NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

July 13, 2022

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 20, 2022, meeting

IV. Review of draft meeting summary for April 20, 2022, meeting (pages 3-7)

V. Secretary's report (page 8)

VI. Old Business
- A. Hetlioz® liquid formulation use in 16 years old patients (clarification) [page 9]
- B. Denials report details from MCO partners (page 10)
- C. Ivermectin utilization in drugs category report (April 2022) [page 11]
- D. Educational newsletter on oral COVID-19 medications (pages 12-13)

VII. New Business
- A. Addendum to calcitonin gene-related peptide (CGRP) receptor antagonists protocol (pages 14-17)
- B. Proposed protocol for Vuity® (pilocarpine ophthalmic) [page 18]
- C. Proposed protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) products (pages 19-20)
- D. Proposed protocol for Bylvay® (odevixibat) [pages 21-22]

VIII. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ HMO 1st Quarter 2022 Prior Authorization Report (page 23)
2. Summary of DURB Action Items (pages 24-25)
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

B. Medication information:
1. COVID-19 Vaccines information
   https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
2. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
   https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html Continuously updated.
3. New Jersey COVID-19 Information Hub (continuously updated)
   https://covid19.nj.gov/

4. New Jersey COVID-19 Dashboard
   https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml (new) continuously updated

5. Know Your Treatment Options for COVID-19 – FDA
   https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19

April 20, 2022, DURB Meeting Summary (draft)

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Moynihan, Dr. Lind (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 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, Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from January 19, 2022, 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
		Ruchi Banker, PharmD, with Gainwell Technologies presented the Secretary's report and other agenda items. - The Department is working with the Commissioners to sign off on DURB-recommended protocols for: October 2020, April 2021, July 2021, October 2021, and January 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - Dr. Swee requested that Dr. Lind comment on the delayed sign off for the October 2020 protocols. Dr. Lind responded that the protocols are with the Department of Health, and he had sent the most recent reminder a week ago but had not received a response.
Old Business		
Review of updated protocols from the previous meeting.		Dr. Swee requested that going forward, changes made in DURB-recommended protocols should be presented as old business. At the meantime, he requested that Sam Emenike, PharmD, update the Board with the changes that were made. Those changes were as follows: 3

		For Gamifant® - Dr. Liem Sanderson (Anthem IngenioRx) suggested including the word "primary" as part of the diagnosis criterion (#1) for hemophagocytic lymphohistiocytosis (HLH). "Weight must be received" was changed to "weight will be monitored" for criterion #5. For Nitisinone products - Criterion #4 was changed from "prescribed by or in consultation with a metabolic disease specialist" to " . . in consultation with a prescriber with expertise in this condition". For Lucemyra® - Ms. Olson and Dr. Barberio suggested changing criterion #4 from "medication is prescribed by or in consultation with a physician specializing in pain management or addiction treatment" to ". . .with a prescriber specializing in pain management or addiction treatment". - The Board recommended deleting criterion #5 which read: "patient has tried and has inadequate response or intolerance, contraindication to oral clonidine or clonidine patch for opioid withdrawal".
New Business		
(A) Proposed protocol for Hetlioz® (tasimelteon)	Approved	The Board reviewed a proposed protocol for Hetlioz, a product indicated for the treatment of non-24 sleep-wake disorder. Dr. Marcus enquired why patients under 16 years of age would be required to take the liquid formulation if they can take the capsule. The Board also wanted to know why adult size teenagers, e.g., 15-year-olds could not take the capsule if they can. The Board recommended the protocol pending obtaining information from the drug manufacturer regarding these questions.
(B) Proposed protocol for cysteamine products	Approved	The Board reviewed a proposed protocol for cysteamine products, Cystagon (cysteamine bitartrate) immediate release capsules and Procysbi (cysteamine bitartrate) delayed release capsules. Both are indicated for the treatment of nephropathic cystinosis. The Board recommended the protocol. 4

(C) Proposed protocol for Revcovi® (elapegademase-lvlr)	Approved	The Board reviewed a protocol for Revcovi, a product indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID). Dr. Swee was concerned that the protocol was asking the treating prescriber for "details of the diagnosis". Dr. Emenike explained that the medication necessity form sent to the prescribers only requires attestation from them that they confirmed the diagnosis based on peer-reviewed guidelines (which lists these genetic or lab data) needed prior to treating the disease state. No further details are required of them from the department. He promised to talk to the State's MCO partners and update the Board with their input on the subject. Ed Vaccaro, R.Ph., with Gainwell Technology informed the Board that another reason for requesting attestation from the prescribers is to deter fraudulent claims. Dr. Barberio suggested changing the word "physician" in criterion number 2 to "provider". Dr. Swee responded that since the information will ultimately come from a physician, the criterion should be left as is. The Board recommended the protocol.
(D) Proposed protocol for Luxturna® (voretigene neparvovec-rzyl)	Approved	The Board reviewed a protocol for Luxturna, a product indicated for the treatment of retinal dystrophy. There were no comments. The Board recommended the protocol.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	Dr. Swee again voiced his concern about the burden that prior authorization placed on providers. He also pointed to the disparity in the denial rates among the MCOs and when compared to fee-for-service rates. His hope that the rates would decrease after the non-formulary denials were excluded from the calculation did not materialize. He is therefore looking forward to data that will be provided by the State in coming meetings to explain these differences.

<table>
<tr>
<td>2. Summary of DURB Actions/Recommendations</td>
<td></td>
<td>The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 4th quarter 2021 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>7.3</td><td>7.3</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>33.3</td><td>11.4</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>34.2</td><td>18</td></tr>
<tr><td>Horizon</td><td>0.6</td><td>33.2</td><td>13</td></tr>
<tr><td>UHC</td><td>0.8</td><td>44</td><td>14.4</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>27.3</td><td>8</td></tr>
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The Board reviewed a summary of their actions from previous meetings (April 2021 thru January 2022).
There were no comments.</td>
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<td>3. DHS/DHSS/MCO Programs Top Drugs Report</td>
<td></td>
<td>Top drugs report for January 2022 (FFS)/December 2021 (MCOs) was provided for review. Dr. Marcus commented on charge(s) for oseltamivir (Tamiflu®) on the report given the low rate of influenza during the reporting period. He also wondered about the absence of the new oral COVID-19 drugs (Paxlovid and molnupiravir) in the report. He was informed that it was too early and moreover a utilization report targeting the two drugs was not done, yet. He requested that the State publish a (quick) newsletter to help providers understand the place of these medications in the fight against COVID-19.

Other discussions by the Board:
- The surge in omicron variant, BA.2 nationwide
- The need to treat patients early if positive for COVID-19
- Possibility of new federal laws having an impact on the price of insulin
- Use of monoclonal antibodies over the new oral medications when patients visit the hospital after positive test for COVID-19</td>
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- The presence of ivermectin on the drugs report despite FDA assertion of its ineffectiveness in COVID-19. (ivermectin has other approved indications)

Ms. Desai, the State's pharmacy services chief informed the Board that their recommended newsletter on ivermectin was distributed to providers early in the week.
Drug expenditure 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 2022</td><td>$11,017,583</td><td>$11,486,068</td></tr>
<tr><td>MCOs</td><td>December 2021</td><td>$101,478,644</td><td>$143,708,498</td></tr>
</table>
</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links to some COVID-19 guides. Although with similar subjects to previous meetings, these are frequently updated sources:
a. COVID-19 Vaccine information
b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
c. New Jersey COVID-19 Information Hub
d. Know Your Treatment Options for COVID-19 - FDA</td></tr>
<tr><td>5. Referenced Materials</td><td></td><td>Updated protocols returned for Board members review of their suggested changes:
A. Proposed protocol for Gamifant® (emapalumab-lzsg) – approved January 2022
B. Proposed Protocol for Nitisinone products – approved January 2022
C. Proposed protocol for Lucemyra® (lofexidine) – approved January 2022</td></tr>
<tr><td>Follow up items:</td><td></td><td>A. Obtain information why patients under 16 are required to take liquid Hetlioz if they can take the pills.
B. Discuss with MCOs the need to request details of diagnosis in protocols
C. MCOs to provide explanations for variations in PA denials
D. Prepare an educational newsletter for new oral medications for COVID-19
H. Investigate uses for ivermectin in drugs report</td></tr>
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NEW JERSEY DRUG UTILIZATION REVIEW BOARD

July 13, 2022

Secretary's Report:

1. The Commissioners have signed off on the DURB-recommended protocols for:
   - October 2020
   - April 2021
   - July 2021
   - October 2021

2. The department is working with the Commissioners to review and sign off on DURB-recommended protocols for:
   - January 2022
   - April 2022

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

4. The Commissioners have approved DURB Annual report for 2021.

5. Under the Governor's Ending the HIV Epidemic initiative, effective July 1, 2022, NJ Medicaid FFS, as well as NJ Medicaid MCOs, will not require any prior authorization or step therapy for all FDA approved HIV medication, including medications for PrEP or PEP. Safety edits will still be in effect. NJ Medicaid MCOs will also be required to provide a 90 days supply of a member's existing medication prior to disenrollment, if requested by a member within 30 days.

Clarification: Use of Hetlioz Liquid Formulation in 16-Year-Old Patients

From Vanda Pharmaceuticals:

The FDA restricted Hetlioz LQ to treat pediatric patients ages 3 to 15 with nighttime sleep disturbances in SMS because this was the age group for which Hetlioz LQ was tested in the clinical study. As noted in the product labeling, the FDA approval of Hetlioz for the treatment of nighttime sleep disturbances in SMS was based on a 9-week, double-blind, placebo-controlled efficacy study, in which patients ages 16 and older took the Hetlioz capsule, and pediatric patients ages 3 to 15 took the liquid formulation.

- The pharmacokinetic profile of oral suspension has not been directly compared to the capsules; therefore, capsules are the only dosage forms recommended for use in adults.

Denials Report Details and Explanations From MCO Partners

July 13, 2022

Awaiting data from MCOs addressing:

1. Time for PA Approval
a. On average, how long does it take for prescribers to respond to initial request?
b. Once all necessary information is received by MCO – how long is the turnaround time for approval?

2. % Approvals
a. What percentage of PA requests (for denied claims) are eventually approved for the initial drug ?
b. In the event the initial (claim) is not approved – what percentage of initial denials are filled with an alternative medication for the same disease state?

3. DMAHS is working on MCO plan to plan "churn" report as requested. We hope to have more details by the next DURB meeting.

Ivermectin Utilization in Drugs Report April 2022

July 2022

As observed by the Board at the April meeting, there was utilization of ivermectin during the tops drugs review period (December 2022). Further investigation identified 69 claims with the following diagnosis:

- COVID-19 related claims – 19
- FDA-approved uses – 9
- Suspected uses ("viral infection) – 10
- Other non-specific diagnoses – 31

  Total - 69

New Jersey Drug Utilization Review Board

May 2022

What You Need To Know About the Oral Medications for COVID-19

On December 22, 2021, the FDA granted Emergency Use Authorization (EUA) to Pfizer for the COVID-19 oral antiviral drug product, Paxlovid®. Paxlovid® is a combination of two drugs, nirmatrelvir and ritonavir. On December 23, 2021, the FDA also granted an EUA to Merck for the COVID-19 oral antiviral drug product, molnupiravir (now referred to by its brand name Lagevrio®).

Who is eligible for these medications?

Paxlovid® and Lagevrio® are both available by prescription only. These drugs are used for the treatment of patients meeting certain criteria, differing by age and weight as indicated below:

- ✓ Have tested positive for COVID-19
- ✓ Have mild to moderate symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, etc.)
- ✓ Are at high risk of progression to severe COVID-19, including hospitalization or death
- ✓ Are 12 years of age or older and weigh at least 40kg (80lb) for Paxlovid®
- ✓ Are 18 years of age or older for Lagevrio®

How do these medications combat COVID-19?

Nirmatrelvir renders the virus incapable of processing polyprotein precursors, thereby preventing viral replication. Ritonavir does not have antiviral activity against COVID-19, but instead is used as an enhancer to increase plasma concentrations of nirmatrelvir.

Molnupiravir works by introducing errors into the virus' genetic code, making the virus incapable of replicating properly.

How should my patients take these medications?

Paxlovid® is co-packaged and orally administered consisting of two (2) tablets of nirmatrelvir (150mg) and one (1) tablet of ritonavir (100mg) to be taken concurrently twice daily for five (5) days.

Initiate treatment as soon as possible after COVID-19 diagnosis and within 5 days of symptom onset.

Lagevrio® is also orally administered as four (4) 200mg capsules twice daily for five (5) days.

Completion of the full 5-day treatment course and continued isolation in accordance with CDC's public health recommendations are important to maximize viral clearance and minimize transmission of COVID-19.

What are possible adverse reactions to oral Covid-19 medications?

Potential side effects include, but are not limited to:

- Impaired sense of taste
- Diarrhea
- Nausea
- Muscle aches

Please check package inserts for additional information.

What are limitations of the use of these medications?

- They are not authorized for the initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19 infection.
- They are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- They are not authorized for use longer than five (5) consecutive days.
- Prescribers are encouraged to check drug-drug interactions with Paxlovid.

Can COVID-19 Symptoms Come Back After Using Paxlovid?

A number of patients have reported testing positive for COVID-19 after taking a five-day treatment course of the drug. According to the FDA, these reports, do not change the conclusions from the Paxlovid clinical trial which demonstrated a marked reduction in hospitalization and death. However, they are continuing to review data from clinical trials and will provide additional information as it becomes available.

Sources for additional reading:

1. CDC's COVID-19 Treatments and Medications
   https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html
2. FDA's EUA for Paxlovid
   https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19
3. FDA's EUA for molnupiravir (updated)
   https://www.fda.gov/media/155053/download
4. FDA Updates on Paxlovid for Health Care Providers. US Food and Drug Administration. May 4, 2022. https://www.fda.gov/drugs/news-events-human-drugs/fda-updates-paxlovid-health-care-providers Accessed: May 19, 2022.

Protocol for Calcitonin Gene-Related Peptide (CGRP) Antagonists for Preventative and Acute Treatment of Migraines

Approved April 2019
Updated October 2020
Updated July 2022

Addendum:

1. Addition of more FDA-approved products in the class:
   a. **Ubrelvy®** (ubrogepant) – December 2019 **(Oral tablets for acute treatment)**
   b. **Nurtec ODT®** (rimegepant) – May 2021 **(Oral disintegrating tablets for preventive and acute treatment)**
   c. **Qulipta®** (atogepant) – September 2021 **(Oral tablets for preventive treatment)**

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

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 (preventive treatment):

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

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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

AND

4. The patient must also meet all of the following:
   a. The patient meets at least one of the following:
      i. Patient has 4 or more migraine days per month **OR**
      ii. The migraine attacks significantly interfere with the patient's daily routines despite acute migraine treatment **OR**
      iii. The patient has contraindications to all acute migraine treatment [e.g., acetaminophen, aspirin, generic Cataflam (diclofenac), generic Voltaren (diclofenac), generic Motrin (ibuprofen), generic Advil (ibuprofen), generic Naprosyn (naproxen), generic Ansaid (flurbiprofen), generic Orudis (ketoprofen), generic Excedrin (acetaminophen/aspirin/caffeine), sumatriptan, rizatriptan/rizatriptan orally disintegrating tablet (ODT), naratriptan, Generic Cafergot (ergotamine/caffeine), Generic Migranal (Dihydroergotamine nasal spray)] **OR**
      iv. The patient was overusing acute migraine treatment [defined as 10 or more days per month for ergot derivatives, triptans, opioids, combination analgesics, and a combination of drugs from different classes that are not individually overused OR 15 or more days per month for nonopioid analgesics, acetaminophen, and NSAIDs (including aspirin)] **OR**
      v. The patient has tried and failed or had intolerance with acute migraine treatment **OR**
      vi. Patient has hemiplegic migraine, migraine with brainstem aura, migraine with prolonged aura, and those who have previously experienced a migrainous infarction

      AND

   b. The patient must meet at least one of the following prior therapy criteria (i-iii):
      i. Patient has experienced therapeutic failure after at least 30 days of therapy OR documented intolerance to at least two of the following (1-6):
         1. One of these Beta-blockers: metoprolol, propranolol, timolol, atenolol, nadolol
         2. Divalproex sodium/sodium valproate
         3. Generic Topamax
         4. One of these Tricyclic Antidepressants: amitriptyline, nortriptyline
         5. One of these Serotonin-Norepinephrine Reuptake Inhibitor: venlafaxine, duloxetine
         6. One of these Triptans (only when used for prevention of menstrual associated migraines): frovatriptan, naratriptan, zolmitriptan **OR**
      ii. The patient has chronic migraines AND has failed at least 2 quarterly injections (6 months) of onabotulinumtoxinA **OR**
      iii. The patient has contraindications to all of the above medications (i. and ii.)

      AND

   c. Medication will not be used in combination with another CGRP antagonist.

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For Ubrelvy/Nurtec ODT (acute treatment):

a. The member is 18 years of age or older **AND**
b. 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

AND

c. Patient has tried 2 different triptan active ingredients and experienced failure or intolerance OR has contraindications (i.e., uncontrolled hypertension, ischemic coronary artery disease, etc.) to their use AND
d. For Ubrelvy requests: Patient is not concomitantly taking a strong CYP3A4 inhibitor (e.g., clarithromycin, ketoconazole) AND
e. The member will only be receiving one of the following: one CGRP inhibitor indicated for the acute treatment of migraines or lasmiditan (Reyvow®)

Continuation of therapy:

1. 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**

2. For preventive treatment: The patient must also meet all of the following:
    a. The patient has had an improvement in migraine prevention (reduction of migraine days/hours/frequency, reduction in acute abortive migraine medications/pain/level of disability, increase in functional capacity) compared to baseline **AND**
    b. The patient will only be receiving one CGRP inhibitor indicated for the preventative treatment of migraines

3. For acute treatment, the patient must also meet all of the following:
    a. The member has had a reduction in pain and/or symptoms compared to baseline
    b. The member will only be receiving one of the following: one CGRP inhibitor indicated for the acute treatment of migraines or lasmiditan (Reyvow®)

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. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
9. 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
10. Estemalik E, Tepper S. Preventive treatment in migraine and the new US guidelines. Neuropsychiatric Dis Treat. 2013;9:709–720.
11. 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
12. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. Available at: https://www.ichd-3.org/

Proposed Protocol for Vuity® (pilocarpine hydrochloride 1.25% ophthalmic solution)

July 2022

Background: *Presbyopia is the gradual loss of the eyes' ability to focus on nearby objects. It's a natural part of aging.*

Vuity *is a cholinergic muscarinic receptor agonist indicated for the treatment of presbyopia in adults.*

Criteria for approval:

1. Patient has a diagnosis of presbyopia
2. Patient is usually 40 to 55 years of age
3. Medication is prescribed by or in consultation with an ophthalmologist
4. Patient has tried and has inadequate response, intolerance, or contraindication to the use of corrective eyeglasses or contact lenses
5. Vuity is not prescribed concurrently with any other ophthalmic pilocarpine formulation
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient is responding positively to therapy
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. Vuity [prescribing information]. AbbVie Inc. North Chicago, IL 60064. October 2021
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically

Proposed Protocol for Paroxysmal Nocturnal Hemoglobinuria Products

July 2022

Empaveli® (pegcetacoplan)
Soliris® (eculizumab)
Ultomiris® (ravulizumab)

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

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

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

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

Criteria for approval:

1. Diagnosis of PNH is confirmed by flow cytometry

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

<u>For Empaveli:</u>

a. Patient is 18 years old or older
b. Prescriber is enrolled in Empaveli REMS program
c. Patient will not be on concomitant therapy with another complement inhibitor such as Ultomiris or Soliris
d. Patient is vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis and Hemophilus influenzae) at least 2 weeks prior to treatment

<u>For Soliris:</u>

a. Patient is 18 years of age or older
b. Prescriber is enrolled in Soliris REMS program
c. Patient will not be on concomitant therapy with another complement inhibitor such as Empaveli or Ultomiris
d. Patient is vaccinated against Neisseria meningitidis infection at least 2 weeks prior to treatment

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For Ultomiris:

a. Patient is 1 month of age or older
b. Prescriber is enrolled in Ultomiris REMS program
c. Patient will not be on concomitant therapy with another complement inhibitor such as Empaveli or Soliris
d. Patient is vaccinated against Neisseria meningitidis infection at least 2 weeks prior to treatment
e. Documentation of patient's current weight

Continuation of therapy:

The patient has responded to treatment compared to baseline as defined by at least one of the following:

a) Decrease in serum LDH from pretreatment level
b) Increase in hemoglobin levels
c) Decrease in number of transfusions needed
d) Absence of unacceptable toxicity from the drug

References:

1. Empaveli [prescribing information]. Apellis Pharmaceuticals Inc; Waltham MA: May 2021
2. Soliris [prescribing information]. Alexion Pharmaceuticals, Inc. Cheshire, CT: September 2011
3. Ultomiris [prescribing information]. Alexion Pharmaceuticals, Inc. Boston, MA: December 2018
4. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
5. Cancado RD et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal hemoglobinuria. Hematol Transfus Cell Ther. 2021; 43(3):341-348
6. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program (2016) 2016 (1): 208–216.

Proposed Protocol for Bylvay® (odevixibat)

July 2022

Background: *Progressive familial intrahepatic cholestasis (PFIC) is a disorder that causes progressive liver disease, which typically leads to liver failure.*

Bylvay *is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis.*

Criteria for approval:

1. Patient has a diagnosis of PFIC confirmed by genetic testing.
2. Patient is ≥ 3 months or older
3. Patient has significant pruritus
4. For PFIC type 2 patients, genetic testing does NOT indicate pathologic variations of the ABCB11 gene that predict non-function or complete absence of the bile salt export pump (BSEP) protein (see exclusion of therapy)
5. Medication is prescribed by or in consultation with a hepatologist or gastroenterologist
6. Patient has tried and has inadequate response, intolerance, or contraindication to treatment with ursodeoxycholic acid, or other agents used for symptomatic relief of pruritus (e.g., antihistamine, rifampicin, cholestyramine).
7. Patient's weight should be monitored
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, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Exclusion (Limitation of Use):

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

Continuation of therapy:

1. Patient is responding positively to therapy as evidenced by improvement in any of the following:
   a. Improvement in pruritus
   b. Reduction of serum bile acids from baseline
2. Patient's weight should be monitored

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

References:

1. Bylvay [prescribing information]. Albireo Pharma Inc. Boston, MA 02109. July 2021
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Gunaydin M and Cil ATB. Progressive familial intrahepatic cholestasis: diagnosis, management, and treatment. Hepat Med. 2018;10:95-104
4. Düll, M.M., Kremer, A.E. Newer Approaches to the Management of Pruritus in Cholestatic Liver Disease. Curr Hepatology Rep 19, 86–95 (2020). https://doi.org/10.1007/s11901-020-00517-x
5. Davit-Spraul A et al. Progressive familial intrahepatic cholestasis. Orphanet Journal of Rare Diseases 2009, 4:1;10.1186/1750-1172-4-1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2647530/ Accessed online on April 29, 2022

NJ DURB Prior Authorization Denial Report - 1st Quarter 2022 (January - March)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**67,239**	**126,333**	**244,884**	**1,124,602**	**407,215**	**105,642**
Total # of Pharmacy Claims Processed	**529,512**	**483,440**	**1,058,520**	**3,569,546**	**1,021,846**	**394,025**
Total # of Members Requesting Prior Authorization*	**1,454**	**2,974**	**6,970**	**17,337**	**7,451**	**2,077**
Total Prior Authorizations Requests Received**	**3,240 (0.6%)**	**4,152 (0.9%)**	**9,655 (0.9%)**	**24,173 (0.7%)**	**9,596 (0.9%)**	**3,019 (0.8%)**
Received Requests Denials	**261 (8.1%)**	**1,481 (35.7%)**	**3,366 (34.9%)**	**8,462 (35.0%)**	**4,202 (43.8%)**	**957 (31.7%)**
Without Non-formulary Denials	**261 (8.1%)**	**393 (9.5%)**	**1,100 (11.4%)**	**2,789 (11.5%)**	**1,376 (14.3%)**	**276 (9.1%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	140 (53.6%)	335 (22.6%)	938 (27.9%)	2,565 (30.3%)	1,159 (27.6%)	273 (28.5%)
Excluded Benefit	121 (46.4%)	38 (2.6%)	136 (4.0%)	224 (2.6%)	217 (5.2%)	3 (0.3%)
Non-formulary	0 (0.0%)	1,088 (73.5%)	2,266 (67.3%)	5,673 (67.0%)	2,826 (67.3%)	681 (71.2%)
Other	0 (0.0%)	20 (1.4%)	26 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0%)
Denials by Therapeutic Drug Classification******						
Antihyperlipidemics	4.2%	6.6%	5.2%	2.6%	4.0%	2.6%
Antidepressants	0.4%	1.0%	1.9%	2.1%	1.3%	0.5%
Antihypertensives	1.1%	1.1%	0.4%	1.0%	2.5%	0.7%
Antianxiety	1.5%	0.1%		0.2%	0.2%	0.0%
Antidiabetics (oral and insulin)	3.4%	8.0%	3.8%	21.1%	11.0%	19.9%
Anticoagulants		0.7%		0.1%	0.8%	0.7%
Thyroid agents	0.4%	0.4%	0.0%	0.3%	0.4%	0.2%
Ulcer Drugs/Antispasmodics/Anticholinergics	29.9%	1.6%	12.8%	2.1%	2.0%	1.6%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants		7.8%	3.4%	3.2%	2.6%	5.3%
Antipsychotic/Antimanic agents	5.4%	0.5%	0.4%	3.5%	1.9%	1.0%
Antiasthmatic and Bronchodilator agents	3.4%	7.6%	2.4%	7.6%	9.2%	4.0%
Antivirals (includes both HIV and Hep C)		1.3%	0.3%	0.9%	0.8%	2.4%
Digestive Aids (Digestive Enzymes)		0.1%	0.1%	0.1%	0.1%	0.5%
Anticonvulsants	1.9%	3.7%	0.5%	1.8%	2.2%	2.8%
Migraine Products		2.0%	2.7%	3.2%	3.7%	3.0%
Analgesics Anti-inflammatory	3.1%	5.1%	1.2%	1.5%	2.2%	2.6%
Analgesic Opioids	1.5%	3.3%	0.8%	2.2%	2.0%	2.9%
Endocrine and Metabolic Agents-Misc (Growth Hormone)		1.2%	1.0%	0.8%	1.0%	1.2%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)		1.4%	0.5%	0.8%	0.6%	0.9%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)		0.3%		0.1%	0.0%	0.1%
Dermatologics (Antipsoriatics-Systemic)		18.9%	10.3%	14.5%	19.1%	15.2%

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

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

*** See below for explanation of categories:

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

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

Non-Formulary: includes categories such as Non-Formulary

Other: includes categories such as Directed Intervention, Multiple Pharmacies, Multiple Prescribers, Other DUR related rejections

**** Denominator contains total drug prior authorization requests denied. Breakdown of Therapeutic Drug Classification categories is a sample of prior authorization claims data and is not inclusive of all drug classes. Denial percentages will not equal one hundred percent.

Summary of DURB Recommendations

July 13, 2022

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
April 2022	Proposed protocol for Hetlioz® (tasimelteon)	- The Board wanted more information about why young teens couldn't use pills and why teens and adults couldn't use the liquid	This information will be presented at the next meeting
	Proposed protocol for cysteamine products (Cystagon® and Procysbi®)	- The Board recommended the protocol	
	Proposed protocol for Revcovi® (elapegademase)	- The Board recommended the protocol	
	Proposed protocol for Luxturna® (voretigene neparvovec-rzyl)	- The Board recommended the protocol	
January 2022	Addendum for proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor products protocol	- The Board recommended the addendum to the protocol	
	Addendum for Spravato® (esketamine) protocol	- The Board recommended the addendum to the protocol	
	Proposed protocol for Gamifant® (emapalumab-lzsg)	- The Board recommended the protocol with a suggestion to change criterion #1 to emphasize "primary" HLH	An updated version was presented and approved at the following meeting.
	Proposed protocol for nitisinone products	- The Board recommended the protocol with suggestions to reword criteria #4 and #6	An updated version was presented and approved at the following meeting.
	Proposed protocol for Lucemyra® (lofexidine)	- The Board recommended the protocol with suggestions to criterion #4 and delete criterion #5	An updated version was presented and approved at the following meeting.
	Proposed protocol for Paxlovid® (nirmatrelvir/ritonavir)	- The Board approved the protocol	
	Proposed protocol for molnupiravir	- The Board approved the protocol	
October 2021	Addendum for Duchenne muscular dystrophy products	- The Board recommended the protocol with a suggestion to reword criterion #6	An updated version was presented and approved at the following meeting.

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Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed protocol for Aduhelm® (aducanumab)	- The Board recommended the protocol with a suggestion to change Mini-Mental State Examination (MMSE) scores from 24-30 to 24-29	An updated version was presented and approved at the following meeting.
	Proposed protocol for Bronchitol® (mannitol)	- The Board recommended the protocol with a suggestion to reword criterion #4	An updated version was presented and approved at the following meeting.
	Proposed protocol for Imcivree® (setmelanotide)	- The Board recommended the protocol	
	Proposed exclusion protocol for Stromectol® (ivermectin)	- The Board recommended the protocol contingent on sending out a "Dear Prescriber" letter	A "Dear Prescriber" letter will be sent with requests for this medication.
July 2021	Addendum for direct acting antiretrovirals (DAAs) for HCV protocol	- The Board recommended approval of the protocol	
	Addendum for Dupixent® (dupilumab) protocol	- The Board recommended approval of the protocol	
	Addendum for Vyondys® (golodirsen) protocol	- The Board recommended approval of the protocol with a change in the name to "Duchenne Muscular Dystrophy protocol"	An updated version was presented and approved at the following meeting
	Addendum for Epidiolex® (cannabidiol) protocol		
	Addendum for Cablivi® (caplacizumab) protocol	- The Board recommended approval of the protocol	
	Proposed protocol for Cabenuva® (cabotegravir/rilpivirine) injectable	- The Board recommended approval of the protocol with a rewording of criterion # A-d	An updated version was presented and approved at the following meeting
	Proposed protocol for biologic response modifier products used in plaque psoriasis	- The Board recommended approval of the protocol with a change in criterion #5. They also recommended alerting the New Jersey Dermatology Society about the change	An updated version was presented and approved at the following meeting
	Proposed protocol for Lumizyme® (alglucosidase alfa)	- The Board recommended approval of the protocol	
	Proposed protocol for Myalept® (metreleptin)	- The Board recommended approval of the protocol	

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