October 19, 2022 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend: Dr. Moynihan, 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 July 13, 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 Department is working with the Commissioners to review and sign off on DURB-recommended protocols for: January 2022, April 2022, and July 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - The proposed dates for **2023** DURB meetings are as follows: - Wednesday, January 25 - Wednesday, April 19 - Wednesday, July 19 - Wednesday, October 18. If the Board approves these dates, it will be published for the general public. - Dr. Swee wanted to know when the Board will know if these meetings will be in person or remote. Dr. Emenike responded that nothing has changed but the State will let us know prior to the January meeting. - The Board approved the proposed dates.

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		- The DURB SFY 2021 annual report was signed off by the DHS and DOH Commissioners. - Dr. Marcus wanted to know what the Governor "ending the HIV Epidemic Initiative" means. Mr. Vaccaro, R.Ph., explained that all prior authorization for this class of drugs has been removed; patients will be allowed to receive up to 90-day supply if they request it within 30 days of dis-enrolling from Managed Care.
Old Business		
Ivermectin utilization report (January – July 2022)		The Board reviewed a follow-up report for ivermectin utilization for the period of January 2022 to July 2022. They concluded that there was little use of the product for COVID-19 which was a prior concern and reason for the report.
MCO Collaborative Response		The Board reviewed a collaborative report from the MCOs in response to questions related to the quarterly PA denial reports. Dr. Swee expressed concern about the disparity among the MCO plans. Dr. Lind cautioned against making conclusions about the PA rates because of the different processes and approach by individual plans. The Board requested similar report quarterly. Dr. Swee said that he was surprised by the churn rate of 0.33 percent, which he said, was low compared to the impression we were previously given.
Proposed Protocol addendum to Calcitonin Gene-Related Peptide (CGRP) antagonists for migraines	Approved	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) used in the treatment of migraines. Dr. Swee said that the updated protocol with the accompanying algorithm was much better. He also informed the Board that neurologists say the products are effective and are leaning towards using them more. So, the Board will keep a close eye on the utilization. To accomplish this, he requested another utilization report in three to six months. The Board approved the addendum.
Paid Claims for semaglutide in SFY 2022 (July 2021-June 2022)		In a previous meeting, Dr. Marcus expressed concern about the use of semaglutide formulations (Ozempic and Rybelsus) for weight loss even though they were not approved for that indication. Although there was a 30% increase in utilization from July 2021 thru June 2022, there was no way to confirm this was due to inappropriate use. The Board requested a follow-up report for the next meeting.

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New Business		
(A) Proposed protocol for Glucagon-Like Peptide-1 receptor agonists for T2D	Approved	The Board reviewed a proposed protocol for glucagon-like peptide-1 receptor (GLP-1) agonists used in the treatment of type 2 diabetes (T2D). The Board recommended that criterion #3 should be reworded to read: "Patient has/had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons:" Dr. Niki Patel, medical representative with Novo Nordisk informed the Board that the 2022 American Diabetic Association (ADA) guidelines recommends initiating treatment with GLP-1 agonists or sodium–glucose cotransporter 2 (SGLT2) inhibitors for patients with cardiovascular disease, atherosclerotic, or heart failure regardless of their baseline A1C, or metformin regimen. Dr. Emenike responded that although these products and SGLT2s are recommended for cardiovascular patients, they would not primarily be the first choice for the purpose of this protocol – general guideline for T2D. Dr. Swee recommended removal of criterion #1 under "continuation of therapy" which required the "documentation of positive response to therapy (HbA1C has improved from baseline). The Board recommended the protocol pending suggested changes.
(B) Proposed protocol for Biologics Used in Moderate to Severe Asthma	Approved	The Board reviewed a proposed protocol for biologics used in the treatment of moderate to severe asthma. The Board recommended the protocol.
(C) Proposed protocol for Cholbam® (cholic acid)	Approved	The Board reviewed a proposed protocol for Cholbam, a medication indicated for bile acid synthesis disorders (BASDs). Dr. Swee raised concern again about the monitoring requirement in the "continuation of therapy" section of the protocol. He stated that providers do not give drugs that are not working. Dr. Emenike explained to the Board that unlike providers on the Board and others in NJ, our experience at MEP with some prescribers in the Medicaid network demonstrated otherwise. They continued to renew medications (pain medications, benzodiazepines, hypnotics, etc.), when it was obvious that the patients no longer needed them. Dr. Marcus stated that the problem is that patients are requesting these medications from

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<tr><td></td><td></td><td>their providers because of direct-to-consumer advertising. Ms. Olson stated that without good data, there is nothing the Board can do.
The Board recommended the protocol pending the update in the continuation of therapy section.</td></tr>
<tr><td>(D) Proposed protocol for Crysvita® (burosumab-twza)</td><td>Approved</td><td>The Board reviewed a proposed protocol for Crysvita, a product indicated for the treatment of X-linked hypophosphatemia (XLH) and FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors. Dr. Swee wanted to know if we had a patient in NJ with the disease and also if the State will pay for treating a patient in another state like Pennsylvania or New York. Dr. Lind responded that all decisions are made on the basis of medical necessity not on the location of service. Ms. Desai informed the Board that there were seven patients (paid claims) for Crysvita during the last fiscal year. All were physician-administered.
The Board recommended the protocol.</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 commented on the continued differences in utilization denials between the plans.
Dr. Marcus made comments about variation in the HIV medications which he thinks may be related to DTC advertising.
Dr. Swee wondered when NJ will see the impact of the Inflation Reduction Act (IRA), on insulin costs. Dr. Lind responded that he has not heard any word on that but will bring information back to the Board when available. Dr. Swee requested that the subject be placed on the agenda for next meeting – possible impact on insulin utilization cost. Ms. Olson stated that the Act would not take effect until 2023.
The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 2nd 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</td><td>8</td></tr>
<tr><td>Aetna</td><td>0.8</td><td>41</td><td>11</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>38</td><td>13</td></tr>
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<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>
<table>
<tr><td>Horizon</td><td>0.7</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>0.9</td><td>45</td><td>16</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>33</td><td>10</td></tr>
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The Board reviewed a summary of their actions from previous meetings (October 2021 thru July 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 August 2022 (FFS) and July 2022 (MCOs) was provided for review.

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>August 2022</td><td>$10,078,120</td><td>$10,444,703</td></tr>
<tr><td>MCOs</td><td>July 2022</td><td>$105,850,383</td><td>$147,662,453</td></tr>
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<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 Vaccines information
b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
c. New Jersey COVID-19 Information Hub (continuously updated)
d. New Jersey COVID-19 Dashboard
e. Know Your Treatment Options for COVID-19 - FDA</td></tr>
<tr><td>Follow up items:</td><td></td><td>A. Ivermectin utilization report - update
B. MCO response to the Board's PA denials report questions - update
B. CGRP antagonists for migraine utilization quarterly report
C. Semaglutide utilization report – update
D. Review of the effect of the Inflation Reduction Act on insulin utilization (agenda item)</td></tr>
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