NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

October 16, 2024

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

AGENDA

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

II. Roll Call

III. Review of meeting transcript for July 17, 2024, meeting
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2024/DURB_July_2024_Meeting_Transcript.pdf

IV. Review of draft meeting summary for July 17, 2024, meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
- a. MCO antidiabetic drugs denials (pages 9)
- b. Calcitonin gene-related peptide (CGRP) inhibitors utilization report (4th quarter 2022 vs. 4th quarter 2023) [page 10]
- c. Updated Duchenne Muscular Dystrophy products protocol (pages 11-14)
- d. Updated Qelbree (viloxazine) protocol (page 15)

VII. New Business
- a. Proposed addendum to the protocol for transthyretin-mediated Amyloidosis (ATTR) products (pages 16-18)
- b. Proposed protocol for ileal bile acid transporter (IBAT) inhibitor products (pages 19-20)
- c. Proposed addendum to the protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products (pages 21-23)
- d. Proposed Protocol for Winrevair® (sotatercept-csrk) [pages 24-25)
- e. Summary of protocols to be retired (pages 26-27)

VIII. A. Informational Highlights/Reports
- i. Gainwell Technologies/NJ MCO 2nd Quarter 2024 Prior Authorization Report (page 28)
- ii. Summary of DURB Action Items (pages 29-31)
- iii. 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/10-2024/FFS_Top_Drugs_Report_July-2024.pdf

MCO Top Drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2024/MCO_Top_Drugs_Report_June-2024.pdf
FFS Top Drugs by Category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2024/FFS_Top_Drugs_by_Category_July-2024.pdf
MCO Top Drugs by Category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2024/MCO_Top_Drugs_by_Category_June-2024.pdf
FFS Antiviral Drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/10-2024/FFS_Antiviral_Drugs_July-2024.pdf

B. Medication/Medical information

i. Legit Ozempic Sales Soar While Counterfeits Put Patients in Danger https://www.usnews.com/news/health-news/articles/2024-08-02/legit-ozempic-sales-soar-while-counterfeits-put-patients-in-danger

ii. Medicare Unveils First 10 Negotiated Drug Price https://www.medpagetoday.com/publichealthpolicy/medicare/111523?xid=NL_breakingnewsalert_2024-08-15&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=DrugPricesAlert_081524&utm_term=NL_Daily_Breaking_News

iii. FDA Approves First Emergency Allergy Nasal Spray https://www.medpagetoday.com/allergyimmunology/allergy/111452?xid=nl_mpt_DHE_2024-08-09&mh=b5c7476e39e5ae230cf10fdcb18e1131&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Evening%202024-08-09&utm_term=NL_Daily_DHE_dual-gmail-definition

July 17, 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 April 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, July 2023, and October 2023 meetings. • The Department is now working with the Commissioners to sign off on the DURB-recommended protocols for January 2024 and April 2024. • The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that no longer participate in the meetings.
Old Business		
(A) NJ Medicaid MCO Churn rate trend (2023-2024 YTD) (B) Updated Ingrezza protocol	Continue to monitor Recommended	The Board reviewed a Medicaid MCOs churn rate report for YTD 2023-2024. Dr. Swee commented that it'd be nice if it was a little less, but is stable, nonetheless. The Board reviewed an updated version of the protocol for Ingrezza with the changes they recommended: • Revised section A, criterion #3 to read: Medication is prescribed by or in consultation with a neurologist, psychiatrist, "or a specialist in the field at treating this disease state".

		• Revised section B, criterion #3 to read: Use with caution in patients with depression, agitation, psychosis. • Revised section B, criterion #4 to read the same as section A, #3 above.
(C) Updated Egrifta protocol	Recommended	The Board reviewed an updated version of the protocol for Egrifta with the changes they recommended: • Delete criterion #4e (waist circumference) • Delete criterion #6 requiring waist circumference for men and women • In continuation of therapy: delete patient response by the assessment of waist circumference from criterion #3 The Board recommended the protocol with the changes.
(D) Updated DAAs for HCV protocol	Recommended	The Board reviewed an updated version of the protocol for DAAs for HCV with the changes they recommended: • Replace "null responder" with "reinfected" in section B, criterion #3
(E) Updated Zurzuvae protocol	Recommended	The Board reviewed the updated version of the protocol for Zurzuvae for HCV with the changes they recommended: • Add "provider with planned follow up" The Board recommended approval of the protocol with the changes.
New Business		
(A) Proposed addendum to the protocol for Dupixent (dupilumab)	Recommended	The Board reviewed a proposed protocol for Dupixent which consolidated all the approved indications, atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis, and prurigo nodularis. The Board recommended approval of the protocol.
(B) Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors. The addendum was to remove step therapy requirements for migraine prevention as recently recommended by the American Headache Society. Dr. Swee requested a utilization report for these products every other meeting to ensure there is "continued" increase in use. The Board recommended approval of the protocol with the changes.

(C) Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec)	Recommended	The Board reviewed a proposed addendum for the protocol for Vyjuvek. The addendum was to: a. Emphasize that the medication will be applied only to open wounds b. Wound size is required with request to guide dosing c. Treatment is only for 24 weeks pending further evaluation The Board recommended approval of the protocol with the changes.
(D) Proposed addendum to the protocol for Duchenne Muscular Dystrophy products	Recommended	The Board reviewed a proposed addendum to the protocol for Duchenne Muscular Dystrophy products. The addendum was to: • Consolidate the products indicated for this disease state by adding Emflaza (deflazacort), which was a solo protocol approved in 2020 and Agamree (vamorolone). • Remove the requirement that only ambulatory patients qualified for Elevidys. Ms. Kathrin Kucharski, with medical affairs at Sarepta informed the Board that the sites that do Elevidys infusion have the capability to weigh the patients in wheelchairs. She also added that the dose is packed at a maximum dose of 70kg. The Board then decided to delete criterion #4 in continuation of therapy section which states: for dose increases, the member's weight must be received. Ms. Olson suggested changing criterion #6 in criteria for approval section from "prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of DMD and other neuromuscular disorders to ". . . pediatric/adult neurologist or a specialist who is an expert in the treatment of DMD." Dr. Swee countered that there are other neuromuscular disorders. The Board decided to only change "physician" to "specialist" in the sentence. The Board recommended approval of the protocol with the change.
(E) Proposed protocol for Qelbree	Recommended	The Board reviewed a proposed protocol for Qelbree, a product indicated for the treatment of attention deficit hyperactive disorder (ADHD). Dr. Marcus expressed concern that the protocol required two step therapy process before Qelbree is made available to the patient. The Board decided to delete criterion #3 which required patients to have a history of failure, intolerance, or contraindication to atomoxetine, clonidine, or guanfacine.

<table>
<tr><td>(F) Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)</td><td>Recommended</td><td>The Board recommended approval of the protocol with the change. Dr. Slim abstained.

The Board reviewed a proposed protocol for Wegovy, indicated to reduce the risk of major adverse cardiovascular events (MACE). Dr. Marcus expressed concern about the requirement for consultation with a cardiologist or vascular specialist. Dr. Emenike explained that although the State does not require this for other indications for GLP-1 agonists, it is required in this case because of the special circumstances (prior MI, prior stroke, etc.) needed for the use of this product.
Ms. Nikki Patel asked on the chat section how long the initial approval would be. Dr. Emenike responded that the State usually allows 6 months for initial approval.

The Board recommended approval of the protocol.</td></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 1st 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>0.8</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>45</td><td>17</td></tr>
<tr><td>Fidelis</td><td>1.2</td><td>31</td><td>7</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>32</td><td>10</td></tr>
<tr><td>UHC</td><td>1.1</td><td>45</td><td>15</td></tr>
<tr><td>Wellpoint</td><td>0.9</td><td>37</td><td>14</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 concluded that it must be a formulary issue because he deals with it frequently in his practice – change patients medications due to formulary changes. He also</td></tr>
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<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>reiterated the Board's request for denials of diabetic medications by the plans. Dr. Emenike promised to provide the report after obtaining formulary drug information from the MCOs.

The Board reviewed a summary of their actions from previous meetings (July 2023 thru April 2024).
Dr. Swee inquired again about the lag time in signing off of the DURB-recommended protocols by the Commissioners. Dr. Lind responded that he cannot make the signatures, but he can move the process along. Dr. Swee asked for Dr. Marcus' input on the top drugs. Dr. Marcus responded that his only concern was the compounding drugs and that has been clarified.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for November 2023 (FFS) and October 2023 (MCOs) was provided for review.
Drug expenditures during the reporting period is noted below:
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>April 2024</td><td>$5,003,988 *</td><td>$5,434,972 *</td></tr>
<tr><td>MCOs</td><td>March 2024</td><td>$114,010,653</td><td>$162,589,785</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. Obesity drugs could bankrupt US healthcare, says Sanders
2. Cell and Gene Therapies: Excitement tempered by reality
3. Scientists Developing Vaccine Against Present and Future COVID Viruses
4. Narcan May Have Moved Over the Counter, but It's Still Underutilized</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Provide a follow up utilization report for calcitonin gene-related peptide (CGRP) inhibitors
2. Provide a denials report antidiabetics.</td></tr>
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Secretary's Report

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

October 16, 2024

1. The Commissioners have signed off on DURB-recommended protocols for **January 2024** and **April 2024**

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

3. The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members

4. Proposed dates for **2025** DURB meetings:
   Wednesday, January 15, 2025
   Wednesday, April 23, 2025
   Wednesday, July 16, 2025
   Wednesday, October 22, 2025

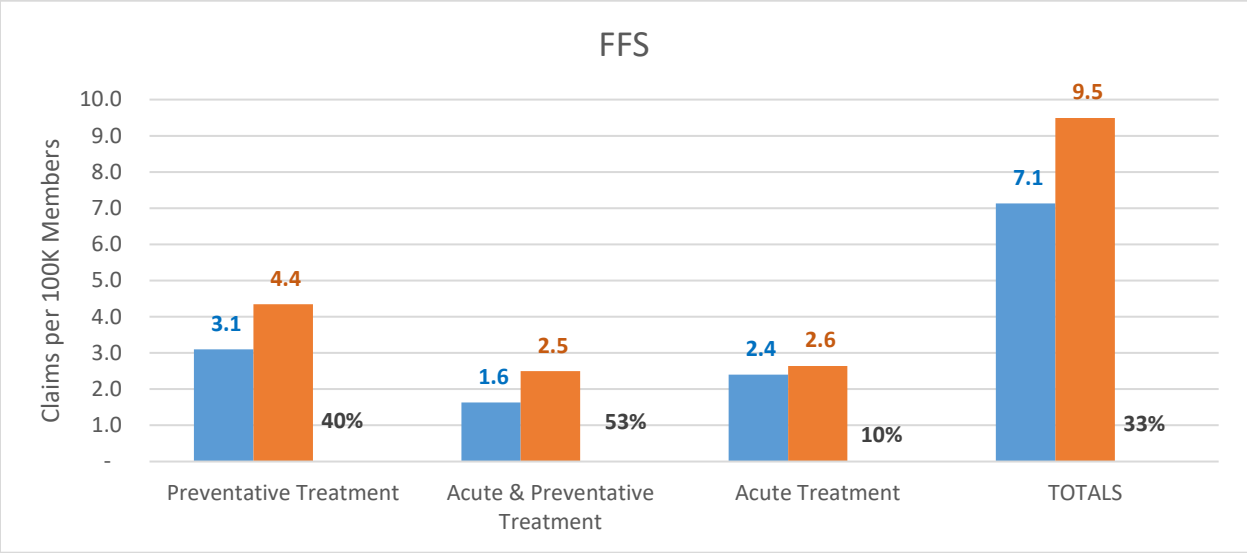
Expansion of Prior Authorization Denial Report, Total Percentage of Denial Prior Authorizations by Drug Category for Antidiabetics (oral and insulin)

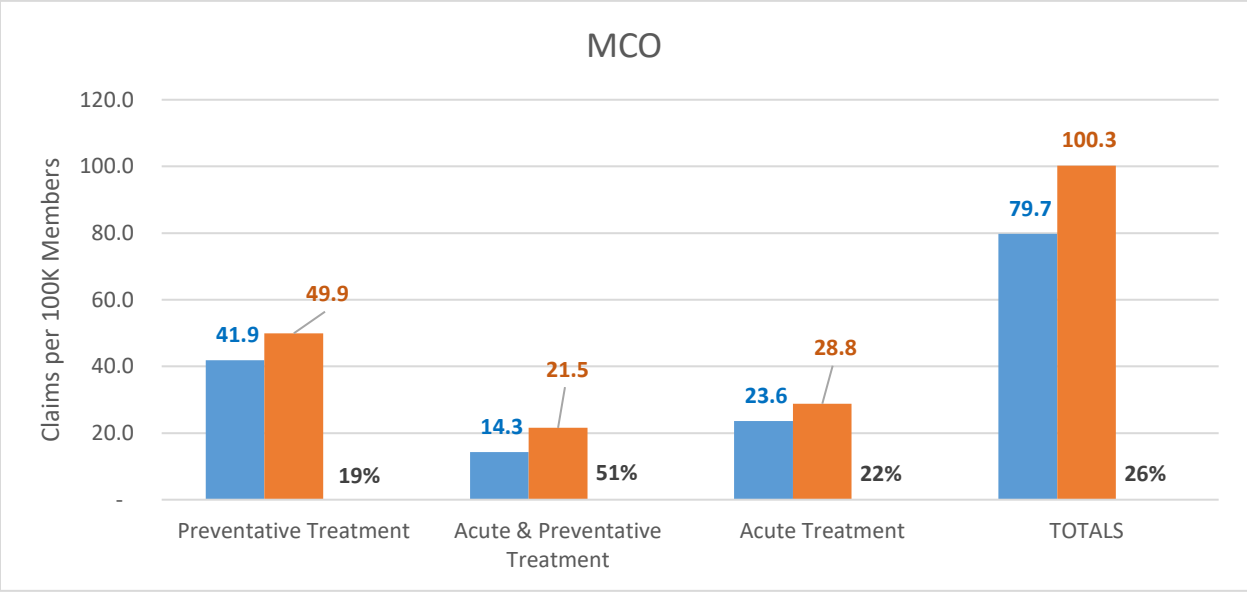
1st Quarter 2024 (January-March)

Category	**Aetna**	**Fidelis**	**Horizon**	**UHC**	**Wellpoint**
Total # of Pharmacy Claims Processed	521,387	387,815	3,585,309	1,001,989	1,152,783
Total # of Prior Authorization Requests Received Denials	2,150	1,417	10,200	4,980	3,807
Antidiabetic Denials (insulin and other diabetic medications) – total number of PA requests denied and as a percentage of total drug prior authorization requests denied (%)	304 (14.3%)	398 (28.1%)	2,427 (23.8%)	1,464 (25.0%)	556 (14.6%)
Antidiabetic Denials (insulin and other diabetic medications) - as a percentage of total pharmacy claims processed (%)	0.06%	0.10%	0.07%	0.15%	0.05%
GLP-1 Agonist Denials - total number of PA requests denied*	186	168	1,530	712	333
GLP-1 Agonist Denials- as a percentage of total Antidiabetic Denials (insulin and other diabetic medications)	61%	42%	63%	49%	60%

**Represents unduplicated data per member, per drug and will not include denials for a member requesting the same product more than once, even if multiple requests are made.*

Calcitonin Gene-Related Peptide (CGRP) Inhibitors Utilization Report
Q4 2022 v. 2023





2022 2023

Addendum to Protocol for Duchenne Muscular Dystrophy Products

Approved July 2024

Approved July 2020
Updated July 2021 - Added viltolarsen (Viltepso®) – FDA-approved in August 2020
Updated October 2021:

a. Added casimersen (Amondys 45) – FDA-approved in February 2021
b. Changed name of protocol to "Protocol for Duchenne Muscular Dystrophy Products"

Updated October 2023 – Added Elevidys – FDA-approved June 2023

Exondys 51® (eteplirsen)
Vyondys 53® (golodirsen)
Viltepso® (viltolarsen)
Amondys 45® (casimersen)
Elevidys® (delandistrogene moxeparvovec-rokl)
Agamree® (vamorolone)
Emflaza (deflazacort)

Addendum:
Addition of Agamree® (vamorolone) – FDA-approved October 26, 2023, and Emflaza protocol (previously DURB approved in July 2020)

Background:
Eteplirsen (Exondys 51)® Golodirsen (Vyondys 53®), Viltolarsen (Viltepso®), and Casimersen (Amondys 45®) are antisense oligonucleotides indicated for the treatment of Duchenne muscular dystrophy (DMD). Delandistrogene moxeparvovec-rokl (Elevidys®) is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD). Vamorolone (Agamree®) and Deflazacort (Emflaza) are corticosteroids indicated for the treatment of Duchenne muscular dystrophy (DMD).
Criteria for Approval:

Antisense Oligonucleotides (Exondys 51, Vyondys 53, Viltepso, Amondys 45)

1. Patient must have a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD).

2. Submission of medical records including the following:
   a. For Exondys 51: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 51 skipping.
   b. For Vyondys 53 and Viltepso: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 53 skipping.
   c. For Amondys 45: Genetic testing confirming the patient has a mutation of the DMD gene that is amenable to exon 45 skipping.

3. Patient is of the appropriate age based on FDA labeling or pharmaceutical compendia

4. Baseline renal function tests (i.e., glomerular filtration rate GFR) as required by medication's label

5. Patient has been stable on a systemic corticosteroid regimen for at least 12 weeks, unless contraindicated or experienced significant adverse effects (must receive documentation)

6. 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

7. Prescriber understands that continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials (PI)

8. Patient's kidney function will be evaluated before and during treatment as required by the medication label

9. Weight will be monitored for drugs that have weight-based dosing

10. Patient will not use in combination with another antisense oligonucleotide.

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

Oral Glucocorticoids (Agamree, Emflaza):

1. Patient must have a confirmed diagnosis of Duchenne Muscular Dystrophy (DMD)

2. Patient is of the appropriate age based on FDA labeling or pharmaceutical compendia

3. Patient has history of trial and failure, intolerance or contraindication to a least a 3-month trial of prednisone

4. Prescribed by or in consultation with a pediatric/adult neurologist or a specialist who is an expert in the treatment of DMD or other neuromuscular disorders

5. Patient is monitored for development of infection

6. Weight will be monitored for drugs that have weight-based dosing

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

Gene Therapies (Elevidys):

1. Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) and meets the following:
   a. Genetic testing confirming the patient has a mutation in the DMD gene, except a deletion mutation in exon 8 and/or exon 9.
   b. Elevidys is contraindicated for patients with deletion mutations in exon 8 and/or exon 9 in the DMD gene.

2. ~~Patient is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)~~

3. Baseline anti-AAVrh74 antibody titers <1:400 as determined by a total binding antibody ELISA

4. Baseline platelet counts, liver function tests, and troponin-I levels are obtained prior to initiating treatment

5. Elevidys will not be used in combination at the same time as the exon-skipping therapies (casimersen, eteplirsen, golodirsen, viltolarsen), but can be used after discontinuation of the other treatment options.

6. Treatment is one time only

7. Patient is of the appropriate age based on FDA labeling or pharmaceutical compendia

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

Continuation of therapy:

1. Updated chart notes demonstrating positive clinical response to therapy (such as improvement and/or stabilization compared to baseline)

2. 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

3. Patient is monitored for infection

~~4. For dose increases, the member's weight must be received~~

5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service,

Micromedex, Clinical Pharmacology, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

6. Patient will not use golodirsen (Vyondys 53®) together with viltolarsen (Viltepso®)

References:

1. Exondys 51 [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; September 2016.
2. Vyondys 53 [package insert]. Sarepta Therapeutics, Inc.; Cambridge, MA. March 2020.
3. Viltepso [package insert]. NS Pharma, Inc. Paramus, NJ 07652
4. Amondys 45 [package insert]. Sarepta Therapeutics, Inc; Cambridge MA. February 2021
5. Elevidys [package insert]. Sarepta Therapeutics, Inc. Cambridge MA. July 2023
6. Agamree [package insert]. Catalyst Pharmaceuticals. Coral Gables, FL. March 2024
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically
8. Mendell JR, et al; Eteplirsen Study Group. Eteplirsen for the treatment of Duchenne muscular dystrophy. Ann Neurol. 2013;74(5):637-647.
9. Lee JJA, Saito T et al. Direct Reprogramming of Human DMD Fibroblasts into Myotubes for In Vitro Evaluation of Antisense-Mediated Exon Skipping and Exons 45-55 Skipping Accomplished by Rescue of Dystrophin Expression. Methods Mol Biol. 2018; 1828: 141-150
10. Bushby K, Finkel R, Birnkrant DJ, Case LE, Clemens PR, Cripe L, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol; 2010 Jan; 9(1):77 93.
11. Mah JK, Clemens PR, Guglieri M, et al. Efficacy and Safety of Vamorolone in Duchenne Muscular Dystrophy: A 30-Month Nonrandomized Controlled Open-Label Extension Trial. JAMA Netw Open. 2022;5(1):e2144178. doi:10.1001/jamanetworkopen.2021.44178
12. Emflaza™ [package insert]. PTC Therapeutics, Inc. South Plainfield, NJ. June 2019.
13. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
14. Bushby K, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional managementThe Lancet Neurol 2018; 17,3; 251-267.
15. Griggs RC et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15;87(20):2123-2131.

Protocol for Qelbree® (viloxazine)
Approved July 2024

Background: *Attention deficit hyperactivity disorder (ADHD) is a widely diagnosed neurodevelopmental disorder giving rise to symptoms of hyperactivity, impulsivity, and inattentiveness that can impair daily functioning. Stimulants, such as methylphenidate and amphetamines, are the mainstay of treatment for ADHD.*

Qelbree *is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adult and pediatric patients.*

Criteria for approval:

1. Patient is of the appropriate age based on FDA labeling or pharmaceutical compendia

2. Patient has a diagnosis of attention deficit hyperactivity disorder (ADHD)

~~3. Patient has a history of failure, intolerance, or contraindication to the use of ONE of the following at therapeutic doses unless the patient has difficulty taking pills:~~
   ~~a. Atomoxetine~~
   ~~b. Clonidine~~
   ~~c. Guanfacine~~

4. Patient has a history of trial and failure, intolerance, or contraindication to the use of at least **one** stimulant indicated for the treatment of ADHD **OR** patient has a history of substance use disorder (SUD)

4. Patient will be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior

5. Patient's heart rate and blood pressure is assessed prior to initiating treatment and periodically while on treatment

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

Continuation of Therapy:
There is improvement from baseline

References

1. Qelbree [package insert]. : Supernus Pharmaceuticals, Inc. Rockville, MD. April 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2022. Updated periodically
3. Robinson CL, Parker K, Kataria S, Downs E, Supra R, Kaye AD, Viswanath O, Urits I. Viloxazine for the Treatment of Attention Deficit Hyperactivity Disorder. Health Psychol Res. 2022 Sep 23;10(3):38360. doi: 10.52965/001c.38360. PMID: 36168642; PMCID: PMC9501833.

Protocol for Transthyretin-mediated Amyloidosis (ATTR) Products

October 2024

October 2019

Onpattro® (patisiran)
Vyndaqel® and Vyndamax® (tafamidis meglumine)
Tegsedi® (inotersen)
Amvuttra® (vutrisiran)
Wainua® (eplontersen)

Addendum: Add two new products recently approved by the FDA (Amvuttra – June 2022; Wainua – December 2023)

Background:
Onpattro® (patisiran) and Amvuttra® (vutrisiran) *contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.*

Vyndaqel® *(tafamidis meglumine) and* ***Vyndamax®*** *(tafamidis) are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.*

Tegsedi® *(inotersen) and* ***Wainua® (eplontersen)*** *are a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.*

Criteria for approval:

1. Documentation of diagnosis is confirmed by genotyping, biopsy, immunohistochemical analysis, scintigraphy, or mass spectrometry

2. Medication is prescribed by or in consultation with a neurologist, cardiologist, or a specialist in the treatment of ATTR.

3. Patient has clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, motor disability, cardiovascular dysfunction, carpal tunnel syndrome, etc.)

4. Weight ~~must be received~~ should be made available for drugs that have weight-based dosing. Height and weight ~~must be received~~ should be made available for drugs that have dosing based on body surface area.

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

6. Patient has no contraindications to the requested drug

7. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-

label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, or national guidelines.

8. Will not be used concurrently with other Transthyretin-mediated Amyloidosis (ATTR) products

For Onpattro, Amvuttra and Wainua requests:

a. Patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated Amyloidosis

For Vyndaqel® and Vyndamax® requests:

a. Medication is being used to treat cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular mortality and cardiovascular-related hospitalization

For Tegsedi® requests:

a. Patient has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis

b. ~~The member must not have any of the following contraindications:~~

I. ~~Patient has platelet count < 100,000/mm3~~

II. ~~History of acute glomerulonephritis caused by Tegsedi~~

Continuation of therapy:

1. Documentation that patient has experienced a positive clinical response to medication (e.g., improved neurologic impairment, motor function, quality of life, etc.)

2. Will not be used concurrently with other Transthyretin-mediated Amyloidosis (ATTR) products

3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, or national guidelines.

4. For dose increases, weight should be made available for drugs that have weight-based dosing. For dose increases, height and weight should be made available for drugs that have dosing based on body surface area.

Tegsedi® Boxed Warning

WARNING: THROMBOCYTOPENIA AND GLOMERULONEPHRITIS See full prescribing information for complete boxed warning. Thrombocytopenia • TEGSEDI causes reductions in platelet count that may result in sudden and unpredictable thrombocytopenia, which can be life-threatening. • Testing prior to treatment and monitoring during treatment is required Glomerulonephritis • TEGSEDI can cause glomerulonephritis that may require immunosuppressive treatment and may result in dialysis dependent

renal failure. • Testing prior to treatment and monitoring during treatment is required TEGSEDI is available only through a restricted distribution program called the TEGS EDI REMS Program

References:

1. 1.Onpattro [package insert]. Alnylam Pharmaceuticals, Inc. San Diego, CA 92121. August 2018.
2. Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) [package insert]. Pfizer Labs Inc. NY, NY 10017. May 2019.
3. Tegsedi [package insert]. Ionis Pharmaceuticals, Inc. Carlsbad, CA 92010. October 2018
4. Amvuttra [package insert]. Alnylam Pharmaceuticals, Inc., Cambridge, MA 02142. February 2023
5. Wainua (eplontersen) [package insert] AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850. December 2023
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7. Maurer MS, Schwartz JH, Gundepaneni B, et al. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2018; 379:1007-1016.
8. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
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13. Adams D, Gonzales-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med 2018;379:11 -21.
14. Benson MD, Waddington-Cruz M, Berk JL. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. N Engl J Med 2018;379:22 -31
15. Ando Y, Waddington-Cruz M, Sekijima Y, Koike H, Ueda M, Konishi H, Ishii T, Coelho T. Optimal practices for the management of hereditary transthyretin amyloidosis: real-world experience from Japan, Brazil, and Portugal. Orphanet J Rare Dis. 2023 Oct 12;18(1):323. doi: 10.1186/s13023-023-02910-3. PMID: 37828588; PMCID: PMC10571420.
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Protocol for Ileal Bile Acid Transporters (IBAT) Inhibitors
October 2024

Bylvay® (odevixibat) – previously DURB approved July 2022
Livmarli® (maralixibat) – previously DURB approved April 2023

Addendum:
Consolidate both protocols for easier access to guidelines.

Background: Bylvay *and* ***Livmarli*** *are ileal bile acid transporter (IBAT) inhibitors indicated for the treatment of pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) and for the treatment of cholestatic pruritis in patients with Alagille Syndrome (ALGS).*

Criteria for approval:

1. Patient has a diagnosis of **one** of the following that has been confirmed by genetic testing:
    a. Progressive familial intrahepatic cholestasis (PFIC), **OR**
    b. Alagille syndrome (ALGS)

2. Patient is of the FDA labeled or compendial approved age

3. Patient has pruritus, if able to report

4. Patient has cholestasis, as indicated by at least ONE of the following:
    a. Total serum bile acid the upper limit of normal (ULN) for age
    b. Conjugated bilirubin >1 mg/dL
    c. Fat soluble vitamin deficiency that is otherwise unexplainable
    d. Gamma Glutamyl Transferase (GGT) >3 × ULN for age
    e. Intractable pruritus explainable only by liver disease

5. Patient has no history of liver transplant

6. Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in treatment of the disease state

7. Unless contraindicated to all, patient has tried and has inadequate response or intolerance to treatment with ursodeoxycholic acid, or other agents used for symptomatic relief of pruritus (e.g., antihistamine, rifampicin, cholestyramine).

8. Patient has no contraindications to the requested drug

9. Will not be used concurrently with other IBAT inhibitors

10. Patient's weight should be monitored

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

Exclusion (Limitation of Use):
Bylvay and Livmarli may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).

Continuation of therapy:

1. Patient is responding positively to therapy as evidenced by improvement in any of the following:
    a. Improvement in pruritus, if able to report
    b. Reduction of serum bile acids from baseline

2. Patient is not taking concurrently with other IBAT inhibitors

3. Patient's weight should be monitored

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

References:

1. Bylvay [prescribing information]. Albireo Pharma Inc. Boston, MA 02109. July 2021
2. Livmarli [prescribing information]. Mirum Pharmaceuticals Inc. Foster City, CA. September 2021
3. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
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Proposed Addendum to the Protocol for Paroxysmal Nocturnal Hemoglobinuria Products
October 2024

Approved July 2022
Empaveli® (pegcetacoplan)
Soliris® (eculizumab)
Ultomiris® (ravulizumab)
Fabhalta® (iptacopan)
Piasky® (crovalimab)
Voydeya® (danicopan)

Addendum: Addition of new FDA-approved products: Fabhalta (December 2023); Piasky, June (2024); Voydeya, April (2024)

Background:
Paroxysmal nocturnal hemoglobinuria (PNH) is a chronic, multi-systemic, progressive, and life-threatening disease characterized by intravascular hemolysis, thrombotic events, serious infections, and bone marrow failure.

***Empaveli** is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria.*
***Soliris** is a complement inhibitor indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.*

***Ultomiris** is a complement inhibitor indicated for the treatment of pediatric and adult patients with paroxysmal nocturnal hemoglobinuria.*

***Fabhalta** is a complement factor B inhibitor, indicated for the treatment of adults with PNH.*

***Piasky** is a complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with PNH and body weight of at least 40 kg*

***Voydeya** is a complement factor D inhibitor indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with PNH*

Criteria for approval:
1. Diagnosis of PNH is confirmed by flow cytometry
2. Patient is of the FDA-labeled or compendial approved age and weight, as applicable
3. Weight should be made available for drugs that have weight-based dosing.
4. Prescriber is enrolled in the appropriate REMS program

5. For requests besides Voydeya: Patient will not be on concomitant therapy with another agent of the same drug class

6. Patient complies with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria

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

For Voydeya:

a. Patient has evidence of extravascular hemolysis while on a complement C5 inhibitor therapy like eculizumab, ravulizumab, or crovalimab
b. Medication will be used concomitantly with a complement C5 inhibitor therapy (e.g., eculizumab, ravulizumab)
c. Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH
d. Hemoglobin is $\leq$ 9.5 g/dL
e. Absolute reticulocyte count $\geq$120 x 10^9/L

Continuation of therapy:

1. The patient has responded to treatment compared to baseline as defined by at least one of the following:
    a. Decrease in serum LDH from pretreatment level
    b. Increase in hemoglobin levels
    c. Decrease in number of transfusions needed
    d. Absence of unacceptable toxicity from the drug

2. For requests besides Voydeya: Patient is not taking concomitantly another agent in the same drug class

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

References:

1. Empaveli [prescribing information]. Apellis Pharmaceuticals Inc; Waltham MA: May 2021
2. Soliris [prescribing information]. Alexion Pharmaceuticals, Inc. Cheshire, CT: September 2011
3. Ultomiris [prescribing information]. Alexion Pharmaceuticals, Inc. Boston, MA: December 2018
4. Fabhalta [prescribing information]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. August 2021
5. Piasky [prescribing information]. Genentech, Inc. South Francisco, CA. June 2024

6. Voydeya [prescribing information]. Alexion Pharmaceuticals. Boston, MA. March 2024
7. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
8. Cancado RD et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. Hematol Transfus Cell Ther. 2021; 43(3):341-348
9. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program (2016) 2016 (1): 208–216.
10. Besa EC. Paroxysmal Nocturnal Hemoglobinuria Treatment & Management. Medscape. June 25, 2024. Accessed August 9, 2024, at: https://emedicine.medscape.com/article/207468-treatment?form=fpf
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Proposed Protocol for Winrevair® (sotatercept-csrk)

October 2024

Winrevair *is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.*

Criteria for approval:

1. Patient is of the FDA labeled or compendial approved age

2. Documentation of pulmonary arterial hypertension (PAH) with WHO functional class II or III symptoms

3. Diagnosis is confirmed by right heart catheterization

4. Medication is prescribed by or in consultation with a pulmonologist, cardiologist, or a specialist with experience in treating PAH

5. Patient has had an inadequate response to at least **two** products for the treatment of PAH, unless contraindicated or not tolerated, such as:
    a. Phosphodiesterase type 5 (PDE5 inhibitor) [e.g., sildenafil, tadalafil]
    b. Endothelin receptor antagonist [e.g., bosentan (Tracleer), ambrisentan (Letaris)]
    c. Prostacyclin agonist [e.g., treprostinil (Remodulin, Tyvaso, Orenitram)]
    d. Soluble guanylate cyclase inhibitors, e.g., riociguat (Adempas)

6. Individual has a platelet count greater than or equal to 50,000/mm3

7. Prescriber attests the patient will be monitored for thromboembolic events and hyperviscosity syndrome, including Hgb and platelet count before each dose for the first 5 doses

8. Weight should be provided for weight-based dosing

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

Continuation of Therapy:

1. Documentation of positive clinical response (ex. improvement in the 6-minute walk distance)

2. Weight should be provided for weight-based dosing

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

References

1. Winrevair. [package insert] Merck & Co., Inc., Rahway, NJ. March 2024
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2022. Updated periodically
3. Mayeux JD, Pan IZ, Dechand J, Jacobs JA, Jones TL, McKellar SH, Beck E, Hatton ND, Ryan JJ. Management of Pulmonary Arterial Hypertension. Curr Cardiovasc Risk Rep. 2021;15(1):2. doi: 10.1007/s12170-020-00663-3. Epub 2020 Nov 18. PMID: 33224405; PMCID: PMC7671829.
4. Klinger J, Elliott G, Levine D. et al. Therapy for Pulmonary Arterial Hypertension in Adults. CHEST 2019; 155 (3): 565-586. Accessed August 21, 2024, at https://journal.chestnet.org/article/S0012-3692(19)30002-9/pdf
5. Hopkins W, Rubin LJ. Treatment of pulmonary arterial hypertension (group 1) in adults: Pulmonary hypertension-specific therapy. In: UpToDate, Mandel J (Ed), Wolters Kluwer. (Accessed on August 21, 2024.)

Protocols Recommended for Retirement

Protocol to retire	Date Approved
The following protocols have been updated:	
Oxycodone CR	October 2010
Victrelis	June 2011
Short-acting opioids	June 2011
Incivek	October 2011
Sovaldi	June 2014
Harvoni	April 2015
Viekera	April 2015
Technivie	October 2015
Daklinza	October 2015
Zepatier	April 2016
Epclusa	October 2016
Exondys	April 2017
Emflaza	June 2017
Spinraza	June 2017
Sovaldi for pediatric patients	June 2017
Harvoni for pediatric patients	June 2017
The following were only applicable to the General Assistance (GA) population, which no longer exists.	
Lidoderm	April 2009
Advair	October 2011
Singulair	January 2012
The following protocols no longer require PA:	
Vivitrol (naltrexone)	October 2006
Suboxone	April 2007
Antibiotic duration	October 2008
Antipsychotics	October 2009
Provigil	April 2007
The following protocols are being retired due to low PA requests and high approval rates:	

Oxandrin (oxandrolone)	June 2006
Selective NSAIDs	January 2010
Tramadol	June 2010
Soma	January 2012

NJ DURB Prior Authorization Denial Report - 2nd Quarter 2024 (April - June)

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**117,497**	**112,544**	**94,426**	**1,027,767**	**355,118**	**196,596**
Total # of Pharmacy Claims Processed	**524,725**	**491,146**	**367,924**	**3,435,454**	**952,589**	**1,083,713**
Total # of Members Requesting Prior Authorization*	**1,939**	**3,463**	**2,600**	**22,014**	**7,892**	**6,773**
Total Prior Authorizations Requests Received**	**4,685 (0.9%)**	**4,877 (1%)**	**4,107 (1.1%)**	**31,249 (0.9%)**	**11,168 (1.2%)**	**9,666 (0.9%)**
Received Requests Denials	**98 (2%)**	**2,252 (46%)**	**1,445 (35.2%)**	**10,742 (34%)**	**4,621 (41%)**	**3,944 (41%)**
Without Non-formulary Denials	**98 (2%)**	**731 (15%)**	**297 (7%)**	**3,860 (12%)**	**1,552 (14%)**	**1,580 (16%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	86 (88%)	698 (31%)	290 (20%)	3,808 (35%)	1,335 (29%)	1,256 (32%)
Excluded Benefit	12 (12%)	33 (1%)	7 (0)%	52 (0%)	217 (5%)	324 (8%)
Non-formulary	0 (0%)	1,521 (68%)	1,148 (79)%	6,882 (64%)	3,069 (66%)	2,634 (60%)
Other	0 (0%)	0 (0%)	0 (0)%	0 (0)%	0 (0)%	0 (0)%
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	13.3%	1.6%	2.6%	3.5%	3.8%	3.7%
Antidepressants	0.0%	2.1%	0.2%	1.4%	1.0%	1.3%
Antihypertensives	3.1%	1.0%	0.4%	0.7%	0.9%	0.4%
Antianxiety	0.0%	0.1%	0.1%	0.2%	0.0%	0.3%
Antidiabetics (oral and insulin)	5.1%	14.0%	25.6%	25.4%	25.1%	13.0%
Anticoagulants	0.0%	0.0%	0.4%	0.1%	0.4%	0.1%
Thyroid agents	0.0%	0.4%	0.0%	0.3%	0.5%	0.1%
Ulcer Drugs/Antispasmodics/Anticholinergics	2.0%	1.9%	1.0%	1.9%	2.7%	1.2%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	1.0%	12.4%	9.1%	3.2%	2.1%	7.5%
Antipsychotic/Antimanic agents	1.0%	2.1%	0.6%	3.2%	1.0%	1.8%
Antiasthmatic and Bronchodilator agents	16.3%	4.3%	4.6%	6.6%	7.8%	3.0%
Antivirals (includes both HIV and Hep C)	1.0%	0.4%	0.6%	0.4%	0.8%	0.3%
Digestive Aids (Digestive Enzymes)	0.0%	0.3%	0.4%	0.1%	0.1%	0.1%
Anticonvulsants	0.0%	2.5%	2.3%	1.3%	2.4%	0.8%
Migraine Products	0.0%	3.9%	3.7%	4.4%	5.6%	4.3%
Analgesics Anti-inflammatory	7.1%	2.3%	3.7%	2.4%	2.4%	1.9%
Analgesic Opioids	6.1%	4.3%	0.9%	1.3%	1.9%	4.5%
Endocrine and Metabolic Agents-Misc (Growth Hormon	0.0%	1.1%	1.9%	1.2%	0.9%	2.1%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	1.0%	1.4%	0.7%	0.5%	0.9%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	18.3%	12.0%	14.4%	11.6%	17.8%

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

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

*** See below for explanation of categories:

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

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

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

October 17, 2024

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
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 will be made and presented at the next meeting
	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 will be made and presented at the next meeting
	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)	• he 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 Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products Proposed addendum to Zurzuvae (zuranolone) protocol	• The Board recommended the addendum to the protocol • 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 • 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 Updated information was presented at the next meeting
January 2024	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitor products Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products Proposed update to the protocol for Synagis (palivizumab) Proposed addendum to the protocol for Lumizyme (alglucosidase alfa) for Pompe disease Proposed protocol for Zurzuvae (zuranolone)	• The Board recommended the protocol • The Board recommended the protocol with suggested changes to criterion #3 for initial approval and criterion #4 for subsequent requests. • The Board recommended the protocol • The Board recommended the protocol • 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 Updated information was presented at the next meeting
October 2023	Proposed addendum to biologic receptor modifiers (BRMs) protocol for plaque psoriasis Proposed protocol for Kanuma (sebelipase alfa)	• The Board recommended the protocol • The Board recommended the protocol	

	Proposed protocol for Vyjuvek (beremagene geperpavec) Proposed addendum to Duchenne muscular dystrophy products protocol	• The Board recommended the protocol with suggested changes to criterion #5 • The Board recommended the protocol with suggested changes to criteria # 2, 6 and 10	The updated information was presented at the next meeting The updated information was presented at the next meeting