July 13, 2022 DURB Meeting Summary

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		- 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-

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		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

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		responded that the newsletter is still pending approval by the Assistant Commissioner of DHS.
New Business		
(A) Addendum 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) – Empaveli, 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 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 pruritus'. 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><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td><td>%W/O NF</td></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>
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<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>
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<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>
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