NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

January 24, 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 October 18, 2023, meeting

IV. Review of draft meeting summary for October 18, 2023, meeting (pages 3-6)

V. Secretary's report (page 7)

VI. Old Business
- A. Calcitonin gene-related peptide (CGRP) inhibitors utilization report (2022 vs. 2023) [page 8]
- B. Updated Duchenne Muscular Dystrophy protocol
- C. Updated Vyjuvek protocol

VII. New Business
- A. Proposed addendum to the protocol for CGRP inhibitors (pages 9-12)
- B. Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9) [pages 13-18]
- C. Proposed update to the protocol for Synagis (palivizumab) [pages 19-21]
- D. Proposed addendum to the protocol for Lumizyme® (alglucosidase alfa) [Pompe disease] (pages 22-24)
- E. Proposed Protocol for Zurzuvae® (zuranolone) [page 25]

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 3rd Quarter 2023 Prior Authorization Report (page 26)
2. Summary of DURB Action Items (pages 27-28)
3. (a) DHS, DHSS and MCO Programs Top Drugs Report/Physicians Administered Drugs (by amount paid and by category)
   (b) Antiviral drugs by amount paid

IX. Medication information:

1. Benefits of Prior Authorizations
   https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10391030/

2. Poison control centers see surge in calls about weight-loss drugs
   https://www.beckershospitalreview.com/pharmacy/poison-control-centers-see-surge-in-calls-about-weight-loss-drugs.html

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3. Longer Use of ADHD Meds May Boost Heart Risk
https://www.medpagetoday.com/psychiatry/adhd-add/107525?xid=nl_mpt_morningbreak2023-11-27&eun=g2076570d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=MorningBreak_112723&utm_term=NL_Gen_Int_Daily_News_Update_active

4. Burnout, Poor Mental Health on the Rise for Healthcare Workers, CDC Says
https://www.medpagetoday.com/publichealthpolicy/workforce/106984

5. High Blood Pressure in Babies Linked to Adult Atherosclerosis
https://www.medpagetoday.com/cardiology/prevention/107658

6. How Much Pain Is 'Enough' to Prescribe Opioids?
https://www.medpagetoday.com/opinion/second-opinions/107676?xid=nl_secondopinion_2023-12-10&eun=g2076570d0r\

7. Reimbursement to Pharmacists for Generic Drugs by Medicare Part D Sponsors
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2024/Reimbursement_to_pharmacies_for_generic_drugs_by_Medicare_Part_D_sponsors.pdf

8. 2024 Medicare Part D Stand-Alone Prescription Drug Plans in New Jersey
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/1-2024/2024_Medicare_Part_D_Stand-Alone_Prescription_Drug_Plans_NJ.pdf

October 18, 2023 DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend: Dr. Moynihan, Ms. Olson, 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 meetings: 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, the Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from July 19, 2023, 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 Department is working with the Commissioners to sign off on DURB recommended protocols for, January 2023, and April 2023, and July 2023. - The DHS Commissioner's office is reviewing the recommended changes for the reappointment and replacement of DURB members. - The proposed dates for 2024 DURB meetings was presented and are as follows: Wednesday, January 24, 2024 Wednesday, April 17, 2024 Wednesday, July 17, 2024 Wednesday, October 16, 2024 Board members did not have any objections to these dates.
Old Business		
(A) Proposed addendum to Biologic Receptor Modifiers (BRMs) for plaque psoriasis protocol W	Approved	The Board reviewed a proposed addendum to the BRMs for plaque psoriasis protocol. For the record and consistency, Dr. Emenike informed the Board about two changes not shown on the addendum: a. At the suggestion of Dr. McMahon, a dermatologist who reviewed the protocol, methotrexate and cyclosporine were removed from criterion #5 as required conventional treatment to try prior to BRMs

Issue	Action	Notes
(B) Risk Evaluation and Mitigation Strategy (REMS) program in institutions		b. American Academy of Dermatology's recommendation for the use of topical steroids as first line therapy was inserted as part of criterion #5. The Board recommended approval of the protocol. As a follow up to a question at the July meeting, Mr. Vaccaro explained the application of the REMS program in a hospital or institutional setting. Dr. Gochfeld also explained her personal experience with the REMS program when prescribing clozapine (Clozaril®), a medication used for schizophrenia.
New Business		
(A) Proposed protocol for Kanuma (sebelipase)	Approved	The Board reviewed a proposed protocol for Kanuma, a product indicated for the treatment of patients with lysosomal acid-lipase deficiency (LAL-D). The Board recommended approval of the protocol.
(B) Proposed protocol for Vyjuvek (beremagene geperpavec)	Approved	The Board reviewed a proposed protocol for Vyjuvek, a product indicated for the treatment of dystrophic epidermolysis bullosa (DEB). Dr. Marcus raised concern about the difficulty of finding a dermatologist that specialize in DEB as specified in criterion #5. Dr. Swee was equally concerned about restricting treatment to just dermatologists and suggested "a physician specializing in the treatment of DEB." Dr. Daniel, with Krystal Biotech, the manufacturer of Vyjuvek informed the Board that although the patients had multiple problems that involved other specialties, the primary care for the condition is given by dermatologists. The Board resolved to change criterion #5 to read: medication is prescribed by or in consultation with a dermatologist. The Board recommended approval of the protocol pending update of this section in the final copy.
(C) Proposed addendum for Duchenne Muscular Dystrophy protocol	Approved	The Board reviewed a proposed addendum for Duchenne Muscular Dystrophy products protocol. Dr. Swee enquired about criteria #10 which excluded the use of Elevidys with other exon-skipping therapies (Exondys 51, Vyondys 53, Viltepso, and Amondys 45). Dr. Basoff, with Sarepta Therapeutics explained that these products can be used prior to gene therapy, with Elevidys, if they are eligible but has to be discontinued prior to. Dr. Marcus asked if there is any detriment to using either

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>product together. Dr. Basoff responded that there has been no studies of concomitant use in humans. He also requested a change to criterion # 2d. After a protracted discussion, Dr. Swee, in the interest of time, invited Dr. Lind to share his thoughts about the suggested changes with him and they will send their final verbiage to the Secretary to update the protocol. Ms. Kimberly Powers a public attendee gave a testimony to the Board about her son's positive experience with gene therapy.
The Board recommended approval of the protocol pending changes to criteria #2, 6, and 10.</td></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report

2. Summary of DURB Actions/Recommendations</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 2023 are shown below.
<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th><th>% w/o NF*</th></tr>
<tr><td>FFS</td><td>0.7</td><td>7</td><td>7</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>39</td><td>9</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>40</td><td>16</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>36</td><td>13</td></tr>
<tr><td>UHC</td><td>1</td><td>48</td><td>17</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>35</td><td>8</td></tr>
</table>
NF = Non formulary
Dr. Swee expressed concern over United Healthcare (UHC) and Amerigroup's high denial rates. The Board will continue to look for explanations.
Dr. Marcus commented on the high denial rate (21.9%) for FFS on the ulcer drugs/antispasmodics/anticholinergic category. He wondered if it was recorded incorrectly. Dr. Emenike promised that the MEP department will look at the numbers again.

The Board reviewed a summary of their actions from previous meetings (October 2022 thru July 2023).
There were no comments.</td></tr>
</table>

October 18, 2023 DURB Meeting Summary (draft)

<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 May 2023 (FFS) and April 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>August 2023</td><td>$13,459,511</td><td>$13,847,607</td></tr><tr><td>MCOs</td><td>July 2023</td><td>$118,177,244</td><td>$163,723,951</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. Opioid National Drug Code and Oral MME Conversion File Update
2. Long COVID Symptoms May Emerge Months After Infection
3. Dementia Risk Linked With Cumulative Heartburn Med Use, Analysis Suggests
4. Poorer Neighborhoods Linked to Higher Asthma Rates in Kids
5. Certain SSRIs May Increase Arrhythmia Risk in Select Patients
Dr. Swee commented that he does not know why some of these subjects are making news now since they are nothing new.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>None</td></tr>
</table>

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

January 24, 2024

Secretary's Report:

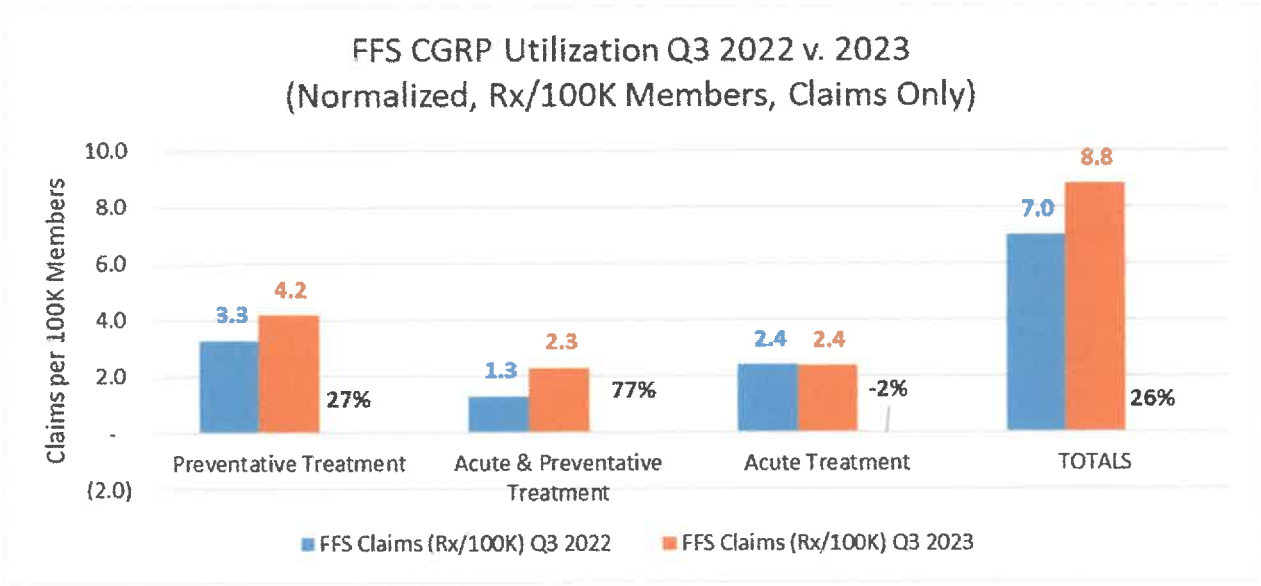
1. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - January 2023
   - April 2023
   - July 2023
   - October 2023

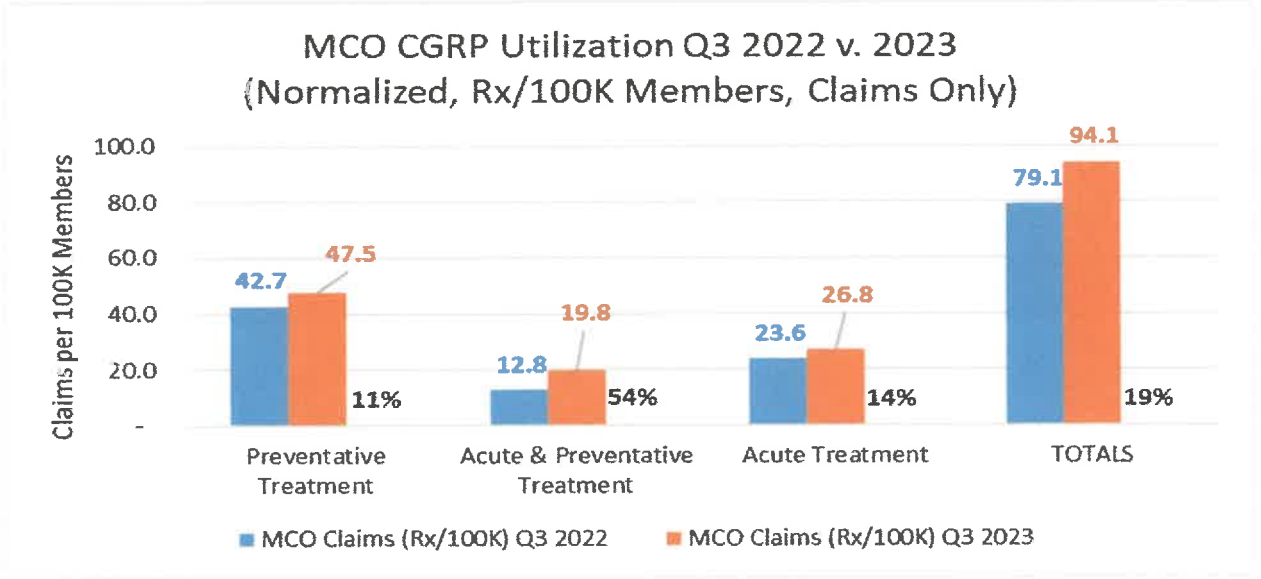
2. The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members

At the last meeting, the Board requested a follow-up report on the utilization of CGRP inhibitors. Below is the report comparing 3rd quarter of 2022 and 3rd quarter of 2023.

Calcitonin Gene-Related Peptide (CGRP) Inhibitors Utilization Report (as of 12-18-23)

January 2024





Proposed Addendum to Protocol for Calcitonin Gene-Related Peptide (CGRP) Antagonists for The Treatment of Migraines

January 2024

Approved April 2019
Updated October 2020
Updated October 2022

Addendum:
Addition of Zavzpret® (zavegepant) nasal spray. Approved by the FDA on 3.10.23

Aimovig® (erenumab)
Ajovy® (fremanezumab)
Emgality® (galcanezumab)
Vyepti® (eptinezumab)
Nurtec ODT® (rimegepant)
Qulipta® (atogepant)
Ubrelvy® (ubrogepant)
Zavzpret® (zavegepant)

Background:
Calcitonin gene-related peptide (CGRP) is a neuropeptide believed to be directly involved in the pathophysiologic processes underlying migraine. CGRP antagonists for prevention of episodic and chronic migraine have provided another treatment option for migraine patients. Although comparative studies between traditional prophylaxis treatments are not available, treatment with these products have been shown to be efficacious. However, the long-term effects, particularly regarding the cardiovascular risks, are still unknown as well as the exact mode of action of the antibodies.

Criteria for approval:

1. Patient is 18 years of age or older; **AND**

2. 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; **AND**

3. Medication-Overuse Headaches (MOH, aka: drug-induced headache, medication-misuse headache, rebound headache) have been evaluated and addressed as follows (a and b):
    a. Patient has been evaluated for MOHs, defined as having 15 or more headache days per month in a patient who regularly overuses drugs (i and/or ii):
        i. Use of non-opioid analgesic (e.g., acetaminophen, non-steroidal anti-inflammatory drug [NSAID], acetylsalicylic acid] for 15 or more days per month for more than 3 months
        ii. Use of any other drugs for acute/symptomatic treatment of headaches for 10 or more days per month for more than 3 months
    b. For patients with MOH, the patient continues to have migraines despite discontinuing the overuse of drugs taken for acute and/or symptomatic treatment of headaches

Chronic Migraine (Aimovig, Emgality, Ajovy, Vyepti, Qulipta):

- Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months

Episodic Migraine (Aimovig, Emgality, Ajovy, Vyepti, Nurtec ODT, Qulipta):

- Headache occurring less than 15 days per month with at least 4 migraine days per month

- For chronic and episodic migraines, there is documented inadequate response, or intolerable side effects to at least 2 quarterly injections (6 months) of OnabotulinumtoxinA (for chronic migraines only) OR to at least two medications for migraine prophylaxis from two different classes, for at least 2 months:
  - Beta-Blockers (e.g., propranolol, metoprolol, atenolol, timolol, nadolol)
  - Anticonvulsants (e.g., valproic acid, or divalproex, topiramate)
  - Tricyclic Antidepressants (e.g., amitriptyline, nortriptyline)
  - Serotonin-norepinephrine reuptake inhibitors (venlafaxine, duloxetine)
  - Other Level A or B treatments (established efficacy or probably effective) according to AAN scheme for classification of evidence): Candesartan, Lisinopril, Memantine

- Medication will not be used in combination with another biologic CGRP antagonist or inhibitor used for prevention of migraines

Acute Migraine (Ubrelvy, Nurtec ODT, Zavzpret):

- Medication is for moderate or severe pain intensity
- Documented inadequate response, or intolerable side effect, with at least two triptans, or patient has a contraindication to triptan use
- Medication will not be used in combination with another biologic CGRP antagonist or inhibitor used for treatment of acute migraines

Ubrelvy:

a. Patient will not be treated for more than 8 migraine days in a 30-day period
b. Patient is not concomitantly taking a strong CYP3A4 inhibitor (e.g., clarithromycin, ketoconazole)

Nurtec ODT:

Patient will not be using more than 18 doses in a 30-day period.

Zavzpret:

Patient will not be treated for more than 8 migraine days in a 30-day period

Episodic Cluster Headaches: (Emgality)

- Headaches occurring at maximum 8 attacks per day, or minimum one attack every other day
- Trial and failure with verapamil for preventive treatment or sumatriptan (nasal or subcutaneous) for acute treatment

Continuation of therapy:

1. Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

2. For migraine prevention: Medication will not be used in combination with another biologic CGRP antagonist or inhibitor for migraine prevention

3. For acute migraine treatment:
    a. Medication will not be used in combination with another biologic CGRP antagonist or inhibitor used for treatment of acute migraines

    Ubrelvy:
    Patient will not be treated for more than 8 migraine days in a 30-day period

    Nurtec ODT:
    Patient will not be using more than 18 doses in a 30-day period.

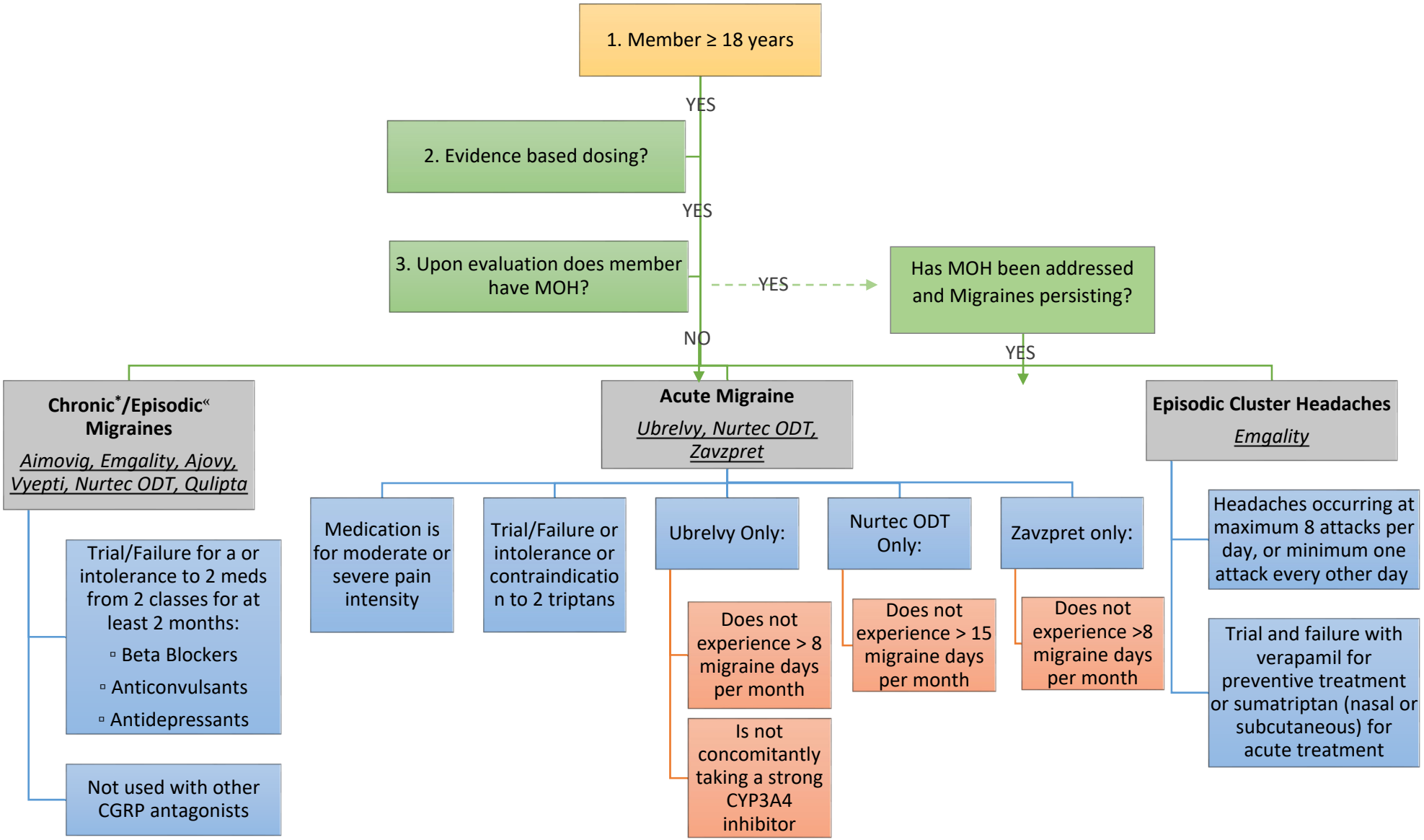
    Zavzpret:
    Patient will not be treated for more than 8 migraine days in a 30-day period

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. Aimovig® [package insert]. Amgen Inc. Thousand Oaks, CA 91320. May 2018.
2. Ajovy® [package insert]. Teva Pharmaceuticals USA, Inc. North Wales, PA 19454. September 2018.
3. Emgality® [package insert]. Eli Lilly and Company. Indianapolis, IN 46285. September 2018.
4. Vyepti® [package insert]. Lundbeck Seattle Biopharmaceuticals, Inc. WA 98011. February 2020.
5. Ubrelvy™ [package Insert]. Allergan USA, Inc. Madison, NJ: December 2019.
6. Nurtec™ ODT [package Insert]. Biohaven Pharmaceuticals, Inc. New Haven, CT May 2021.
7. Qulipta® [package insert]. Forest Laboratories Ireland Ltd. Dublin, Ireland. September 2021
8. Zavzpret® [package insert]. Pfizer Labs. Division of Pfizer Inc. New York, NY 10001. March 2023
9. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
10. Giamberardino MA, Affaitati G, Costantini R et al. Calcitonin gene-related peptide receptor as a novel target for the management of people with episodic migraine: current evidence and safety profile of erenumab. J Pain Res. 2017 Dec 8;10:2751-2760
11. Estemalik E, Tepper S. Preventive treatment in migraine and the new US guidelines. Neuropsychiatric Dis Treat. 2013;9:709–720.
12. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18. Available at: https://headachejournal.onlinelibrary.wiley.com/doi/10.1111/head.13456
13. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. Available at: https://www.ichd-3.org/

Protocol for Calcitonin Gene-Related Peptide (CGRP) Antagonists for the Treatment of Migraines



Continuation of therapy:

1. Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
2. Medication is prescribed according to labeling, clinical guidelines or is evidence based

*Chronic Migraine defined as Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months
« Episodic Migraine defined as Headache occurring less than 15 days per month with 4 to 14 migraine days per month

Protocol for the Safe and Efficient Use of PCSK9 (proprotein convertase subtilisin kexin type 9) Modifiers

January 2024

Approved January 2016
Updated July 2020
Updated January 2022

Addendum:

1. Add a 2022 American College of Cardiology (ACC) expert consensus decision pathway (ECDP) recommended LDL-C threshold for ASCVD patients who are at very high risk for subsequent cardiovascular event
2. Add Leqvio® (inclisiran)
3. Change protocol name to "Protocol for the Safe and Efficient Use of PCSK9 (proprotein convertase subtilisin kexin type 9) Modifiers"

Praluent® (alirocumab) is a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor antibody indicated:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease; OR
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Repatha® (evolocumab) is a PCSK9 inhibitor antibody indicated:

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; OR
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C; OR.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

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Leqvio® (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated:

- As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LDL-C); OR
- As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

Criteria for Approval:

1. Recent laboratory documentation of LDL must be received and must meet one of the following:
    a. LDL-C ≥ 70 mg/dL for documented ASCVD (Must receive documentation of ASCVD as noted under section C below)
    b. LDL-C ≥ 100 mg/dL for familial hypercholesterolemia without documented ASCVD
    c. LDL-C ≥ 55 mg/dL for established ASCVD at the highest risk of a subsequent cardiovascular (CV) event. Highest risk is defined as:
        i. Having suffered 2 major adverse cardiovascular events (MACE), e.g., AMI, unstable angina, HF); **OR**
        ii. Having suffered 1 major cardiovascular with at least 2 of the following high-risk conditions present (age >65 years; familial hypercholesterolemia; history of CABG or PCI outside of the major CV event; diabetes; congestive heart failure; hypertension, CKD defined as eGFR 15-59 ml/min; current smoking; elevated LDL-C >100mg/dL despite maximally tolerated statin)
2. Patient must not be receiving another PCSK9 modifier
3. Patient is not pregnant
4. Medication will be administered by a healthcare professional (Leqvio only)
5. Patient must have a confirmed diagnosis of **one** of the following:

    A. **Homozygous familial hypercholesterolemia (HoFH)**
        a. Patient is 18 years of age or older for Praluent or 10 years of age or older for Repatha; **AND**
        b. The patient must not be receiving lomitapide (Juxtapid®) or mipomersen (Kynamro®) **AND**
        c. For a patient with a diagnosis of HoFH without ASCVD and who has a documented contraindication/intolerance to ezetimibe AND statin therapy, the patient must be using Evolocumab (Repatha) together with another LDL-C lowering therapy (e.g., LDL apheresis).
        d. Documentation (medical records, patient's chart) of genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or ARH adaptor protein 1/LDLRAP1 gene locus OR
        e. Untreated LDL-C >500 mg/dL or treated LDL-C ≥300 mg/dL with ONE of the following:
            (i) Cutaneous or tendon xanthoma before age 10 **OR**

(ii) Untreated LDL-C levels consistent with heterozygous FH in both parents (untreated total cholesterol >290 mg/dL or untreated LDL-C >190 mg/dL; **OR**

B. **Primary Hyperlipidemia, including Heterozygous familial hypercholesterolemia (HeFH)**
   a. Patient is 18 years of age or older for Praluent or Leqvio; OR 10 years of age or older for Repatha; **AND**
   b. Patient has diagnosis of HeFH confirmed by one of the following:
      (i) Genetic testing showing a LDL-receptor mutation, familiar defective Apo-B-100, or a PCSK9 mutation **OR**
      (ii) Pretreatment (prior to any hypercholesterolemia therapy) or highest level on treatment total cholesterol >290 mg/dL (>7.5 mmol/L) AND Tendon xanthomas in patient, patient's first degree relative, or patient's second-degree relative **OR**
      (iii) Pretreatment (prior to any hypercholesterolemia therapy) or highest level on treatment LDL-C >190 mg/dL (>4.9 mmol/L) AND Tendon xanthomas in patient, patient's first degree relative, or patient's second degree relative **OR**
      (iv) Patient meets definite FH as determined using the Dutch Lipid Clinic Network criteria by a score of greater than 8 (see table 1); **OR**

C. **Clinical atherosclerotic cardiovascular disease (ASCVD)**
   a. Patient is 18 years of age or older
   b. Patient has a history of ASCVD or cardiovascular event
      (i) Provide documentation (medical records, patient's chart) of the condition/event
      (ii) ASCVD is defined as a diagnosis of ONE of the following:
         1. Acute coronary syndrome
         2. History of myocardial infarction (MI)
         3. History of Stable or unstable angina
         4. History of Coronary or other arterial revascularization (e.g., PTCA, CABG)
         5. History of Stroke
         6. History of Transient ischemic attack (TIA)
         7. Peripheral arterial disease presumed to be of atherosclerotic origin
         8. Findings from CT angiogram or catheterization are consistent with clinical ASCVD; OR
         9. Other documented atherosclerotic diseases such as:
            a. coronary atherosclerosis
            b. renal atherosclerosis
            c. aortic aneurysm secondary to atherosclerosis
            d. carotid plaque (≥ 50% stenosis)

7. The prescriber must plan to continue prescribing ezetimibe (unless the patient has a documented contraindication or intolerance to ezetimibe therapy) and a maximally tolerated statin (unless the patient has a documented contraindication or intolerance to statin therapy) together with the requested PCSK-9 inhibitor.
8. The patient must meet one of the following for ezetimibe (a or b):

a. Patient is currently on ezetimibe AND has documented adherence to ezetimibe for at least the past 90 continuous days (dates and length of therapy must be provided) **OR**
b. The patient has a documented contraindication or intolerance to ezetimibe therapy

9. Patient has documented adherence to maximally tolerated statins for a combined total of at least the past 90 continuous days **OR**
   a. Documentation that the patient was not able to tolerate a high-intensity statin, but used a high-intensity statin and decreased the daily dose of statin OR trial of two lower intensity statins
10. 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

Initial Approval: Six months

Criteria for Reauthorization:

1. The patient must not be receiving more than one PCSK-9 modifier.
2. For homozygous familial hypercholesterolemia, the patient must not be concurrently receiving lomitapide (Juxtapid) or mipomersen (Kynamro).
3. The patient must not be pregnant.
4. The patient has been adherent to and must plan to continue using PCSK-9 inhibitor, maximally tolerated statin, and ezetimibe therapy (unless patient has a contraindication or intolerant to statin and/or ezetimibe therapy) for the past 90 continuous days with documentation provided AND demonstrated by the following:

   Subsequent Requests: The patient has experienced at least a 35%* reduction in LDL-C compared to the initial request (laboratory documentation of LDL-C must be received from within the past 30 days).

   Will be approved for 1 year if patient meets criteria

   ** If the patient has HeFH with a baseline LDL-C ≥ 160 mg/dl, patient has experienced at least a 24% reduction in LDL-C compared to the initial request.*

5. For a patient with a diagnosis of HoFH without ASCVD and who has a documented contraindication/intolerance to
6. ezetimibe AND statin therapy, the patient must be using Evolocumab (Repatha) together with another LDL-C lowering therapy (e.g., LDL apheresis).
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

Table 1. Dutch Lipid Clinic Network Diagnostic criteria**

Criteria	Points
Family History	
1st degree relative with known premature* coronary and vascular disease, OR 1st degree relative with known LDL-C level above the 95th percentile	1
1st degree relative with tendinous xanthomata and/or arcus cornealis, OR Children aged <18 years old with LDL-C level above the 95th percentile	2
Clinical History	
Patient with premature* coronary artery disease	2
Patient with premature* cerebral or peripheral vascular disease	1
Physical examination	
Tendinous xanthomata	6
Arcus cornealis prior to age 45 years	4
Cholesterol levels mg/dL (mmol/liter)	
LDL-C ≥ 330 mg/dL (≥ 8.5 mmol/L)	8
LDL-C 250-329 mg/dL (6.5-8.4 mmol/L)	5
LDL-C 190-249 mg/dL (5.0-6.4 mmol/L)	3
LDL-C 155-189 mg/dL (4.0-4.9 mmol/L)	1
DNA analysis	
Functional mutation in the LDLR, apo B, or PCSK9 gene	8

8. *Premature: < 55 years in men; < 60 years in women
9. ** Definite diagnosis based on score of >8.

References:

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2. Repatha. Prescribing Information. Amgen. Thousand Oaks, CA. 9/2021.
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Proposed Update to Synagis (palivizumab) Protocol

January 2024

Background:

Respiratory syncytial or RSV, is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious. Infants and older adults are more likely to develop severe RSV and need hospitalization.

Synagis (palivizumab) is a respiratory syncytial virus F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients

Synagis is authorized during New Jersey's RSV season (November 1 through April 30). Approvals can begin as early as October 15. Consideration will be given outside this window with adequate medical reasons.

Updates includes expanded eligibility for 4 classes of patients, and exclusion for Beyfortus.

1. Impaired ability to clear secretions
2. Cystic fibrosis
3. Severe immunodeficiencies
4. Cardiac transplant

Criteria for approval:

A. Prematurity

i. Patient is < 12 months of age at the start of the RSV season with a gestational age < 29 weeks, 0 days

B. Chronic Lung Disease of prematurity

i. Patient is < 12 months of age at the start of the RSV season and has all of the following:
   a. Diagnosis of CLD; AND
   b. Gestational age < 32 weeks, 0 days; AND
   c. Required greater than 21-percent oxygen for at least the first 28 days after birth; OR

ii. Patient is < 24 months of age at the start of the RSV season and has all of the following:
   a. Diagnosis of CLD; AND
   b. Gestational age < 32 weeks, 0 days; AND
   c. Required greater than 21-percent oxygen for at least the first 28 days after birth; AND
   d. Required medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 months period before the start of the current RSV season

C. Hemodynamically Significant Congenital Heart Disease (CHD)

i. Patient is < 12 months of age at the start of the RSV season and has all of the following:
   a. Diagnosis of hemodynamically significant CHD including the following:
      a. Infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
      b. Infants with moderate to severe pulmonary hypertension

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D. **Impaired ability to clear secretions**
   a. Patient is < 12 months of age at the start of the RSV season and has either congenital abnormalities of the airway or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough

E. **Cystic fibrosis**
   a. Patients is < 12 months of age at the start of the RSV season and meets the following:
      i. Clinical evidence of Chronic lung disease (CLD) **AND/OR**
      ii. Nutritional compromise (defined as weight is at or below the 10th percentile based on growth charts)
   b. Patients is < 24 months of age at the start of the RSV season and meets the following:
      i. Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) **OR**
      ii. Nutritional compromise (defined as weight is at or below the 10th percentile based on growth charts)

F. **Severe Immunodeficiencies**
   a. Patient is < 24 months of age at the start of the RSV season and has severe immunodeficiencies (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, receiving chemotherapy) during the RSV season.

G. **Cardiac Transplant**
   a. Patient is < 24 months of age at the start of the RSV season and has cardiac transplantation during the RSV season

Exclusions

a. Patient has not received Beyfortus (nirsevimab) in the current RSV season
b. Patient must not have experienced breakthrough RSV hospitalization during the current RSV season

References:

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Proposed Addendum to Protocol for Pompe Disease Products

January 2024

Approved July 2021

Lumizyme® (alglucosidase alfa)
Nexviazyme® (avalglucosidase alfa)
Pombiliti® (cipaglucosidase alfa-atga + **Opfolda®** (miglustat)

Addendum:

1. Add Nexviazyme® (avalglucosidase alfa)
2. Add new product for the treatment of late-onset Pompe disease [Pombiliti® (cipaglucosidase alfa-atga + Opfolda® (miglustat)]
3. Rename protocol to "Pompe disease products protocol"

Background:
Pompe disease is a rare, autosomal recessive disorder caused by deficiency of the glycogen-degrading lysosomal enzyme, acid alpha-glucosidase (GAA). Late-onset Pompe disease is a multisystem condition, with a heterogeneous clinical presentation that mimics other neuromuscular disorders.

Lumizyme *(alglucosidase alfa) is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease or GAA deficiency.*

Pombiliti *(cipaglucosidase alfa-atga) is a hydrolytic lysosomal glycogen-specific enzyme indicated, in combination with Opfolda, an enzyme stabilizer, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT), e.g., improvement in % predicted forced vital capacity (FVC) in the sitting position, change in 6-minute walk test (6MWT), etc.*

Opfolda *(miglustat) is an enzyme stabilizer indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy, e.g., improvement in % predicted forced vital capacity (FVC) in the sitting position, change, in 6-minute walk test (6MWT), etc.*
etc.

Nexviazyme *(avalglucosidase alfa) is a hydrolytic lysosomal glycogen-specific enzyme indicated for the treatment of patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).*

Criteria for approval:

A. **For Nexviazyme/Pombiliti + Opfolda**

1. Patient meets the minimum age per drug labeling:
   a. Nexviazyme: Patient is 1 year old or older
   b. Pombiliti + Opfolda: Patient is 18 years old or older

2. Patient has a diagnosis of late-onset Pompe disease as confirmed by ONE of the following:
   a. Absence or deficiency (< 40% of the lab specific normal mean) acid alpha-glucosidase deficiency activity in fibroblasts, lymphocytes, or muscle; **OR**

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b. Increased lysosomal glycogen; **OR**
c. Molecular genetic testing for deletion or mutation in the GAA gene; **OR**
d. Confirmation of positive GAA activity assay in dry blood spots (DBS)

3. For Pombiliti + Opfolda:
   a. Pombiliti is given in combination with Opfolda
   b. Patient is not pregnant

B. **Lumizyme**

1. Patient has a diagnosis of infantile-onset Pompe disease as confirmed by ONE of the following:
   a. Absence or deficiency (< 1% of the lab specific normal mean) acid alpha-glucosidase deficiency activity in fibroblasts, lymphocytes, or muscle; **OR**
   b. Increased lysosomal glycogen; **OR**
   c. Molecular genetic testing for deletion or mutation in the GAA gene; **OR**
   d. Confirmation of positive GAA activity assay in dry blood spots (DBS)

2. Patient has a diagnosis of late-onset (non-infantile) Pompe disease as confirmed by ONE of the following:
   a. Absence or deficiency (< 40% of the lab specific normal mean) GAA activity in lymphocytes, fibroblasts, or muscle; **OR**
   b. Increased lysosomal glycogen; **OR**
   c. Molecular genetic testing for deletion or mutation in the GAA gene; **OR**
   d. Confirmation of positive GAA activity assay in dry blood spots (DBS); **AND**
3. Patient will not receive Lumizyme with either Nexviazyme or Pombiliti + Opfolda

4. Patient has no evidence of cardiac hypertrophy

C. Medication is prescribed by or in consultation with a geneticist, metabolic disorders specialist, or an expert in the disease state

D. Patient's weight must be provided and have been taken within the last four weeks to ensure accurate dosing

E. Patient does not have any contraindication(s) to the requested medication

F. 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. Patient has experienced a positive clinical response to therapy (e.g., improved cardiac/respiratory function etc.)

2. For Pombiliti + Opfolda: Pombiliti continues to be prescribed in combination with Opfolda

3. For dose increase requests, weight must be received

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

Note: Lumizyme, Pombiliti, and Nexviazyme have Black Box warnings for risk of anaphylaxis, hypersensitivity, and cardiorespiratory failure.

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1. Lumizyme [Product information]. Genzyme Corporation . Cambridge MA 02142. 2/2020
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3. Opfolda [packet insert]. Amicus Therapeutics US, LLC. Philadelphia, PA 19104. September 2023
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Proposed Protocol for Zurzuvae® (zuranolone)

January 2024

***Zurzuvae** is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults.*

Criteria for approval:

1. Patient is 18 of age or older; **AND**
2. Patient has a diagnosis of postpartum depression with onset during pregnancy or within 4 weeks postpartum; **AND**
3. Patient is ≤ 12 months postpartum; **AND**
4. Medication is prescribed by or in consultation with a psychiatrist, OB/GYN, pediatrician, or primary care provider; **AND**
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, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient has previously completed a 14-day course of Zurzuvae
2. Medication is prescribed by or in consultation with a psychiatrist or OB/GYN
3. Prescriber attests that an additional course of Zurzuvae is needed – the initial treatment course did not adequately resolve patients PPD symptoms
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. Zurzuvae [prescribing information]. Biogen Inc. Cambridge, MA. 02142 August 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Viguera A. Postpartum unipolar major depression: Epidemiology, clinical features, assessment, and diagnosis. In: UpToDate April 2023. Payne J, Lockwood CJ (Eds). Wolters Kluwer. (Accessed on December 8, 2023)
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NJ DURB Prior Authorization Denial Report - 3rd Quarter 2023 (July - September)

	FFS	Aetna	Amerigroup	Fidelis	Horizon	UHC
Total # of Enrolled Beneficiaries	**66,754**	**141,710**	**247,548**	**114,194**	**1,233,944**	**424,279**
Total # of Pharmacy Claims Processed	**394,978**	**536,445**	**1,127,608**	**413,369**	**3,666,723**	**1,009,146**
Total # of Members Requesting Prior Authorization*	**1,194**	**3,346**	**6,667**	**2,572**	**24,317**	**7,361**
Total Prior Authorizations Requests Received**	**3,076 (0.8%)**	**4,719 (0.9%)**	**9,435 (0.8%)**	**3,910 (1.0%)**	**32,268 (0.9%)**	**9,609 (1.0%)**
Received Requests Denials	**71 (2%)**	**1,718 (36%)**	**3,553 (38%)**	**1,500 (38%)**	**10,365 (32%)**	**4,767 (50%)**
Without Non-formulary Denials	**71 (2%)**	**609 (13%)**	**1,451 (15%)**	**465 (12%)**	**3,821 (12%)**	**1,666 (17%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	67 (94%)	503 (29%)	1,166 (33%)	460 (31%)	3,607 (35%)	1,393 (29%)
Excluded Benefit	4 (6%)	106 (6%)	237 (7%)	5 (0%)	214 (2%)	273 (6%)
Non-formulary	0 (0%)	1,109 (65%)	2,102 (59%)	1,035 (69%)	6,544 (63%)	3,101 (65%)
Other	0 (0%)	0 (0%)	48 (1%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	18.3%	4.6%	3.5%	2.5%	2.9%	4.2%
Antidepressants		1.3%	1.5%	0.3%	1.5%	1.0%
Antihypertensives	1.4%	0.9%	0.6%	0.6%	0.6%	0.9%
Antianxiety		0.3%	0.1%	0.1%	0.2%	0.1%
Antidiabetics (oral and insulin)	8.5%	10.9%	12.8%	26.0%	27.0%	23.8%
Anticoagulants		0.0%		0.5%	0.1%	0.4%
Thyroid agents		0.1%	0.1%	0.1%	0.2%	0.4%
Ulcer Drugs/Antispasmodics/Anticholinergics	2.8%	2.8%	1.5%	1.1%	1.6%	2.1%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants		13.6%	6.1%	6.5%	3.4%	2.4%
Antipsychotic/Antimanic agents		1.2%	1.7%	1.5%	3.0%	1.6%
Antiasthmatic and Bronchodilator agents	12.7%	6.2%	2.9%	3.6%	6.1%	8.1%
Antivirals (includes both HIV and Hep C)		1.2%	0.6%	1.6%	0.4%	0.6%
Digestive Aids (Digestive Enzymes)		0.2%	0.1%	0.9%	0.1%	0.1%
Anticonvulsants		2.0%	0.8%	3.3%	1.5%	2.2%
Migraine Products	1.4%	4.0%	3.6%	3.3%	4.7%	4.4%
Analgesics Anti-inflammatory	12.7%	2.6%	2.7%	3.1%	2.0%	4.7%
Analgesic Opioids	2.8%	7.1%	6.9%	2.7%	1.7%	1.3%
Endocrine and Metabolic Agents-Misc (Growth Hormone)		1.5%	1.5%	1.5%	1.0%	1.1%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)		1.1%	0.8%	0.6%	1.1%	0.5%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)		0.1%	0.1%	0.1%	0.0%	0.1%
Dermatologics (Antipsoriatics-Systemic)		20.2%	18.2%	10.9%	13.1%	11.5%

* 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

January 24, 2024

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
October 2023	Proposed addendum to biologic receptor modifiers (BRMs) protocol for plaque psoriasis	- The Board recommended the protocol	
	Proposed protocol for Kanuma (sebelipase alfa)	- The Board recommended the protocol	
	Proposed protocol for Vyjuvek (beremagene geperpavec)	- The Board recommended the protocol with suggested changes to criterion #5	The updated protocol will be shared with the Board at the next meeting
	Proposed addendum to Duchenne muscular dystrophy products protocol	- The Board recommended the protocol with suggested changes to criteria # 2, 6 and 10	The updated protocol will be shared with the Board at the next meeting
July 2023	Proposed protocol for Chimeric Antigen Receptor T-cell (CAR T-cell) products	- The Board recommended the protocol	
	Proposed protocol for Qalsody (tofersen)	- The Board recommended the protocol	
	Proposed addendum to the biologic receptor modifiers (BRMs) protocol for plaque psoriasis	- The Board tabled the protocol pending consult with a dermatologist	
April 2023	Proposed protocol for Skysona® (elivaldogene autotemcel)	- The Board recommended the protocol	
	Proposed protocol for Zynteglo® (betibeglogene autotemcel)	- The Board recommended the protocol	
	Proposed protocol for Hemgenix® (etranacogene dezaparvovec)	- The Board recommended the protocol	
	Proposed protocol for Leqembi® (lecanemab-irmb)	- The Board recommended the protocol	
	Proposed protocol for Livmarli® (maralixibat)	- The Board recommended the protocol with a suggestion to change criterion #5 to read: Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease	The updated information was presented at the next meeting
January 2023	Addendum to Spinraza®/Zolgensma® protocols	- The Board recommended the protocol	
	Addendum to Imcivree® (setmelanotide) protocol	- The Board recommended the protocol	
	Addendum to Dupixent® protocol (atopic dermatitis)	- The Board recommended the protocol	

Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed protocol for Gattex® (teduglutide)	- The Board recommended the protocol with suggestion to remove the word "adult" in the background section.	The updated information was presented at the next meeting