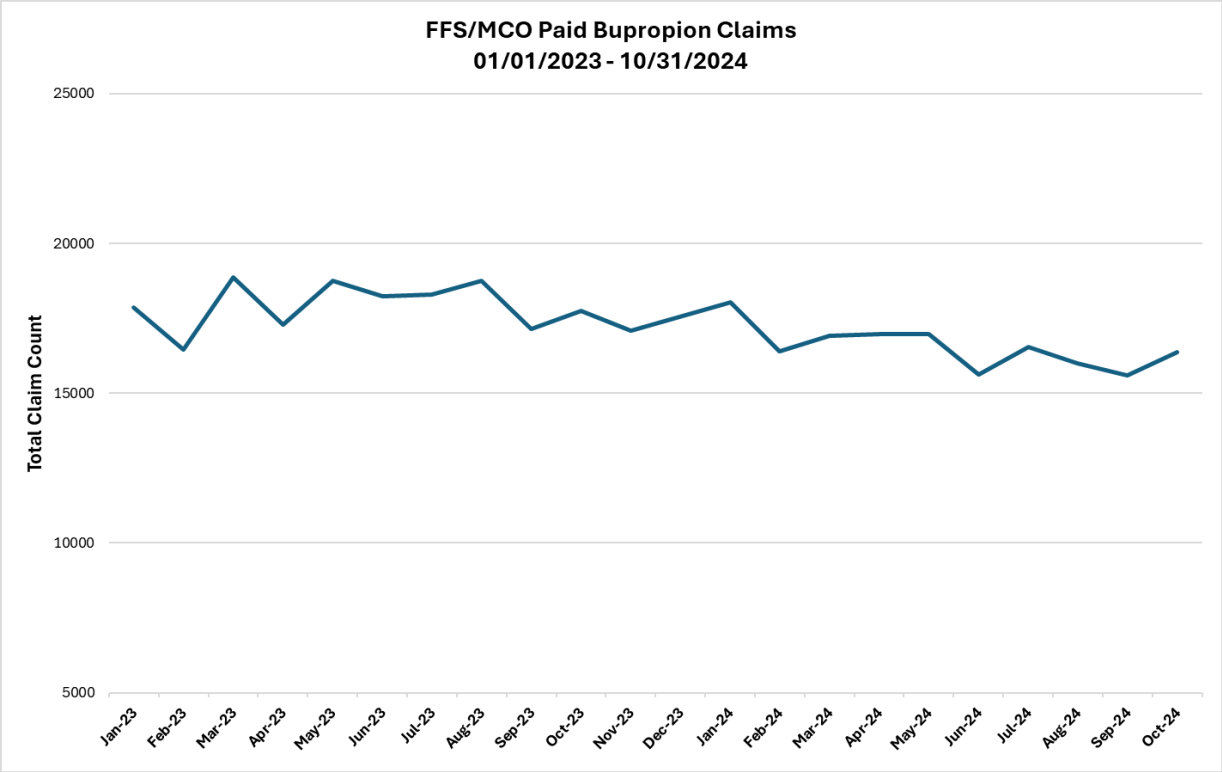
2. DURB annual report for SFY 2024 has been sent to the Board members for their review and comments

3. Follow up to PNH Protocol questions:

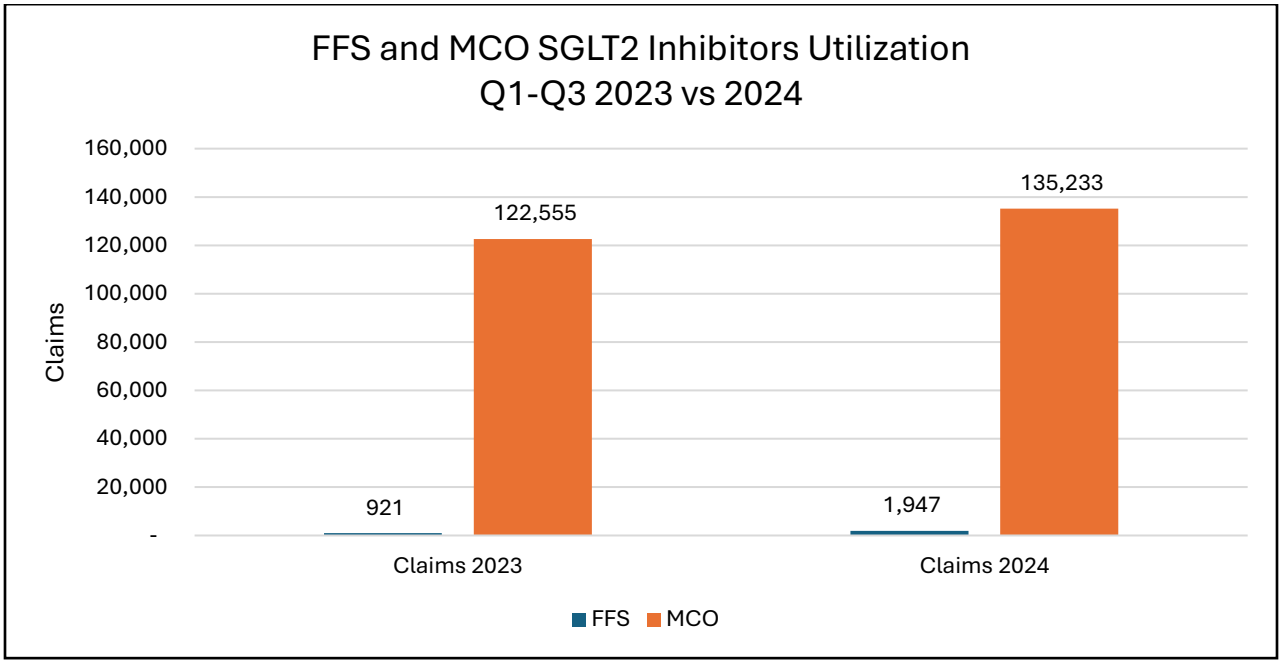
   At the October 2024 DURB meeting, the DURB questioned the reason for PiaSky® being limited to those ages 13 and older. As per PiaSky's prescribing information: "PiaSky is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg."
   Ray Paprocky, Healthcare Director, Rare Disease at Genentech provided an explanation from a Genentech Medical Science Liaison, Dakoata Rosenfelft:
   "PiaSky's clinical trial program enrolled 12 pediatric patients (≥40kg) aged 13-17 across COMMODORE 1, 2, and 3, respectively. We have no data for patients younger than this".

Utilization Trends (January 2024)

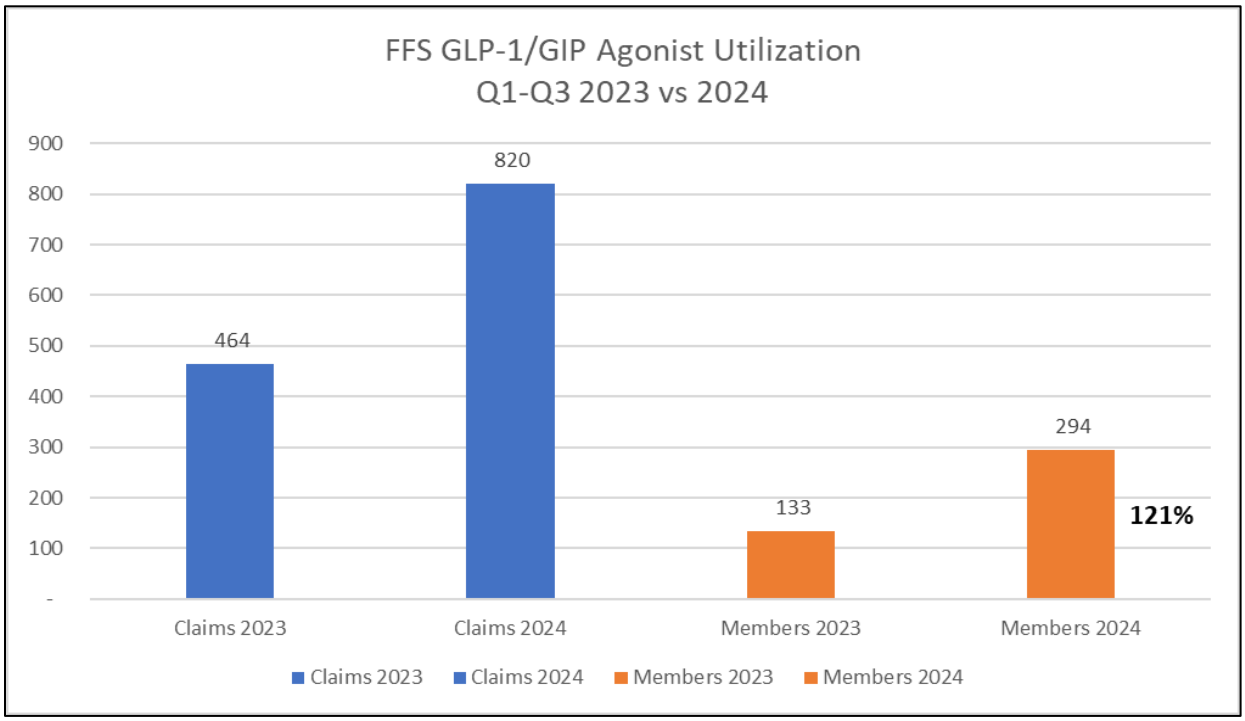
Bupropion Utilization

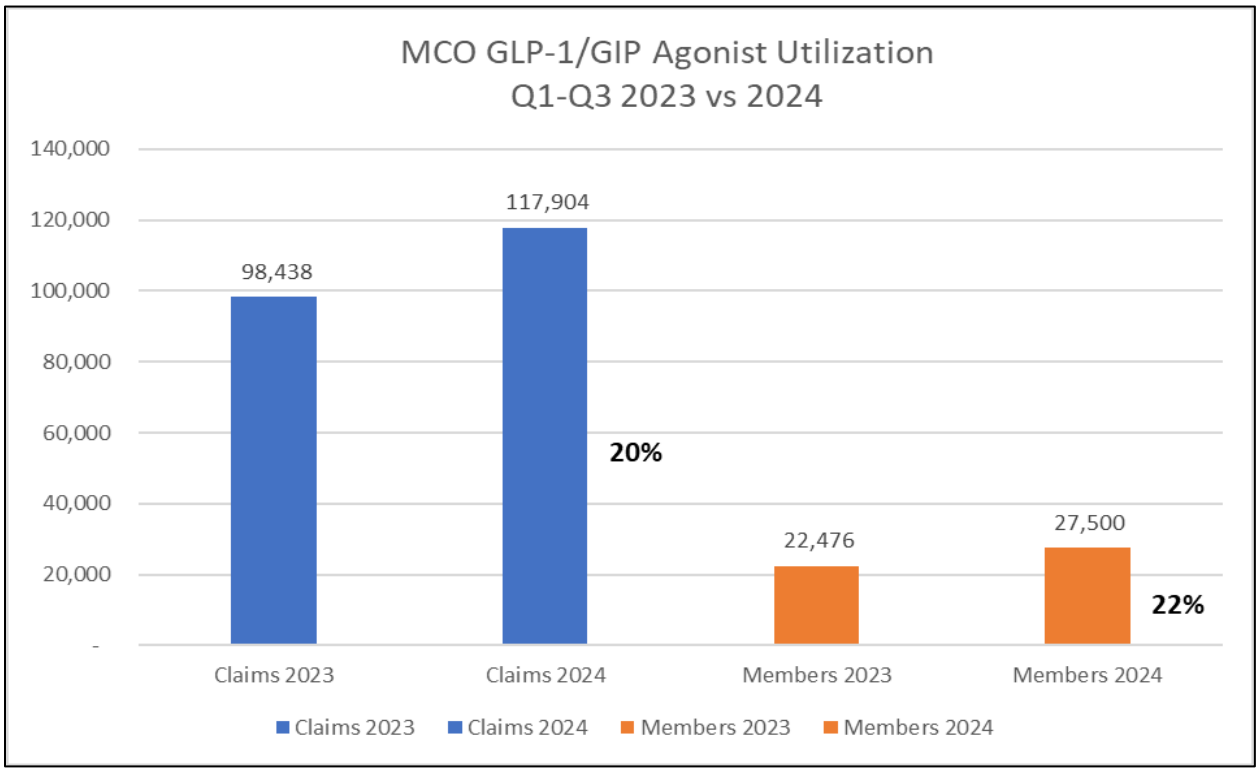


Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors Utilization

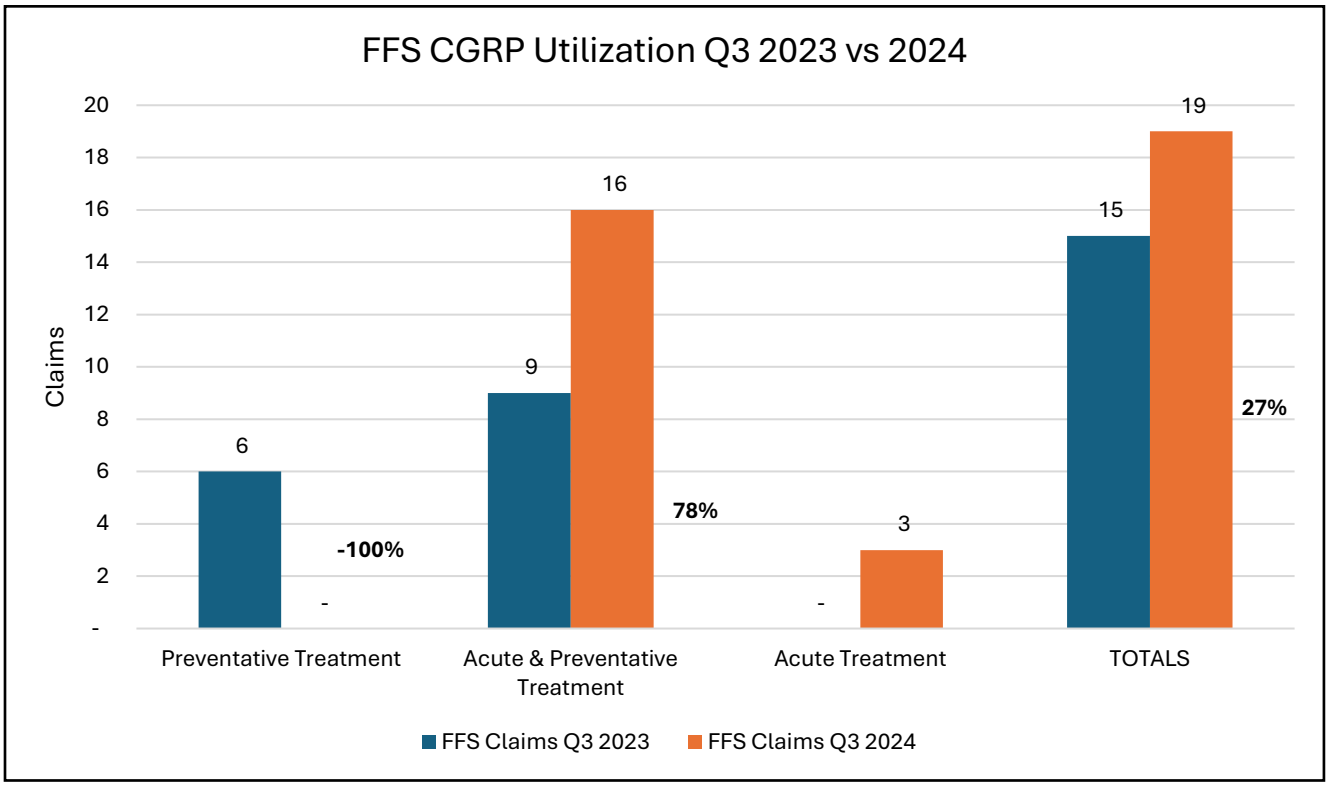


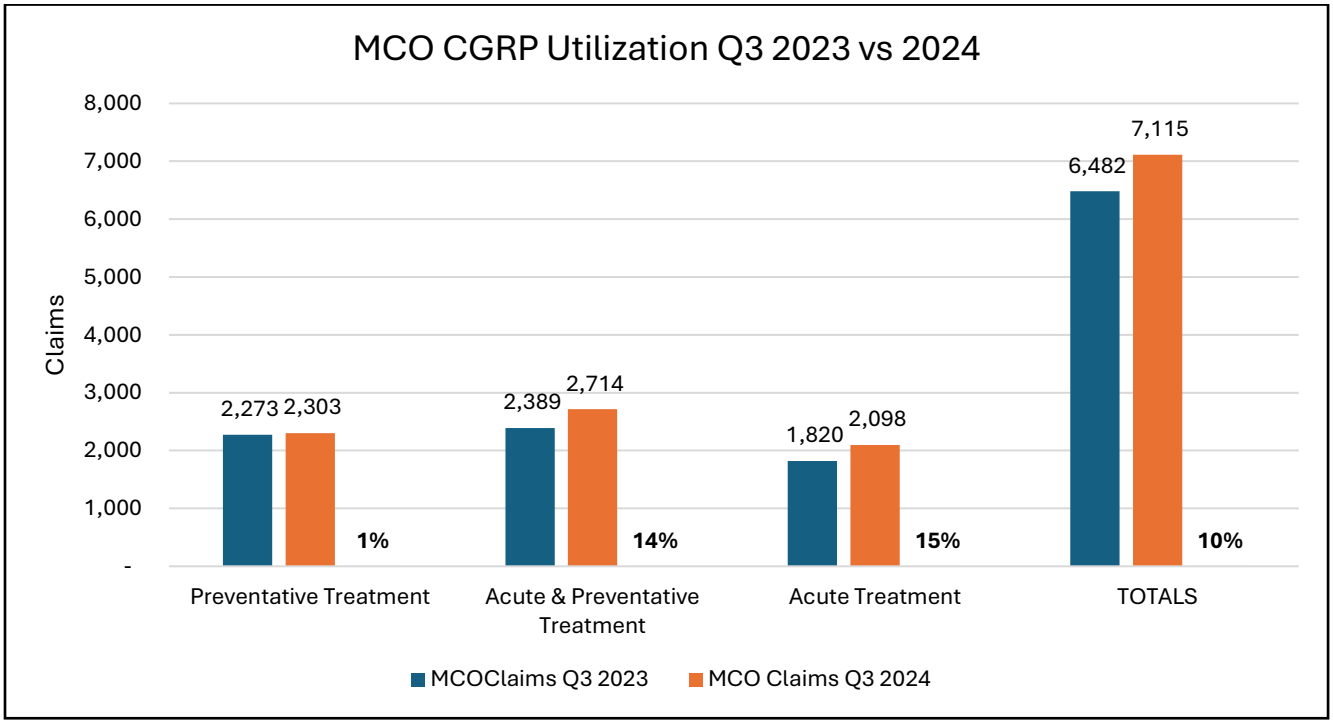
Utilization of Glucagon-like peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-dependent Insulinotropic Polypeptide (GIP) Agonist





Utilization of Calcitonin Gene-Related Peptide (CGRP) Inhibitors





Expansion of Prior Authorization Denial Report

Prior Authorization Denials by Drug Category for Antidiabetics (oral and insulin)

2nd Quarter 2024 (April-June)

Category	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Pharmacy Claims Processed	491,146	367,924	3,435,454	952,589	1,083,713
Total # of Pharmacy Claims Processed – Antidiabetics (oral and injectable)	16,355	23,735	151,251	39,097	66,666
Total # of Prior Authorization Requests Received	4,877	4,107	31,249	11,168	9,666
Total # of Prior Authorization Requests Received – Antidiabetics (oral and injectable)	548	742	6,021	2,269	816
Percentage of Antidiabetics Pharmacy Claims requiring Prior Authorization (%)	**3.4%**	**3.1%**	**4.0%**	**5.8%**	**1.2%**
Total # of Prior Authorization Requests Received Denials	2,252	1,445	10,742	4,621	3,944
Antidiabetic Denials (oral and injectable) - total number of PA requests denied	309	371	2,731	1,160	511

Rows in green were presented in the NJ DURB Prior Authorization Denial Report 2nd Quarter 2024

Category	Aetna	Fidelis	Horizon	UHC	Wellpoint
Antidiabetic Denials (oral and injectable) - total number of PA requests denied	309	371	2,731	1,160	511
Antidiabetic Denials (oral and injectable) **denied for formulary reasons**	110	77	528	673	312
Antidiabetic Denials (oral and injectable) **denied for non-formulary reasons**	199	294	2,203	487	199
Antidiabetic Denials (oral and injectable) **non-formulary denials for missing/incomplete information**	147 (73.9%)	0*	44 (20.2%)	202 (41.5%)	0*

** "Missing/incomplete information" is not tracked. Claims denied due to incomplete information are categorized as "Clinical Criteria Not Met."*

Examples of Clinical Criteria Not Met

Antidiabetic Prior Authorization Denials

- Prediabetes indication or no diabetes diagnosis
    - Example: Clinician prescribed Mounjaro® documenting a diagnosis of pre-diabetes
- No labs received (plans reached out to providers to try and obtain labs)
    - Example: Clinician prescribed Jardiance® but did not submit eGFR values
- Obesity, Overweight indication (no diabetes diagnosis)
    - Example: Clinical prescribed Ozempic® documenting a diagnosis of obesity without diabetes
- Type 2 diabetes mellitus with no clinicals or claims history to support trial/failure of metformin
    - Example: Clinician prescribed Synjardy® XR with no claims history of trial and failure of metformin
    - Example: Clinician prescribed Ozempic® with no claims history of metformin use
- Dosing, no supporting evidence for atypical dosing
    - Example: Clinician prescribed Kombiglyze® XR dosed at one tablet twice daily. Per package labeling Kombiglyze® XR is administered once daily.

Proposed Protocol for Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

January 2025

Approved April 2024 (Ingrezza)

Ingrezza® (valbenazine)
Austedo® (deutetrabenazine)
Xenazine® (tetrabenazine)

Background:
Tardive dyskinesia *is a syndrome that includes a group of iatrogenic movement disorders caused by the blockade of dopamine receptors. The movement disorders include akathisia, dystonia, buccolingual stereotypy, myoclonus, chorea, tics, and other abnormal involuntary movements, which are commonly caused by the long-term use of typical antipsychotics.*
Chorea *is a neurological disorder characterized by spasmodic involuntary movements of the limbs or facial muscles.*

The purpose of this addendum is to include all VMAT2 inhibitors used in the treatment of tardive dyskinesia and Huntington's chorea and remove the prescriber restrictions.

Criteria for approval:

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

2. ~~Medication is prescribed by or in consultation with a neurologist, psychiatrist or another specialist in the field at treating this disease state~~

3. Patient will not use concomitantly with another VMAT inhibitor

4. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

5. **Tardive dyskinesia:**
    a. Patient has a diagnosis of ~~moderate to severe~~ tardive dyskinesia ~~confirmed by an Abnormal Movement Scale (AIMS) score of 3 or 4 on any one of the items 1 through 7~~
    b. ~~Diagnosis of tardive dyskinesia with symptoms that have been present for at least 4 to 8 weeks~~

6. **Chorea associated with Huntington's disease**
    a. Patient has a diagnosis of chorea associated with Huntington's disease that is disruptive to functioning
    b. Huntington disease has been confirmed by genetic testing
    c. Use with caution in patients with depression, agitation, psychosis

Continuation of therapy:

1. Documentation of positive clinical response to therapy ~~based in change in AIMS for tardive dyskinesia~~

2. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimen or in accordance with a medically-appropriate off-label indications 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. Ingrezza® [prescribing information]. Neurocrine Biosciences, Inc. San Diego, CA 92130. August 2023
2. Austedo® [prescribing information] Teva Pharmaceuticals USA, Inc.North Wales, PA 19454. April 2017
3. Xenazine® [prescribing information] Recipharm Fontaine SAS. 21121 Fontaine-les-Dijon, France. June 2015
4. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
5. Vasan S, Padhy RK. Tardive Dyskinesia. [Updated 2023 Apr 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448207/
6. Merical B, Sánchez-Manso JC. Chorea. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430923/

Proposed Protocol for Alopecia Areata Products
January 2025

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

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

Criteria for Approval:

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

2. Patient has a diagnosis of severe alopecia areata

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

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

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

5. Patient has no contraindication to therapy

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

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

8. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence;

Continuation of therapy:

1. Documentation of positive clinical response to therapy

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

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

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

References:

1. Litfulo™ [packet insert] Pfizer Labs Division of Pfizer Inc. New York, NY 10001. June 2023
2. Olumiant® [packet insert] Lilly USA, LLC Indianapolis, IN 46285. May 2022
3. Shawky AM, Almalki FA, Abdalla AN, Abdelazeem AH, Gouda AM. A Comprehensive Overview of Globally Approved JAK Inhibitors. Pharmaceutics. 2022 May 6;14(5):1001
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Proposed Protocol for Lyfgenia™ (lovotibeglogene autotemcel)
January 2025

Background:

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

Criteria for approval:

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

References:

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

Proposed Protocol for Casgevy® (exagamglogene autotemcel) for Sickle Cell Disease

January 2025

Background:

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

Criteria for approval:

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

References:

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

Gainwell Technologies/NJ MCO 3rd Quarter 2024 Prior Authorization Report

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**92,088**	**106,029**	**88,218**	**967,104**	**355,118**	**189,781**
Total # of Pharmacy Claims Processed	**516,373**	**417,459**	**351,261**	**3,238,551**	**952,589**	**1,025,403**
Total # of Members Requesting Prior Authorization*	**1,952**	**3,144**	**2,365**	**18,535**	**7,892**	**6,166**
Total Prior Authorizations Requests Received**	**4,639 (0.9%)**	**4,097 (1.0%)**	**3,640 (1.0%)**	**26,800 (0.8%)**	**11,168 (1.2%)**	**8,792 (0.9%)**
Received Requests Denials	**80 (2%)**	**1,990 (49%)**	**1,328 (36.5%)**	**9,652 (36%)**	**4,621 (41.4%)**	**3,562 (41%)**
Without Non-formulary Denials	**80 (2%)**	**650 (16%)**	**263 (7%)**	**3,661 (14%)**	**1,552 (13.9%)**	**1,570 (18%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	71 (89%)	581 (29%)	256 (19%)	3,607 (37%)	1,335 (29%)	1,213 (34%)
Excluded Benefit	9 (11%)	69 (3%)	7 (1%)	54 (1%)	217 (5%)	357 (10%)
Non-formulary	0 (0%)	1,340 (67%)	1,065 (80%)	5,991 (62%)	3,069 (66%)	1,992 (56%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	5.0%	2.4%	3.0%	3.8%	3.8%	3.3%
Antidepressants	0.0%	1.4%	0.2%	1.6%	1.0%	0.7%
Antihypertensives	1.3%	1.0%	0.4%	0.9%	0.9%	0.7%
Antianxiety	3.8%	0.2%	0.1%	0.3%	0.0%	0.2%
Antidiabetics (oral and insulin)	16.3%	13.8%	29.5%	23.0%	25.1%	13.6%
Anticoagulants	1.3%	0.1%	0.1%	0.2%	0.4%	0.0%
Thyroid agents	0.0%	0.6%	0.0%	0.3%	0.5%	0.1%
Ulcer Drugs/Antispasmodics/Anticholinergics	3.8%	2.5%	0.6%	2.4%	2.7%	2.0%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	0.0%	14.3%	10.5%	3.8%	2.1%	10.3%
Antipsychotic/Antimanic agents	0.0%	1.3%	1.1%	3.3%	1.0%	1.4%
Antiasthmatic and Bronchodilator agents	17.5%	3.6%	3.5%	5.6%	7.8%	2.9%
Antivirals (includes both HIV and Hep C)	0.0%	0.3%	0.4%	0.6%	0.8%	0.4%
Digestive Aids (Digestive Enzymes)	1.3%	0.3%	0.2%	0.1%	0.1%	0.1%
Anticonvulsants	1.3%	3.1%	2.0%	1.4%	2.4%	0.9%
Migraine Products	0.0%	5.7%	4.5%	4.6%	5.6%	3.2%
Analgesics Anti-inflammatory	3.8%	1.6%	2.1%	2.6%	2.4%	2.3%
Analgesic Opioids	10.0%	5.4%	1.0%	1.5%	1.9%	5.5%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.0%	1.7%	1.6%	0.9%	1.7%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.7%	1.0%	0.9%	0.5%	0.7%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.0%	0.1%	0.0%	0.0%	0.1%
Dermatologics (Antipsoriatics-Systemic)	0.0%	14.0%	11.7%	14.7%	11.6%	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. 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

January 15, 2025

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
October 2024	Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products	• The Board recommended the addendum to the protocol	
	Proposed protocol for ileal bile acid transporter (IBAT) inhibitor products	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products	• The Board recommended the addendum to the protocol pending further clarification from the manufacturer, Genentech regarding age of eligibility	This information will be provided at the next meeting
	Proposed Protocol for Winrevair™ (sotatercept-csrk)	• The Board recommended the addendum to the protocol pending more information from specialists in the disease state	This information will be provided at the next meeting
July 2024	Proposed addendum to the protocol for Dupixent® (dupilumab)	• The Board recommended the addendum to the protocol	

	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Vyjuvek® (beremagene geperpavec)	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Duchenne Muscular Dystrophy products	• The Board recommended the protocol with suggested changes to: • 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	These changes were presented at the last meeting (October)
	Proposed protocol for Qelbree® (viloxazine)	• The Board recommended the protocol with suggested change to: a. Delete criterion #3 which required treatment failure with atomoxetine, clonidine, or guanfacine	This change was presented at the last meeting (October)

	Proposed protocol for Wegovy® to reduce the risk of major adverse cardiovascular events (MACE)	• The Board recommended the protocol	
April 2024	Proposed protocol for Ingrezza® (valbenazine)	• The Board recommended the protocol	
	Proposed protocol for Egrifta® (tesamorelin)	• The Board recommended the protocol with suggested change to delete criterion #4c (waist circumference)	Updated information was presented at the next meeting
	Proposed addendum to the protocol for Spinal Muscular Atrophy (SMA) products	• The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products	• The Board recommended the protocol suggested change to criterion #B3 to read: Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected	Updated information was presented at the next meeting

	Proposed addendum to Zurzuvae® (zuranolone) protocol	• The Board recommended the protocol with suggestion to change criterion #3 to read: Medication is prescribed by or in consultation with an appropriate healthcare provider with planned follow up.	Updated information was presented at the next meeting
January 2024	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitor products	• The Board recommended the protocol	
	Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products	The Board recommended the protocol with suggested changes to criterion #3 for initial approval and criterion #4 for subsequent requests.	Updated information was presented at the next meeting
	Proposed update to the protocol for Synagis® (palivizumab)	• The Board recommended the protocol	
	Proposed addendum to the protocol for Lumizyme® (alglucosidase alfa) for Pompe disease	• The Board recommended the protocol	
	Proposed protocol for Zurzuvae® (zuranolone)	• The Board recommended the protocol with suggested changes to criteria #1, 2, 4 for initial approval and criterion #2 in continuation of therapy section	Updated information was presented at the next meeting