NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

July 17, 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 April 17, 2024, meeting https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2024/DURB_April_2024_transcript.pdf

IV. Review of draft meeting summary for April 17, 2024, meeting (pages 3-10)

V. Secretary's report (page 11)

VI. Old Business
- A. MCO churn rate report (page 12)
- B. Updated Ingrezza protocol (pages 13-14)
- C. Updated Egrifta protocol (pages 15-16)
- D. Updated DAAs for HCV protocol (pages 17-18)
- E. Updated Zurzuvae protocol (page 19)

VII. New Business
- A. Proposed addendum to the protocol for Dupixent (dupilumab) (pages 20-23)
- B. Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors (pages 24-27)
- C. Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec) (pages 28-29)
- D. Proposed addendum to the protocol for Duchenne Muscular Dystrophy products (pages 30-34)
- E. Proposed protocol for Qelbree (viloxazine) (pages 35-36)
- F. Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE) (pages 37-38)

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ MCO 1st Quarter 2024 Prior Authorization Report (page 39)
2. Summary of DURB Action Items (pages 40-42)
3. (a) 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/7-2024/FFS_Top_Drugs_Report_Apr-2024.pdf

MCO Top Drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2024/MCO_Top_Drugs_Report_March-2024.pdf

FFS Top drugs by category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2024/FFS_Top_Drugs_by_Category_Apr-2024.pdf

MCO Top Drugs by Category:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2024/MCO_Top_Drugs_by_Category_March-2024.pdf

FFS Antiviral Drugs:
https://www.nj.gov/humanservices/dmahs/boards/durb/agendas/7-2024/FFS_Antiviral_Drugs_Apr-2024.pdf

B. Medication/Medical information

1. Obesity drugs could bankrupt US healthcare, says Sanders
https://pharmaphorum.com/news/obesity-drugs-could-bankrupt-us-healthcare-says-sanders

2. Cell and Gene Therapies: Excitement tempered by reality
https://medicaiddirectors.org/resource/cgt-excitement-and-reality/

3. Scientists Developing Vaccine Against Present and Future COVID Viruses
https://www.drugs.com/news/scientists-developing-vaccine-against-present-future-covid-viruses-119056.html?utm_source=ddc&utm_medium=email&utm_campaign=Daily+Mednews+++May+7++2024&utm_content=Scientists+Developing+Vaccine+Against+Present+and+Future+COVID+Viruses&hash2=2f2d27208920fb433cf3207028cab550

4. Narcan May Have Moved Over the Counter, but It's Still Underutilized
https://www.medpagetoday.com/opinion/toxicology-report/109915?xid=nl_mpt_DHE_2024-05-01&eun=g2076570d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=Daily%20Headlines%20Evening%202024-05-01&utm_term=NL_Daily_DHE_dual-gmail-definition

April 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. Dr. Swee introduced Dr. Jihad Slim, a new member of the Board with the following statement: Dr. Slim is an infectious disease specialist in Newark. He's currently affiliated with St. Michael's Medical Center, and he also oversees the fellowship program at Newark Beth Israel. He has experience treating conditions such as sexually transmitted diseases, hepatitis C, and HIV, among other conditions. He serves as the Medical Director for the New Jersey Department of Health, Division of HIV, STD, and TB Services, and is an ex-officio member of this Board. Welcome, Dr. Slim.
Review of Minutes	Approved	Minutes from January 24, 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

Issue	Action	Notes
Secretary's Report		- The Department is working with the Commissioners of Health (DOH and Human Services (DHS) to review and sign off on DURB-recommended protocols from July 2023 and January 2024 DURB meetings - The Commissioners have signed off on DURB-recommended protocols for, January 2023, and April 2023 meetings. - The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that no longer participate in the meetings. - The Board approved an educational newsletter, entitled "Morphine Milligram Equivalence, which was distributed in March 2024
Old Business		
(A) Synagis utilization report (CY2022 vs. CY2023)	Continue to monitor	The Board reviewed a utilization report for Synagis for the CY 2022 versus CY 2023. There were 463 unduplicated recipients and 1,554 claims for 2022 versus 368 unduplicated recipients and 1,159 claims for 2023. The Board concluded that although there was a slight decrease in utilization, it was still going in the right direction. The Board reviewed the updated version of the protocol for protein convertase subtilisin kexin type 9 (PCSK-9) modifiers. During review at the April meeting, the Board made a couple of suggestions: - Change criterion #3 to read "consider benefit versus risk for pregnant or nursing patients (was "patient is not pregnant")

Issue	Action	Notes
(B) Updated protein convertase subtilisin kexin type 9 modifiers protocol		- Change time period for subsequent lab requests from 30 to 90 days The Board recommended approval of the protocol with the changes.
New Business		
(A) Proposed protocol for Ingrezza® (valbenazine)	Recommended	The Board reviewed a proposed protocol for Ingrezza, a vesicular monoamine transporter 2 (VMAT2) inhibitor used for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease. - Ms. Olson suggested changing criterion A3 to read: medication is prescribed by or in consultation with a neurologist, psychiatrist, APN who is a specialist in the field for this disease state. - The Board suggested changing criterion B3 to read: Use with caution in patients with depression, agitation, or psychosis The Board recommended approval of the protocol with the suggested changes.
(B) Proposed protocol for Egrifta® (tesamorelin)	Recommended	The Board reviewed a proposed protocol for Egrifta, a growth hormone-releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. Dr. Swee had a concern about criterion 4c, documentation of waist circumference. Dr. Slim informed the Board that reduction in waist circumference was one of the primary endpoints during clinical trials but is not considered vital in real life

Issue	Action	Notes
		situations. Dr. Barberio also suggested that in her clinic, the prescribers focused on weight but not waist circumference. The Board decided to delete that criterion. The Board recommended approval of the protocol with the suggested change.
(C) Proposed addendum for spinal muscular dystrophy (SMA) products protocol	Recommended	The Board reviewed a proposed addendum for the protocol for SMA products. The addendum is the deletion of criterion #2 (patient has SMA types I, II, III). A neurologist had suggested that this is no longer applicable in modern practice. The other change was to alert prescribers that Spinraza will not be used concomitantly with either Evrysdi or Zolgensma. The Board recommended approval of the protocol.
(D) Proposed addendum to the protocol for DAAs for hepatitis C	Recommended	The Board reviewed a proposed addendum to the protocol for direct acting antiviral (DAA) hepatitis C drugs. The addendum included: 1. Removal of criterion # 6 which read: Initial quantity dispensed will be limited to 14 days dosage units (14-14-28-28 format) 2. Delete Viekira Pak (discontinued January 2019) 3. Restructure protocol to minimize barriers to access

Issue	Action	Notes
(E) Proposed protocol for Zurzuvae	Recommended	Dr. Swee inquired about the current cost of these products in comparison to their debut high cost in 2014. Dr. Emenike responded that they have come down some especially with the availability of the generics. The focus now is how to provide access to the multimillion-dollar products in the market. Dr. Slim suggested changing criterion #3 under treatment experienced patients to read: provide previous history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected. The Board recommended approval of the protocol with the suggested changes. The Board reviewed a proposed addendum to the protocol for Zurzuvae. The addendum was to remove the continuation of therapy section which, follow up research confirmed that the medication will only be given for 14 days. Dr. Marcus suggested to include a plan for follow-up after the scheduled treatment. Dr. Gochfeld agreed, saying that medication alone is never enough for depression. The Board agreed to change criterion #3 to read: medication is prescribed by or in consultation with an appropriate healthcare provider with planned follow up. The Board recommended approval of the protocol with the recommended change.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td></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 4th 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>0.8</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>0.8</td><td>42</td><td>17</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>38</td><td>17</td></tr>
<tr><td>Fidelis</td><td>1.1</td><td>33</td><td>9</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>32</td><td>11</td></tr>
<tr><td>UHC</td><td>0.9</td><td>49</td><td>17</td></tr>
</table>
NF = Non formulary

Note: WellCare is now Fidelis.</td></tr>
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<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>Dr. Swee expressed concern about the denial rates for the non-formulary products. Dr. Marcus also raised concern about the denials of antidiabetics. Dr. Emenike informed the Board that the denials may not necessarily be absolute because the MCOs have formularies (PDLs) and may have approved a similar agent down the road which may not have been captured in the present report. Dr. Swee suggested that for the next report, the antidiabetics be divided into non-formulary and formulary products.

The Board reviewed a summary of their actions from previous meetings (April 2023 thru January 2024).

Dr. Swee inquired about the lag time (9 months behind) in signing off of the DURB-recommended protocols by the Commissioners. Dr. Lind responded that the Commissioners have put in lots of effort in catching up, so we are making progress in that area.</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>January 2024</td><td>$4,314,569 *</td><td>$4,674,834 *</td></tr>
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</td></tr>
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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>MCOs</td><td>December 2023</td><td>$112,698,240</td><td>$ 159,204,807</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. Can a Common Diabetes Drug Turn Patients' Urine into Alcohol?

2. Measles' Deadliest Sequelae

3. Highly Potent Statin Stands Out for Diabetes, Cataract Risks</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Separate non-formulary antidiabetics from formulary antidiabetics in the next PA denials report
2. Dr. Marcus will send Dr. Emenike some concerns regarding changes in drug rankings from one meeting to the other for review and possible explanations</td></tr>
</table>

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

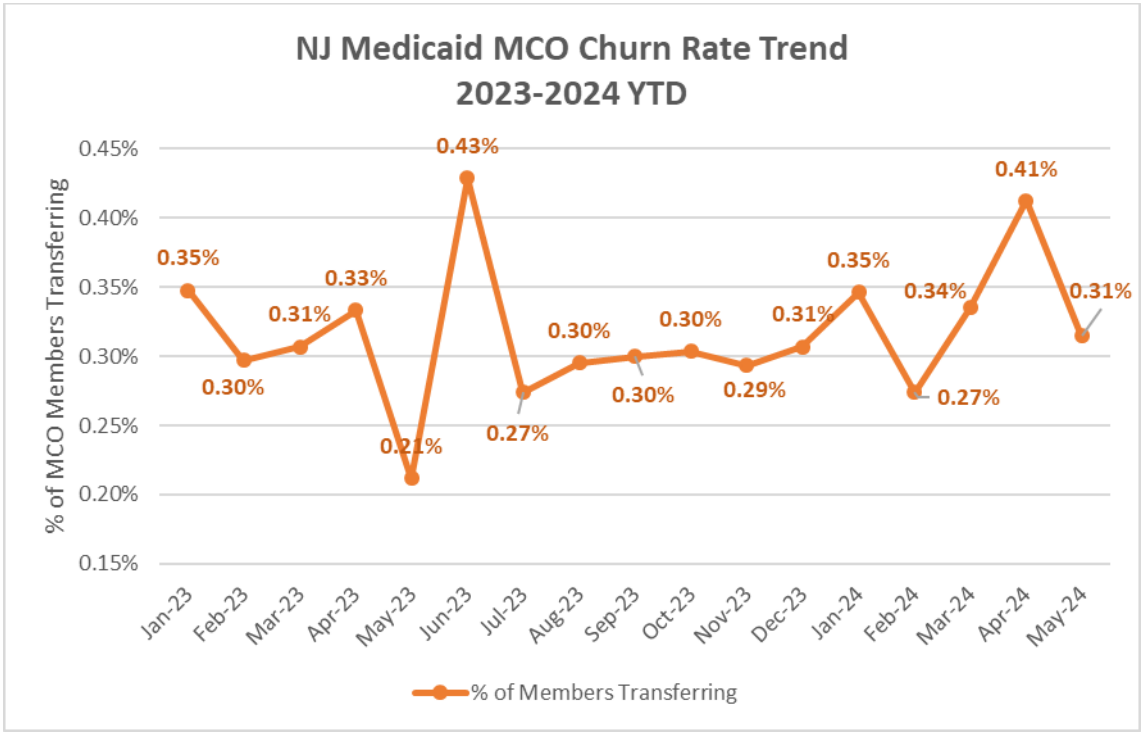
July 17, 2024

Secretary's Report:

1. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - July 2023
   - October 2023
   - January 2024
   - April 2024

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

MCO Churn Rate Report:



Protocol for Ingrezza® (valbenazine)

Approved April 2024

Ingrezza *is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia OR chorea associated with Huntington's disease.*

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

Chorea *is a neurological disorder characterized by spasmodic involuntary movements of the limbs or facial muscles.*

Criteria for approval:

A. Tardive dyskinesia:

1. Patient has a diagnosis of moderate to severe tardive dyskinesia (TD) confirmed by an Abnormal Movement Scale (AIMS) score of 3 or 4 on any one of the items 1 through 7

2. Diagnosis of TD with symptoms has been present for at least 4 to 8 weeks

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

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

OR

B. Chorea associated with Huntington's disease

1. Patient has a diagnosis of chorea associated with Huntington's disease that is disruptive to functioning

2. Huntington disease has been confirmed by genetic testing.

3. Use with caution in patients with depression, agitation, psychosis

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

Continuation of therapy:

1. Documentation of positive clinical response to therapy based in change in AIMS for TD

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

References:

1. Ingrezza [prescribing information]. Neurocrine Biosciences, Inc. San Diego, CA 92130. August 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Bhidayasiri R, Fahn S, et al. Evidence-based guideline: Treatment of tardive syndromes. Neurology; July 30, 2013:
   81 (5) 463-469. https://doi.org/10.1212/WNL.0b013e31829d86b6
4. Vasan S, Padhy RK. Tardive Dyskinesia. [Updated 2023 Apr 24]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448207/
5. Merical B, Sánchez-Manso JC. Chorea. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430923/

Protocol for Egrifta® (tesamorelin)

Approved April 2024

Egrifta *is a growth hormone-releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.*

Criteria for approval:

1. Patient has a diagnosis of HIV-associated lipodystrophy

2. Patient is currently receiving anti-retroviral therapy

3. Medication is prescribed by, or consultation with an infectious disease specialist, an HIV practitioner, or an endocrinologist

4. Documentation that the following baseline labs, information has been obtained within the last 30-day period and is available:
   a. Hemoglobin A1C
   b. Insulin-like Growth Factor-1 (IGF-1)
   ~~**c. waist circumference**~~

5. Patient has no contraindication to treatment such as:
   a. Active malignancy
   b. Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma
   c. Pregnancy (consider risk)

~~**6. Patient has a waist circumference ≥95 cm (37.4 inches) [men]; ≥94 cm (37.0 inches) [women] at start of therapy**~~

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

Continuation of therapy:

1. Patient is responding positively to therapy as evidenced by documentation of decrease in visceral adipose tissue while on therapy.

2. There is no evidence of exacerbation of glucose intolerance and increased IGF-1 levels

3. Medication will be discontinued in 6 months if there is no treatment response~~, assessed by a decrease in waist circumference~~

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

Limitations of use:

a. Long-term cardiovascular safety of Egrifta has not been established
b. Not indicated for weight loss management
c. There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta

References:

1. Egrifta [prescribing information]. Theratechnologies Inc., Montréal, Québec, Canada H3A 1T8. July 2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Glesby MJ. (2022). Treatment of HIV-associated lipodystrophy. UpToDate. Retrieved February 4, 2023 from https://www.uptodate.com/contents/treatment-of-hiv-associated-lipodystrophy

Addendum to the Protocol for Direct Acting Antivirals for Hepatitis C

Updated April 2024

Approved June 2016
Updated and approved October 2017
Updated and approved July 2018
Updated and approved July 2021

Addendum:

1. **Remove previous criterion # 6 which read: Initial quantity dispensed will be limited to 14 days dosage units (14-14-28-28 format)**
2. **Delete Viekira Pak (discontinued January 2019**
3. Restructure protocol to minimize barriers to access

This protocol covers (but is not limited to) the following medications:

Sovaldi® (sofosbuvir)
Harvoni® (sofosbuvir/ledipasvir)
Zepatier® (elbasvir/grazoprevir)
Epclusa® (sofosbuvir/velpatasvir)
Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)
Mavyret® (glecaprevir/pibrentasvir)

Please refer to individual drug package insert for specific genotypes and other guidelines

Criteria for Approval

A) For Treatment Naïve Patients:

1. Patient is treatment naïve and has a confirmed diagnosis of hepatitis C **AND**
2. Medication is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

B) For Treatment Experienced Patients:

1. Medication is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

2. Diagnosis of **chronic hepatitis C,** labs showing detectable HCV RNA levels from within the **past 90 days** and genotype must be received,

3. Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser**, reinfected**, partial responder, or non-compliant.

4. Patient has been educated on the importance of compliance with their treatment regimen.

5. Patient must not have any of the following:
    a. Contraindications to requested Hepatitis C therapy (See PI for complete list)
    b. Patient must not be on any therapies identified by the prescribing information or AASLD/IDSA guidelines as therapies not recommended for co-administration, (see PI and guidelines for complete list)
    c. Limited life expectancy (<12 months due to non-liver related comorbidities). Per AASLD guidelines [2015], HCV therapy would not improve symptoms or prognosis in this patient population and do not require treatment.

6. If combined with ribavirin patient will meet ALL of the following:
    6.1 Patient has no contraindication (See PI for complete list) to ribavirin
    6.2 Neither the patient nor the partner of the patient is pregnant
    6.3 If patient or their partner is of childbearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy.
7. For patients with decompensated cirrhosis, the requested drug(s) must be prescribed by or in consultation with a liver transplant specialist
8. Prescriber attests that patient has been assessed for HBV infection
9. For regimens that depend on testing [e.g., baseline high fold-change NS5A RASs (includes G1a polymorphisms at amino acid positions 28, 30, 31, or 93), Baseline Q80K polymorphism, Y93H], a copy of the lab work must be received.

References:

1. American Association for the Study of Liver Diseases (AASLD)/Infectious Disease Society of America (IDSA). Recommendations for Testing, Managing, and Treating Hepatitis C. January 29, 2014. Updated on January 21, 2021. Accessed on: May 25, 2021.Available at https://www.hcvguidelines.org/sites/default/files/full-guidance-pdf/AASLD-IDSA_HCVGuidance_January_21_2021.pdf. Published Harvoni® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; October 2014.
2. Sovaldi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; December 2013.
3. Zepatier® [Prescribing Information]. Merck & Co. Inc., Whitehouse Station, NJ; January 2016.
4. Epclusa® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; June 2016.
5. Vosevi® [Prescribing Information]. Gilead Sciences, Foster City, CA 94404; July 2017.
6. Mavyret® [Prescribing Information]. AbbVie Inc., North Chicago, Il 60064: August 2017.

Addendum to the Protocol for Zurzuvae® (zuranolone)

Approved April 2024

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

Addendum:
Remove continuation of therapy section of protocol.

Criteria for approval:

1. Patient has moderate to severe symptoms of postpartum depression;
2. Patient is ≤ 12 months postpartum;
3. Medication is prescribed by or in consultation with appropriate healthcare **provider with planned follow up;**
4. Treatment is one time only per pregnancy
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

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)
4. Liu X, Wang S, Wang G. Prevalence and Risk Factors of Postpartum Depression in Women: A Systematic Review and Meta-analysis. J Clin Nurs. 2022 Oct;31(19-20):2665-2677

Proposed Addendum to the Protocol for dupilumab (Dupixent®)

July 2024

Approved April 2019
Updated July 2020
Updated July 2021
Updated January 2023

Addendum:
Addition of all FDA-labeled indications for dupilumab (Dupixent)

Background:
Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of: atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis.

Criteria for approval:

1. Medication dosage is appropriate for the patient's indication and age

2. Medication will not be used concomitantly with another biologic immunomodulator or JAK inhibitor

3. Medication is prescribed by or in consultation with a specialist in the field at treating the specific disease state

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, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

A. Atopic Dermatitis

1. Patient has a diagnosis of moderate to severe disease atopic dermatitis

2. Patient has a minimum of 10% body surface area involvement OR has clinically difficult to treat areas (e.g., face, neck, genital) that interfere with quality of life

3. Patient has tried and failed or has contraindication for the use of ALL of the following:
    a. One medium to very high potency topical prescription corticosteroid $\geq$ 2 weeks
    b. One topical calcineurin inhibitor (e.g., Elidel®, Protopic®) for $\geq$ 4 weeks

4. Patient will continue to use topical emollients concomitantly in problem areas (e.g., face, neck, genital) to help prevent flares

5. Success of treatment will be assessed regularly.

B. Asthma

1. Patient has a diagnosis of moderate to severe asthma;

2. Patient has asthma with one of the following:

   a. Patient has an eosinophilic phenotype and has blood eosinophil counts greater than or equal to 150 cells/microliter; **OR**
   b. Patient has oral corticosteroid-dependent asthma and has been on and adherent to an oral corticosteroid regimen;

3. Patient has been on and is currently treated with maximally tolerated conventional therapies, unless there is documented intolerance, contraindication, or hypersensitivity to all, which include:
   a. An inhaled corticosteroid regimen in the past 12 months; **AND**
   b. A regimen containing either a long-acting beta agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist, theophylline, or zileuton for the last 6 months

4. The patient has had either of the following events despite regular use of conventional therapies (above):
   a. Two or more exacerbations requiring systemic corticosteroids (steroid bursts) within the past 12 months: OR
   b. Serious asthma exacerbations requiring hospitalization, intubation/mechanical ventilation, or visits to the emergency room or urgent care within the past 12 months

C. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**:

1. Patient has a confirmed diagnosis of CRSwNP

2. The member meets at least **one** of the following
   a. Had an inadequate response to sinonasal surgery
   b. Not a candidate for sinonasal surgery
   c. Had an inadequate response to oral systemic corticosteroids or has intolerance, contraindication, or hypersensitivity to all oral systemic corticosteroids.

3. The member had an inadequate response to a 3-month trial of at least one intranasal corticosteroids (INCS) or has intolerance, contraindication, or hypersensitivity to all intranasal corticosteroids

4. The member has ongoing symptoms of nasal congestion/blockage/obstruction with moderate to severe symptom severity and has another symptom such as loss of smell, rhinorrhea (anterior/posterior), etc.

5. Medication is being used as add-on therapy for CRSwNP

D. Eosinophilic Esophagitis:

1. Patient has a diagnosis of eosinophilic esophagitis (EOE) and has an eosinophilic count of ≥15 intraepithelial eosinophils per high power field on light microscopy following a treatment course of a proton pump inhibitor (PPI)

2. Patient has symptoms of regurgitation, dysphagia, food impaction

3. Patient has had an inadequate response to at least 90 days trial of one appropriate corticosteroid unless intolerant, hypersensitive or contraindicated

E. Prurigo Nodularis:

1. Patient has a diagnosis of prurigo nodularis (PN)

2. Patient has ≥20 nodular lesions

3. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score ≥7 on a scale of 0 to 10

4. Patient has had inadequate response to one previous PN treatment, unless intolerant, hypersensitive or contraindicated to all.

Continuation of therapy:
1. Documentation of positive clinical response

2. Medication will not be used concomitantly with another biologic with the same indication.

References:

1. Dupixent® [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. April 2024
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2022. Updated periodically
3. Institute for Clinical and Economic Review (ICER). June 2016. Accessed December 27, 2018 at: https://icer-review.org/wp-content/uploads/2017/06/MWCEPAC_AD_RAAG_060817.pdf
4. Sidbury R, Davis DM et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol, July 2014 Volume 71, Issue 1, Pages 116–132
5. Global Initiative for Asthma (GINA). Global Strategy For Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2022. Available at www.ginasthma.org
6. UpToDate literature review on Chronic rhinosinusitis with nasal polyposis: Management and prognosis (8/2023)
7. Dellon, Evan S MD, MPH1, et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). American Journal of Gastroenterology 108(5):p 679-692, May 2013
8. Gonsalves NP, Aceves SS, Diagnosis and Treatment of Eosinophilic Esophagitis. J Allergy Clin Immunol. 2020 January ; 145(1): 1–7. doi:10.1016/j.jaci.2019.11.011.

9. Yosipovitch, G., Mollanazar, N., Ständer, S. et al. Dupilumab in patients with prurigo nodularis: two randomized, double-blind, placebo-controlled phase 3 trials. Nat Med 29, 1180–1190 (2023). https://doi.org/10.1038/s41591-023-02320-9

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

July 2024

Approved April 2019
Updated October 2020
Updated October 2022
Updated January 2024

Addendum:
Deletion of step therapy requirements for migraine prevention as recommended by the American Headache Society (March 2024)

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 will not be used in combination with another biologic CGRP antagonist or inhibitor used for prevention of migraines; **AND**

4. 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~~

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

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/

14. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024; 64: 333-341. doi:10.1111/head.14692

Addendum to the Protocol for Vyjuvek® (beremagene geperpavec-svdt)

July 2024

Approved October 2023

Addendum:

a. Emphasize that medication will be applied only to open wounds
b. Wound size required – to guide dosing
c. Treatment is only for 24 weeks pending further evaluation

Background: *Dystrophic epidermolysis bullosa (DEB) is one of the major types of EB, a rare hereditary group of trauma-induced blistering skin disorders. DEB is caused by inherited pathogenic variants in the COL7A1 gene, which encodes type VII collagen, the major component of anchoring fibrils which maintain adhesion between the outer epidermis and underlying dermis.*

Vyjuvek *is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.*

Criteria for approval:

1. Patient is 6 months or older

~~2.~~ Patient has a diagnosis of DEB with documentation of mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Diagnosis is confirmed by ONE of the following:
   a. Skin biopsy for immunofluorescence mapping
   b. Transmission electron microscopy
   c. Genetic testing

~~**3. Patient has at least one open wound that is not infected**~~

4. Patient does not have current evidence or history of squamous cell carcinoma (SCC) in the area to be treated

5. Medication is prescribed by or in consultation with a dermatologist.

6. Medication will be applied by a healthcare professional

7. Medication is applied only to open wounds that are not infected

8. Size of wound is provided

9. Treatment is for up to 24 weeks

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, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient had a positive clinical response to therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure)

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

3. Medication is applied only to open wounds that are not infected

4. Size of wound is provided

References:

1. Vyjuvek [prescribing information]. Krystal Biotech Inc. Pittsburgh, PA 15203 May 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Hou P et al. Innovations in the Treatment of Dystrophic Epidermolysis Bullosa (DEB): Current Landscape and Prospects. Therapeutics and Clinical Risk Management 2023:19
4. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. Br J Dermatol 2020; 182:574
5. Khan A, Riaz R, Ashraf S, Akilimali A. Revolutionary breakthrough: FDA approves Vyjuvek, the first topical gene therapy for dystrophic epidermolysis bullosa. Ann Med Surg (Lond). 2023 Oct 17;85(12):6298-6301. doi: 10.1097/MS9.0000000000001422. PMID: 38098548; PMCID: PMC10718329.

Addendum to Protocol for Duchenne Muscular Dystrophy Products

Approved October 2023

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 physician 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 physician 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.

Proposed Protocol for Qelbree® (viloxazine)

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)

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

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

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

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.

Proposed Protocol for Wegovy for Reduction of Major Adverse Cardiovascular Events (MACE)

July 2024

Criteria for approval:

1. Patient is of the FDA labeled age for this indication
2. Patient has established cardiovascular (CV) disease as evidenced by at least **one** of the following:
   a. Prior myocardial infarction; **OR**
   b. Prior ischemic or hemorrhagic stroke; **OR**
   c. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), or peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease. **OR**
   d. Positive nuclear stress test **OR**
   e. Ischemic cardiomyopathy **OR**
   f. History of revascularization (CABG, PCI, or angioplasty)
3. Documentation that member has a body mass index (BMI) ≥27
4. Medication is prescribed by, or in consultation with a cardiologist or vascular specialist.
5. Use with caution in patients with type 1 diabetes mellitus.
6. Patient does not have any contraindications for use of Wegovy.
7. Patient will not be utilizing another GLP-1 receptor agonist concomitantly.
8. Documentation that member has received individualized healthy lifestyle counseling.
9. Prescriber will maintain the patient on appropriate cardiovascular pharmacotherapy for their cardiovascular disease.
10. Patient's target dose will be in the range of manufacturer dosing shown to reduce major cardiovascular events as tolerated.

Continuation of therapy:

1. Once the patient has attained the maintenance dose of 2.4mg weekly, the patient is tolerating that dose or documentation must be provided for justification of use of a different dose

2. There is no documented evidence of worsening in the patient's cardiovascular health that is being caused by Wegovy

3. Patient remains on appropriate cardiovascular pharmacotherapy for their cardiovascular disease.

NOTE: Wegovy has a black box warning regarding thyroid C-cell tumors. Please see full prescribing information for details.

References:

1. Wegovy [packet insert]. Novo Nordisk Inc. Plainsboro, NJ 08536. March 2024
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Lincoff AM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023 Dec 14;389(24):2221-2232. doi: 10.1056/NEJMoa2307563. Epub 2023 Nov 11. PMID: 37952131
4. Lingvay I,et al. Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Obesity (Silver Spring). 2023 Jan;31(1):111-122. doi: 10.1002/oby.23621. Epub 2022 Dec 10. PMID: 36502289; PMCID: PMC10107832.

NJ DURB Prior Authorization Denial Report - 1st Quarter 2024 (January- March)

	FFS	Aetna	Fidelis	Horizon	UHC	Wellpoint
Total # of Enrolled Beneficiaries	**105,919**	**120,522**	**99,393**	**1,088,808**	**380,543**	**213,709**
Total # of Pharmacy Claims Processed	**441,526**	**521,387**	**387,815**	**3,585,309**	**1,001,989**	**1,152,783**
Total # of Members Requesting Prior Authorization*	**1,458**	**3,099**	**2,773**	**20,505**	**8,181**	**6,356**
Total Prior Authorizations Requests Received**	**3,569 (0.8%)**	**4,822 (0.9%)**	**4,462 (1.2%)**	**31,672 (0.9%)**	**11,168 (1.1%)**	**10,354 (0.9%)**
Received Requests Denials	**68 (2%)**	**2,150 (45%)**	**1,417 (31%)**	**10,200 (32%)**	**4,980 (45%)**	**3,807 (36.8%)**
Without Non-formulary Denials	**68 (2%)**	**807 (17%)**	**310 (7%)**	**3,308 (10%)**	**1,690 (15%)**	**1,489 (14%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	79 (95%)	706 (33%)	294 (21%)	3,087 (30%)	1,438 (29%)	1230 (32%)
Excluded Benefit	4 (5%)	90 (4%)	16 (1%)	221 (2%)	252 (5%)	259 (7%)
Non-formulary	0 (0%)	1,343 (63%)	1,107 (78%)	6,892 (68%)	3,290 (66%)	2,318 (61%)
Other	0 (0%)	11 (0.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	7.2%	1.8%	2.6%	3.1%	3.5%	3.7%
Antidepressants	0.0%	0.8%	0.6%	1.5%	1.2%	1.3%
Antihypertensives	1.2%	0.7%	0.5%	0.7%	0.7%	1.0%
Antianxiety	0.0%	0.1%	0.1%	0.2%	1.1%	0.2%
Antidiabetics (oral and insulin)	7.2%	14.3%	28.1%	23.8%	0.5%	14.6%
Anticoagulants	0.0%	0.0%	0.2%	0.0%	1.7%	0.0%
Thyroid agents	0.0%	0.2%	0.0%	0.2%	0.6%	0.0%
Ulcer Drugs/Antispasmodics/Anticholinergics	1.2%	3.2%	0.9%	1.9%	1.0%	1.9%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants	1.2%	10.8%	5.9%	3.8%	1.2%	6.6%
Antipsychotic/Antimanic agents	1.2%	1.0%	1.1%	2.8%	1.2%	2.1%
Antiasthmatic and Bronchodilator agents	7.2%	5.2%	4.2%	6.6%	0.9%	2.8%
Antivirals (includes both HIV and Hep C)	0.0%	1.0%	0.6%	0.3%	0.2%	0.3%
Digestive Aids (Digestive Enzymes)	2.4%	0.5%	0.6%	0.2%	1.0%	0.1%
Anticonvulsants	0.0%	3.2%	3.3%	1.5%	1.4%	1.3%
Migraine Products	1.2%	4.4%	3.3%	4.4%	1.3%	4.2%
Analgesics Anti-inflammatory	14.5%	3.7%	3.5%	2.4%	1.3%	2.3%
Analgesic Opioids	9.6%	6.7%	0.9%	1.5%	1.3%	6.1%
Endocrine and Metabolic Agents-Misc (Growth Hormone)	0.0%	1.2%	1.8%	1.0%	0.6%	1.7%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)	0.0%	0.7%	1.0%	0.8%	1.2%	0.8%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)	0.0%	0.0%	0.3%	0.0%	0.9%	0.0%
Dermatologics (Antipsoriatics-Systemic)	0.0%	17.9%	12.1%	14.3%	1.8%	17.1%

* 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

July 17, 2024

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
April 2024	Proposed protocol for Ingrezza® (valbenazine)	- The Board recommended the protocol with suggested changes to: a. Criterion #3 to read: Medication is prescribed by or in consultation with a neurologist, psychiatrist, APN who is a specialist in the field for this disease state. b. Same as above for Huntington's disease criterion #4 c. Criterion #3 for HD to read: Use with caution in patients with depression, agitation, or psychosis.	These changes will be made and presented at the next meeting
	Proposed protocol for Egrifta® (tesamorelin)	- The Board recommended the protocol with suggested change to delete criterion #4c (waist circumference)	This change will be made and presented at the next meeting
	Proposed addendum to the protocol for Spinal Muscular Atrophy (SMA) products	- The Board recommended the addendum to the protocol	
	Proposed addendum to the protocol for Direct Acting Antivirals (for hepatitis C) products	- The Board recommended the protocol suggested change to criterion #B3 to read: Provide previous treatment history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected	This change will be made and presented at the next meeting
	Proposed addendum to Zurzuvae (zuranolone) protocol	- The Board recommended the protocol with suggestion to change criterion #3 to read: Medication is prescribed by or in consultation with an appropriate healthcare provider with planned follow up.	This change will be made and presented at the next meeting
January 2024	Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitor products	- The Board recommended the protocol	
	Proposed addendum to the protocol for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor products	- The Board recommended the protocol with suggested changes to criterion #3 for initial approval and criterion #4 for subsequent requests. - The Board recommended the protocol	Updated information was presented at the next meeting

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	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 criteria #1, 2, 4 for initial approval and criterion #2 in continuation of therapy section	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) Proposed protocol for Vyjuvek (beremagene geperpavec) Proposed addendum to Duchenne muscular dystrophy products protocol	- The Board recommended the protocol - The Board recommended the 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
July 2023	Proposed protocol for Chimeric Antigen Receptor T-cell (CAR T-cell) products Proposed protocol for Qalsody (tofersen) Proposed addendum to the biologic receptor modifiers (BRMs) protocol for plaque psoriasis	- The Board recommended the protocol - The Board recommended the protocol - The Board tabled the protocol pending consult with a dermatologist	
April 2023	Proposed protocol for Skysona® (elivaldogene autotemcel) Proposed protocol for Zynteglo® (betibeglogene autotemcel) Proposed protocol for Hemgenix® (etranacogene dezaparvovec) Proposed protocol for Leqembi® (lecanemab-irmb) Proposed protocol for Livmarli® (maralixibat)	- The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol - The Board recommended the protocol	

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
		- 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