NEW JERSEY DRUG UTILIZATION REVIEW BOARD
VIRTUAL PLATFORM

October 19, 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 July 20, 2022, meeting

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

V. Secretary's report (page 8)

VI. Old Business
- A. Ivermectin utilization report (January – July 2022) [page 9]
- B. MCO response to PA denials reports/State's churn rate report (pages 10-12)
- C. Addendum to calcitonin gene-related peptide (CGRP) receptor antagonists protocol (pages 13-16)
- D. Summary of DURB suggested changes to proposed protocols (see links to protocols below) [page 17]
  - i. Vuity® (pilocarpine ophthalmic)
  - ii. Complement inhibitor products or PNH (Soliris®, Empaveli®, Ultomiris®)
  - iii. Bylvay® (odevixibat)
- E. Semaglutide utilization for weight loss? (July 2021 thru June 2022) [page 18]

VII. New Business
- A. Proposed protocol for Glucagon-like peptide 1 (GLP-1) agonists used in T2D (pages 19-20)
- B. Proposed protocol for biologics used in moderate to severe asthma treatment (pages 21-22)
- C. Proposed protocol for Cholbam® (cholic acid) [page 23]
- D. Proposed protocol for Crysvita® (burosumab) [pages 24-25]

VIII. DURB Annual Summary Review for SFY 2022 (Board members only)

IX. A. Informational Highlights/Reports
1. Gainwell Technologies/NJ HMO 2nd Quarter 2022 Prior Authorization Report (page 26)
2. Summary of DURB Action Items (pages 27-28)
3. (a) DHS, DHSS and MCO Programs Top Drugs Report/Physicians Administered Drugs (by amount paid and by category)
   (b) Antiviral drugs by amount paid

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 continuously updated

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

X. Updated Materials:
   a. Proposed protocol for Vuity® (pilocarpine ophthalmic) – approved July 2022
      https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/10-2022/Vuity_Approved_Protocol.pdf

   b. Proposed protocol for complement inhibitor products (Soliris®, Empaveli®, Ultomiris®) – approved July 2022
      https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/10-2022/PNH_products_approved_protocol.pdf

   c. Proposed protocol for Bylvay® (odevixibat) – approved July 2022
      https://www.state.nj.us/humanservices/dmahs/boards/durb/agendas/10-2022/Bylvay_Approved_Protocol.pdf

July 13, 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 April 20, 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
Secretary's Report 3		- The Commissioners have signed off on DURB-recommended protocols for: October 2020, April 2021, July 2021, and October 2021. - The Department is working with the Commissioners to review and sign off on DURB-recommended protocols for: January 2022 and April 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - Dr. Swee requested an explanation for reappointment and replacement of Board members. Dr. Lind responded that a special staff member, Adam Neary, was assigned strictly to review and modify the reappointment process. - The Commissioners have also approved the DURB Annual Report for 2021. - Under the Governor's Ending the HIV Epidemic Initiative, effective July 1, 2022, New Jersey and fee-for-service, as well as New Jersey Medicaid MCOs will not require any prior authorization or step therapy for all FDA-approved HIV medications, including medications for Pre-exposure Prophylaxis (PrEP) or Post-exposure Prophylaxis (PEP). Safety edits will still be in place. NJ Medicaid MCOs will also be required to provide a 90

July 13, 2022 DURB Meeting Summary (draft)

Issue	Action	Notes
		day supply of a member's existing medication(s) prior to disenrollment, if requested by member within 30 days. Safety edits will still be in place. Retrospective review will take place for HIV meds as per CMS requirements. - Dr. Marcus requested clarification of this process. Ed Vaccaro, R.Ph, explained further concluding that this is a positive program for the patient.
Old Business		
Hetlioz follow-up		In response to the Board's request at the April 2022 meeting, Vanda Pharmaceuticals provided information on why the liquid formulation for Hetlioz was limited to 3 to 15 year-olds, and adults were limited to the capsules:the pharmacokinetic profile of oral suspension has not been directly compared to the capsules; therefore, capsules are the only dosage form recommended for use in adults. The Board strongly recommended that the State should allow providers to make the judgment about whether a capsule or liquid would be preferred for their patient population.
MCOs Denial Report		Ms. Desai, the State's Pharmaceutical Chief, informed the Board that the MCOs needed more time to review the denials report since this will be done manually. Ms. Desai also explained that Amerigroup, who had higher percentage of non-formulary denials went back and reviewed each denial manually, they found a glitch which was corrected, therefore their denial percentage is now in line with the other MCOs.
Ivermectin Utilization Report		The Board reviewed a report on ivermectin utilization for the month of December 2021. Based on the report, Dr. Swee pointed out that it is still being used for other indications. Dr. Emenike explained that it is usually a very complicated process to extract diagnoses from the system hence we did our best to identify what was going on. Dr. Swee suggested that another report be presented at the next meeting for clarity.
COVID-19 newsletter	Approved	The Board reviewed a provider's newsletter on the new oral COVID-19 medications. In response to Dr. Swee's question if it had already been distributed, Ms. Desai

July 13, 2022 DURB Meeting Summary (draft)

Issue	Action	Notes
		responded that the newsletter is still pending approval by the Assistant Commissioner of DHS.
New Business		
(A) Addendeum for Calcitonin Gene-Related Peptide (CGRP) Antagonist		The Board reviewed an addendum for calcitonin gene-related peptide (CGRP) antagonist - addition of 3 new products to this class of medications. Dr. Swee requested Dr. Moynihan's opinion, to which, Dr. Moynihan responded that she will review the protocol more closely. Dr. Swee requested that a flowchart should be created to make the protocol easier to understand. The Board tabled this protocol for the next meeting.
(B) Proposed protocol for Vuity® (pilocarpine hydrochloride 1.25% ophthalmic solution)	Approved	The Board reviewed a proposed protocol for Vuity, a product indicated for the treatment of presbyopia. Ms. Olson recommended to add "prescribed by or in consultation with an optometrist." The Board agreed. Dr. Swee suggested that the State provide a report in six months to evaluate the utilization of this medication. The Board recommended the protocol pending the change.
(C) Proposed protocol for Paroxysmal Noctural Hemoglobinuria products	Approved	The Board reviewed a proposed protocol for products used in the treatment of paroxysmal nocturnal hemoglobinuria (PNH) - Epaveli, Soliris and Ultomiris. Dr. Emenike explained that the purpose of the protocol is to ensure that diagnosis is confirmed by flow cytometry. Dr. Marcus questioned why ~~is~~ the REMS program is associated with all three medications Jamie Tobitt (Medical Affairs at Apellis Pharmaceuticals) explained that REMS program for Empaveli ensures that patients are properly vaccinated against encapsulated bacteria; ; patients are aware of symptoms in case those infections occur and since the medication is self-administered, the patients are aware of how to receive, store, administer and dispose of the medication properly. Dr. Marcus questioned whether the REMS program would be ongoing every time patients get the medication. Mr. Tobitt explained that patients are initially educated then ongoing monitoring takes place. Dr. Marcus asked if any specific pneumococcal vaccine is recommended (i.e., newer one has more subgroups that it covers). Mr. Tobitt stated that the package insert for Empaveli specifies which vaccinations are necessary and depending on what patients have already received and also what they may need in addition to receiving the drug. Mr. Binoy Daniel (Alexion pharmaceuticals) also informed the Board that

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>the REMS program for Soliris and Ultomiris is the same as mentioned. He went on to explain that the vaccination requirements is in accordance with the the Advisory Committee on Immunization Practices (ACIP) guidelines. The Board decided to use the ACIP guidelines as part of the criteria for all three medications.
The Board recommended the protocol pending this update.</td></tr>
<tr><td>(D) Proposed protocol for Bylvay® (odevixibat)</td><td>Approved</td><td>The Board reviewed a proposed protocol for Bylvay, a product indicated for the treatment of progressive familial intrahepatic cholestasis (PFIC). Dr. Emenike explained that the purpose of the protocol is to ensure confirmation of diagnosis of PFIC by genetic testing and significant pruritus. Dr. Swee had concerns about how a parent or 3 month old child could report pruritius. Dr. Lind suggested that the protocol should state "patient has significant pruritus if they are able to report." The Board recommended to accept this change. Dr. Swee requested to make the change in continuation of therapy as well.
The Board recommended the protocol pending these changes.</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>Dr. Swee requested an update on the PA denial report. Ms. Desai responded that MCO pharmacy directors requested additional time because they had to review the data manually. Amerigroup had manually reviewed each denial and found a glitch which was corrected, therefore their percentage is now in line with other MCOs.

The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 1st quarter 2022 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>0.6</td><td>8.1</td><td>8.1</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>35.7</td><td>9.5</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>34.9</td><td>11.4</td></tr>
<tr><td>Horizon</td><td>0.7</td><td>35.0</td><td>11.5</td></tr>
<tr><td>UHC</td><td>0.9</td><td>43.8</td><td>14.3</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>31.7</td><td>9.1</td></tr>
</table></td></tr>
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July 13, 2022 DURB Meeting Summary (draft)

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (July 2021 thru April 2022).
There were no comments.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for April 2022 (FFS)/March 2022 (MCOs) was provided for review. Dr. Marcus commented that he would like to see three areas of denials, antihyperlipidemics, antidiabetics and ulcer drugs.

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>April 2022</td><td>$9,695,654</td><td>$10,210,547</td></tr>
<tr><td>MCOs</td><td>March 2022</td><td>$112,583,948</td><td>$158,293,791</td></tr>
</table>
</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Dr. Marcus suggested that the Board review possible use of semaglutide for weight loss among the Medicaid population.
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>Follow up items:</td><td></td><td>A. Updated ivermectin utilization report
B. Dr. Moynihan to review CGRP antagonists protocol
C. Vuity utilization report in six months
D. Semaglutide (Wegovy) utilization for use for weight loss report</td></tr>
</table>

NEW JERSEY DRUG UTILIZATION REVIEW BOARD

October 19, 2022

Secretary's Report:

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

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

3. Proposed dates for 2023 DURB meetings:
   Wednesday, January 25, 2023
   Wednesday, April 19, 2023
   Wednesday, July 19, 2023
   Wednesday, October 18, 2023

Ivermectin Utilization Report:

January – July 2022

This report summarizes pharmacy claims for ivermectin during this time period. As many pharmacy claims do not have a diagnosis attached to them, medical claims within 30 days prior by same provider were reviewed to identify the ivermectin indication. Use of ivermectin was categorized into the following categories:

- FDA Approved indications – ex: onchocerciasis, strongyloidiasis
- Off-label indications [evidence based; compendia approved] – ex: scabies, lice
- Suspected Covid-19 – ex: viral infection, novel coronavirus
- Unknown diagnosis – medical claims diagnosis was unrelated to any ivermectin indications

DIAGNOSIS	NUMBER OF MEDICAL CLAIMS
FDA APPROVED INDICATION	5
OFF-LABEL INDICATION	103
SUSPECTED COVID-19	30
UNKNOWN DIAGNOSIS	232
TOTAL	**370**

Based on 264 ivermectin claims identified during this period (January to July 2022), 370 medical claims were reviewed. None of the claims were for the higher quantities used for treatment of Covid-19. There were a total of 19 claims that had Covid-19 diagnoses submitted on a claim as well as 11 claims for suspected viral infection.

MCO Collaborative response

Supplementing the Quarterly DUR denials report: -

Background: -

- Each MCO manages the pharmacy benefit through a formulary developed by a P&T committee and these formulary files are submitted to DMAHS quarterly, and any revisions are reviewed by DMAHS.
- Per 1927(d)(5) of the SSA each plan has an exception process available to request a drug not listed on the formulary and all prior approval process are DMAHS reviewed and approved
- Each MCO provides quarterly to DMAHS the PA denial report. This includes all Prior auth requests received during that quarter in the DMAHS provided template
- The board has expressed concerns on MCO denials, and we have each looked further into our processes to ensure that we are following approved policies and criteria for the formulary requests.
    - The two questions as requested by Zankhana as additional info to respond to the board are included in the table below.

Q4 2021 data	Aetna	Amerigroup	Horizon	UHC	WellCare
Total PA requests received	3,926	8,018	21,784	8399	5679
Received requests denied (only formulary denials)	450	741	2732	1212	490
Denied PA re-reviewed and approved (either PA or appeals in within 6 months)	105	188	519	295	130
1- What percentage of PA requests (for denied claims) are eventually approved for the initial drug?	23.3%	25.3%	19.0%	24.3%	26.53%
2- Once all necessary information is received by MCO – how long is the turnaround time for approval (q4 2021 data)	6.18 Hours	6.68 Hours	3.3 hours	5.6 hours	7.09 hours

Summary of the data review process for these responses-

1. All of us collaborated on this approach to ensure we were giving the board similar data to review and for consistency across all plans we have shared data from Q4 2021. We looked at all denials in Q4 for formulary drugs and then looked to see how many of these were approved either via a P2P, subsequent PA or an appeal within that same quarter and the next quarter (Q4 21 and Q1 22).

2. For the average TAT, we used the same quarter Q4 2021, and this is the actual number of hours from the time we receive all the information on a case to review to the time of decision and notification to providers and members.

MCO Churn Report:

DMAHS reviewed MCO churn data from January –August 2022. On average, **0.33%** of Medicaid members transfer between MCO plans each month.

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

Approved April 2019
Updated October 2020
Updated October 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)**
   d. Addition of new FDA-approved indications

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:

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

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

- Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months
- There is documented inadequate response, or intolerable side effects, 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)
  - Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine)

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

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

- Headache occurring less than 15 days per month with 4 to 14 migraine days per month
- there is documented inadequate response, or intolerable side effects, 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)
  - Antidepressants (e.g., amitriptyline, nortriptyline, venlafaxine, duloxetine)

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

Acute Migraine Treatment (Ubrelvy, Nurtec ODT):

- 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:**
  - Patient does not experience more than 8 migraine days per month
  - Patient is not concomitantly taking a strong CYP3A4 inhibitor (e.g., clarithromycin, ketoconazole)

- **Nurtec ODT:**
  - Patient does not experience more than 15 migraine days per month

Episodic Cluster Headaches Treatment: (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

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Continuation of therapy:

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

2. Medication is prescribed 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. For acute migraine treatment: medication will not be used in combination with another biologic CGRP antagonist for the acute treatment of migraines

4. For migraine prevention: medication will not be used in combination with another biologic CGRP antagonist for the prevention of migraines.

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/

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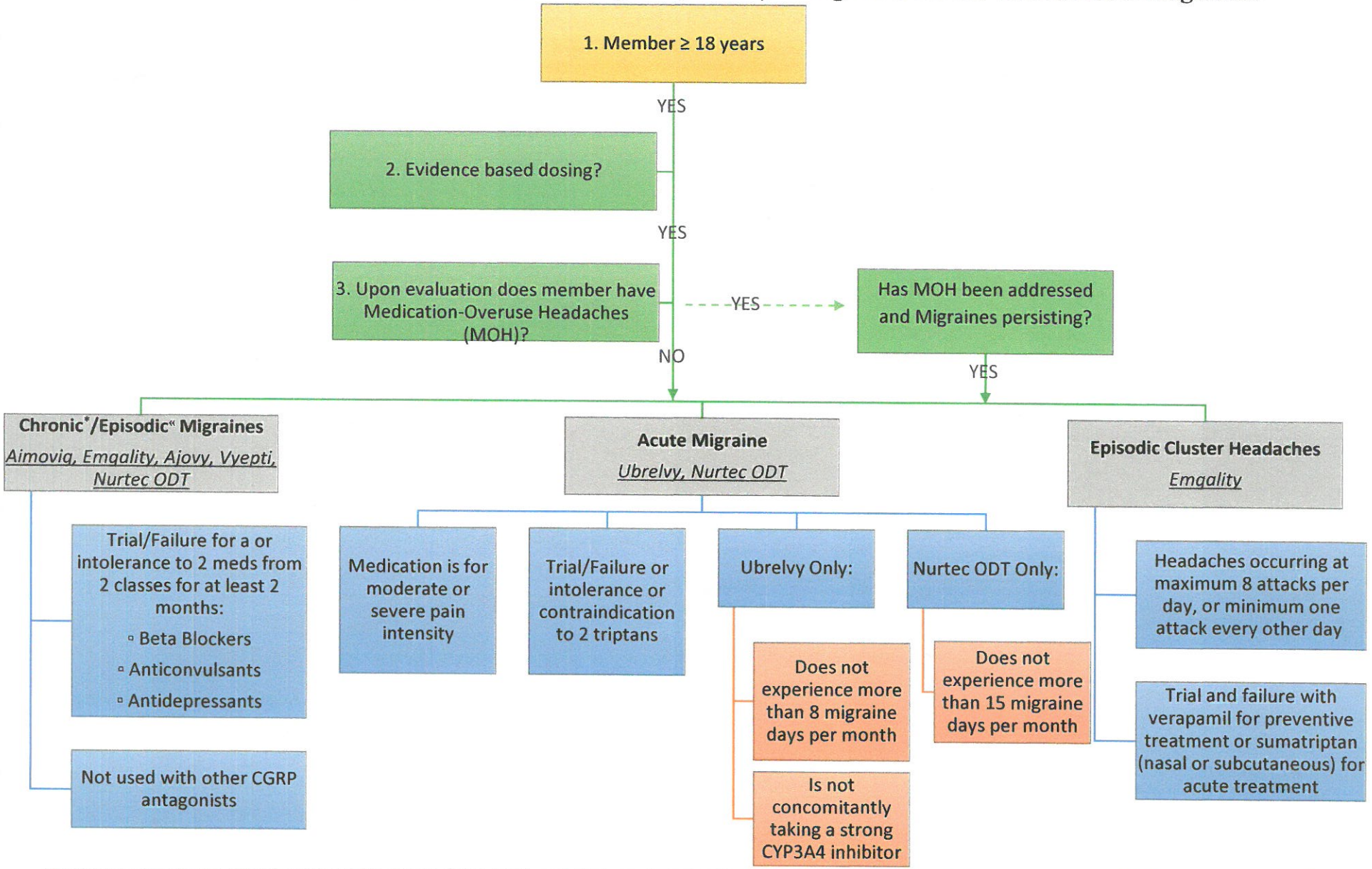
Protocol for Calcitonin Gene-Related Peptide (CGRP) Antagonists for the Treatment of Migraines



Continuation of therapy:

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

*Chronic Migraine defined as Headache occurring on 15 or more days per month with at least 8 migraine days per month for more than 3 months

« Episodic Migraine defined as Headache occurring less than 15 days per month with 4 to 14 migraine days per month

Summary of Board-Suggested Changes to Proposed Protocols

July 2022

A. Addendum to calcitonin gene-related peptide (CGRP) receptor antagonists protocol: The Board tabled the protocol with a suggestion to create a flowchart for better understanding.

B. Vuity (pilocarpine ophthalmic): The Board recommended the protocol with a suggestion to add optometrist to criterion #3

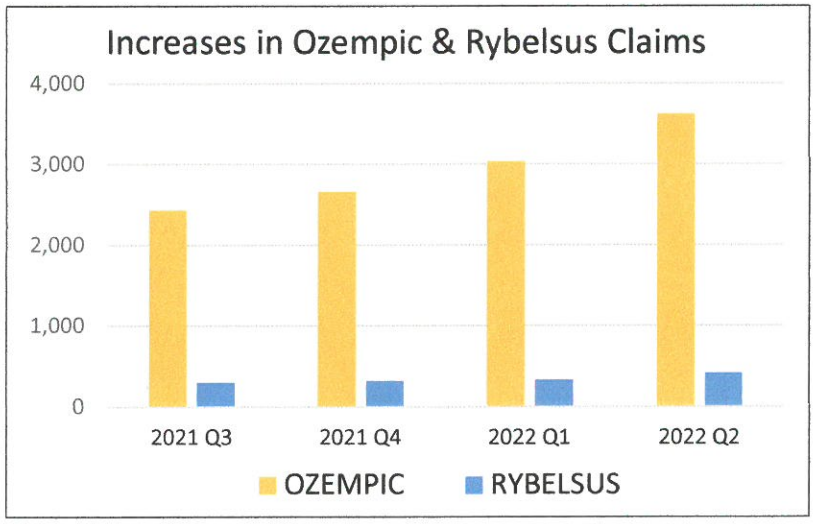
C. Proposed protocol for complement inhibitor products (Soliris®, Empaveli®, Ultomiris®): The Board recommended the protocol with a suggestion to follow Advisory Committee on Immunization Practices (ACIP) guidelines for determining vaccination needs for the three products

D. Bylvay® (odevixibat): The Board recommended the protocol with a suggestion to add "if able to report" to criterion #3

FFS & MCO paid claims for semaglutide, SFY2022 (July 2021-June 2022), as of 10/6/2022

Excludes claims with TPL or Part D

Brand Name	Quarter	Claims	Days Supply	Qty	Avg Qty Per Claim	Amt Paid
OZEMPIC	2021 Q3	2,430	83,190	6,009	2.5	$ 2,219,223
OZEMPIC	2021 Q4	2,659	90,615	6,826	2.6	$ 2,490,786
OZEMPIC	2022 Q1	3,033	102,578	7,671	2.5	$ 2,908,596
OZEMPIC	2022 Q2	3,621	121,036	9,208	2.5	$ 3,468,053
RYBELSUS	2021 Q3	300	9,564	9,584	31.9	$ 264,393
RYBELSUS	2021 Q4	318	10,080	10,080	31.7	$ 277,354
RYBELSUS	2022 Q1	332	10,500	10,500	31.6	$ 304,194
RYBELSUS	2022 Q2	416	13,326	13,326	32.0	$ 386,110



Proposed Protocol for Glucagon-Like Peptide-1 Receptor Agonists for Type 2 Diabetes

October 2022

Adlyxin (lixisenatide)
Bydureon, Bydureon Bcise (exenatide Microspheres)
Byetta (exenatide)
Mounjaro (tirzepatide)
Ozempic (semaglutide)
Rybelsus (semaglutide)
Soliqua (insulin glargine/lixisenatide)
Trulicity (dulaglutide)
Victoza (liraglutide) – 10 years of age and older
Xultophy (insulin degludec/liraglutide)

Background:
The GLP-1RAs have been shown to significantly improve glycemic parameters and reduce body weight. These agents work by activating GLP-1 receptors in the pancreas, which leads to enhanced insulin release and reduced glucagon release-responses that are both glucose-dependent-with a consequent low risk for hypoglycemia.

Criteria for approval:

1. Diagnosis of type 2 diabetes mellitus; **AND**

2. Patient meets the age limit for requested product when appropriate; **AND**

3. Patient cannot use metformin for one of the following reasons:
    a. Therapeutic failure or, suboptimal response, to at least 3 months of metformin at maximum or highest tolerated dose
    b. Contraindication or intolerance to any metformin use
    c. Has a diagnosis of Crohn's disease, irritable bowel syndrome, or Ulcerative Colitis
    d. Has severe renal impairment (eGFR below 45ml/min/1.73m^2); **AND**

4. Will not be used concurrently with other GLP-1 (glucagon-like peptide-1) agonists

5. Documentation of HbA1C $\geq$ 7 measured within the past 6 months**; AND**

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

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Continuation of therapy:

1. Documentation of positive clinical response to therapy (HbA1C has improved from baseline)

2. Patient has no contraindication for treatment

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

NOTE: There is a BOXED WARNING RISK OF THYROID C-CELL TUMORS. GLP-1 analogues are associated with thyroid cancer in patients with diabetes.

References:
1. Adlyxin [package insert]. Sanofi-Aventis U.S. LLC; Bridgewater, NJ: July 2021.
2. Bydureon BCise [package insert]. AstraZeneca Pharmaceuticals LP; Wilmington, DE: July 2021
3. Byetta [package insert]. AstraZeneca Pharmaceuticals LP; Wilmington, DE: June 2021.
4. Mounjaro [package insert]. Lilly USA, LLC, Indianapolis, IN: May 2022.
5. Ozempic [package insert]. Novo Nordisk Inc.; Plainsboro, NJ: April 2021.
6. Rybelsus [package insert]. Novo Nordisk Inc.; Plainsboro, NJ: July 2021.
7. Soliqua [package insert]. Sanofi-Aventis U.S. LLC; Bridgewater, NJ: November 2016
8. Trulicity [package insert]. Eli Lilly and Company; Indianapolis, IN: April 2021.
9. Victoza [package insert]. Novo Nordisk Inc.; Plainsboro, NJ: November 2020.
10. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
11. American Diabetes Association. Standard of Medical Care in Diabetes - 2021. Diabetes Care 2021;44 (Supplement 1).

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Proposed Protocol for Biologics Used in Moderate to Severe Asthma

October 2022

Cinqair (reslizumab) ≥ 18 years
Dupixent (dupilumab) ≥ 6 years
Fasenra (benralizumab) ≥ 12 yee
Nucala (mepolizumab) ≥ 6 years old
Tezspire (tezepelumab-ekko) ≥ 12 years
Xolair (omalizumab) ≥ 6 years old

Background:
Severe asthma is present, by definition, when adequate control of asthma cannot be achieved by high-dose treatment with inhaled corticosteroids and additional controllers (long-acting inhaled beta 2 agonists, montelukast, and/or theophylline) or by oral corticosteroid treatment (for at least six months per year) or is lost when the treatment is reduced.

Criteria for approval:

1. Confirmed Diagnosis of one of the following:
    - **a.** Severe asthma with Eosinophilic phenotype with blood eosinophil counts greater than 150 cells/microliter **OR**
        - **i.** Moderate to Severe asthma **(Dupixent)**
        - **ii.** Severe asthma **(Fasenra, Cinqair, Nucala)**
    - **b.** Oral corticosteroid dependent asthma **(Dupixent) OR**
    - **c.** Severe asthma **(Tezspire) OR**
    - **d.** Moderate to severe persistent asthma with one of the following:
        - **i.** a positive skin test **OR**
        - **ii.** in vitro reactivity to a perennial aeroallergen
    - **e.** **Moderate to severe persistent asthma with one of the following: (Xolair)**
        - **i.** **a positive skin test OR**

        in vitro reactivity to a perennial aeroallergen
2. Medication is used as add on therapy for patients on conventional asthma treatment
3. Medication and dosage is used for the appropriate age
4. Medication is prescribed by or in consultation with a pulmonologist, allergist, or immunologist

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5. Must have experienced ≥ 2 exacerbations within the last 12 months despite meeting all of the following (exacerbation is defined as requiring the use of oral/systemic corticosteroids, urgent care/hospital admission, or intubation):
    a. Adherence to two long-term controller medications, including a high-dose inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA) or a long-acting muscarinic antagonist (LAMA) OR
    b. Patient must have had an adequate trial (at least 90 consecutive days) of a leukotriene modifier or a long-acting muscarinic antagonist (LAMA) as a third long-term controller medication

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. Documentation of positive clinical response to therapy by at least one of the following:
    a. A decrease in frequency of exacerbation from baseline
    b. Improved lung function, defined as FEV1 increase of at least 100ml over baseline

2. Decreased utilization of rescue medications

References:

1. Cinqair [package insert]. Teva Respiratory, LLC; West Chester, PA: June 2020
2. Dupixent [package insert]. Regeneron Pharmaceuticals, Inc. Tarrytown, NY: October 2021
3. Fasenra [package insert] AstraZeneca Pharmaceuticals, LP; Wilmington, DE: February 2021
4. Nucala [package insert]. GlaxoSmithKline LLC; Philadelphia, PA: October 2021.
5. Tezspire [package insert]. AstraZenaca AB; Sodertalie, Sweden SE; December 2021
6. Xolair [package insert]. Genentech, Inc.; South San Francisco, CA; July 2021
7. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2016. Updated periodically
8. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. European Res J 2020;55(1):1-21. https://pubmed.ncbi.nlm.nih.gov/31558662/ Accessed on October 4, 2022
9. McGregor MC, Krings JG, et al. Role of Biologics in Asthma. American Journal of Respiratory and Critical Care Medicine. December 2018; 199 (4):433-445.
10. Gupta SK, Mitra K. Criteria for Steroid Dependence. Chest Journal.1988; 93 (4):896

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Proposed Protocol for Cholbam® (cholic acid)

October 2022

Background: *Bile acid synthesis disorders (BASDs) are a group of rare metabolic disorders characterized by defects in the creation (synthesis) of bile acids.*

Cholbam *is a bile acid indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) and as an adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.*

Criteria for approval:

1. Patient has a documented diagnosis of:
   a. Bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs)
      i. Diagnosis is confirmed by mass spectrometry or other biochemical testing, genetic testing, or enzyme assay
      ii. Liver dysfunction, with labs showing elevated transaminases, bilirubin, presence of cholestasis at baseline have been submitted

      OR

   b. Peroxisomal disorders, including Zellweger spectrum disorder in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption
      i. Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing
      ii. The patient exhibits manifestations of liver disease

2. Medication is prescribed by or in consultation with a hepatologist or gastroenterologist

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

Continuation of therapy:

1. Patient is responding positively to therapy such as evidenced by improvement symptoms, lab values, liver function and/or cholestasis

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. Cholbam [prescribing information]. Asklepion Pharmaceuticals LLC. Baltimore, MD 21202. March 2015
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically

Proposed Protocol for Crysvita® (burosumab-twza)

October 2022

Background: *X-linked hypophosphatemia (XLH) is a rare, hereditary, progressive musculoskeletal disease that often causes pain and short stature, as well as decreased physical function, mobility, and quality of life.*

Crysvita *is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for:*

- *The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.*
- *The treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.*

Criteria for approval:

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

2. Medication is prescribed by or in consultation with a geneticist, nephrologist, or endocrinologist

3. The patient does not have any contraindications to therapy:
    a. Concomitant use with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol)
    b. Serum phosphorus within or above the normal range for age
    c. Severe renal impairment or end stage renal disease, defined as an estimated glomerular filtration rate (GFR) of <30 mL/min in children or creatinine clearance (CrCl) < 30mL/min in adults

For X-linked Hypophosphatemia (XLH):

1. Patient has a diagnosis of X-linked hypophosphatemia (XLH) confirmed by one of the following:
    a. Genetic testing; OR
    b. Elevated levels of serum fibroblast growth factor 23

2. Patient is 6 months of age or older

3. Pediatric patients must have had an inadequate response from oral phosphate and active vitamin D analogs

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For Tumor-induced Osteomalacia (TIO):

4. Patient has a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors confirmed by one of the following:
    a. Genetic testing; OR
    b. Elevated levels of serum fibroblast growth factor 23

5. The patient is 2 years of age or older

6. The tumor cannot be curatively resected or localized (located)

Continuation of therapy:

1. Increase in serum phosphorus levels

2. Improvement in symptoms (e.g., skeletal pain, linear growth, etc.), and/or improvement in radiographic imaging

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. Crysvita [prescribing information]. Kyowa Kirin, Inc. Bedminster, NJ 07921 June 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Dahir K, Roberts MS et al. X-Linked Hypophosphatemia: A New Era in Management. Journal of the Endocrine Society, Volume 4, Issue 12, December 2020, bvaa151. Accessed on September 6, 2022 at: https://doi.org/10.1210/jendso/bvaa151

NJ DURB Prior Authorization Denial Report - 2nd Quarter 2022 (April - June)

	FFS	Aetna	Amerigroup	Horizon	UHC	Wellcare
Total # of Enrolled Beneficiaries	**64,599**	**129,891**	**247,308**	**1,144,594**	**411,525**	**107,121**
Total # of Pharmacy Claims Processed	**464,381**	**508,348**	**1,081,664**	**3,776,149**	**1,048,574**	**417,917**
Total # of Members Requesting Prior Authorization*	**1,374**	**3,005**	**7,022**	**18,395**	**7,352**	**2,013**
Total Prior Authorizations Requests Received**	**2,914 (0.6%)**	**4,202 (0.8%)**	**9,955 (0.9%)**	**26,893 (0.7%)**	**9,411 (0.9%)**	**2,997 (0.7%)**
Received Requests Denials	**226 (7.8%)**	**1,720 (40.9%)**	**3,820 (38.4%)**	**9,179 (34.1%)**	**4,227 (44.9%)**	**996 (33.2%)**
Without Non-formulary Denials	**226 (8%)**	**452 (11%)**	**1,309 (13.1%)**	**3,321 (12.3%)**	**1,543 (16.4%)**	**297 (10%)**
Percentage Breakdown of Denials***						
Clinical Criteria Not Met	120 (53.1%)	428 (24.9%)	1,102 (28.8%)	3,049 (33.2%)	1,310 (31.0%)	295 (29.6%)
Excluded Benefit	106 (46.9%)	23 (1.3%)	175 (4.6%)	272 (3.0%)	233 (5.5%)	2 (0.2%)
Non-formulary	0 (0.0%)	1,268 (73.7%)	2,511 (65.7%)	5,858 (63.8%)	2,684 (63.5%)	699 (70.2%)
Other	0 (0.0%)	1 (0.1%)	32 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Denials by Therapeutic Drug Classification****						
Antihyperlipidemics	4.4%	5.5%	4.9%	2.9%	4.4%	2.9%
Antidepressants		0.9%	1.2%	2.1%	1.2%	0.3%
Antihypertensives	1.3%	0.8%	0.5%	0.8%	2.6%	0.7%
Antianxiety		0.4%		0.3%	0.2%	0.0%
Antidiabetics (oral and insulin)	1.3%	7.8%	3.9%	17.8%	12.6%	21.7%
Anticoagulants	0.4%	0.2%		0.1%	0.3%	0.7%
Thyroid agents		0.3%	0.2%	0.3%	0.3%	0.0%
Ulcer Drugs/Antispasmodics/Anticholinergics	29.6%	2.4%	11.0%	1.8%	1.9%	1.1%
ADHD/Anti-Narcolepsy/AntiObesity/Anorexiants		8.2%	3.2%	3.2%	2.1%	5.1%
Antipsychotic/Antimanic agents	3.5%	1.1%	0.3%	3.2%	1.7%	0.8%
Antiasthmatic and Bronchodilator agents	5.3%	7.2%	2.2%	8.0%	10.0%	5.1%
Antivirals (includes both HIV and Hep C)		1.1%	0.1%	1.1%	0.8%	2.2%
Digestive Aids (Digestive Enzymes)	0.4%	0.2%	0.1%	0.1%	0.1%	0.3%
Anticonvulsants		3.2%	0.8%	2.0%	2.4%	1.9%
Migraine Products		2.9%	2.4%	3.6%	4.6%	2.2%
Analgesics Anti-inflammatory	4.4%	3.1%	0.9%	1.6%	2.4%	4.1%
Analgesic Opioids	0.9%	3.6%	1.1%	2.0%	2.2%	3.6%
Endocrine and Metabolic Agents-Misc (Growth Hormone)		1.1%	1.1%	1.2%	1.6%	1.6%
Psychotherapeutic And Neurological Agents - Misc (Multiple Sclerosis agents)		1.7%	0.5%	0.8%	0.5%	1.0%
Respiratory Agents-Misc (Cystic Fibrosis Agent – Combinations)		0.1%	0.1%	0.0%	0.0%	0.2%
Dermatologics (Antipsoriatics-Systemic)	0.4%	15.6%	9.7%	15.1%	17.3%	13.0%

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

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

*** See below for explanation of categories:

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

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

Non-Formulary: includes categories such as Non-Formulary

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

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

Summary of DURB Recommendations

October 19, 2022

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
July 2022	Addendum to calcitonin gene-related peptide (CGRP) receptor antagonist protocol	- The Board tabled the protocol with a suggestion to create a flow chart that will make it easier to understand	
	Proposed protocol for Vuity® (pilocarpine ophthalmic)	- The Board recommended the protocol with a suggestion to add optometrist to criterion #3	An updated version will be presented at the next meeting
	Proposed protocol for complement inhibitor products (Soliris®, Empaveli®, Ultomiris®)	- The Board recommended the protocol with a suggestion to follow Advisory Committee on Immunization Practices (ACIP) guidelines for determining vaccination needs for the three products	An updated version will be presented at the next meeting
	Proposed protocol for Bylvay® (odevixibat)	- The Board recommended the protocol with a suggestion to add "if able to report" to criterion #3	An updated version will be presented at the next meeting
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	

Summary of DURB Recommendations

Meeting Date	Action Item	Status/DURB recommendation	Impact/Comments
	Proposed protocol for Paxlovid® (nirmatrelvir/ritonavir)	- The Board approved the protocol	An updated version was presented and approved at the following meeting.
	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.
	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 - The Board recommended the protocol	An updated version was presented and approved at the following meeting.
	Proposed protocol for Imcivree® (setmelanotide)	- 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.
	Proposed exclusion protocol for Stromectol® (ivermectin)		