January 25, 2023 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Moynihan, Dr. Lind (ex-officio) Unable to attend: Dr. Barberio, Mr. Schafer
Dr. Swee's pre meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the first Board meeting of the year: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of the following filings: - On December 19, 2022, it was posted on the DHS/DMAHS website - Also on December 19, 2022, it was published in the issue of the NJ Register at 54 N.J.R 2410(a) - On December 20, 2022, it was published in the Atlantic City Press, the Bergen Record, the Camden Courier Post, the Newark Star-Ledger, and the Trenton Times. - On December 21, 2022, it was sent to the local Medical Assistance Customer Centers and County Boards of Social Services to be posted in an area accessible to both employees and the general public - Also on December 21, 2022, it was sent to the Statehouse Press Office
Review of Minutes	Approved	Minutes from October 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
Secretary's Report		- The Commissioners have signed off on DURB-recommended protocols for: January 2022. - The Department is working with the Commissioners to also sign off on DURB recommended protocols for , April 2022, July 2022, and October 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members.

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		- The MCOs have informed the State that they will provide another PA denials report requested at the last meeting at a later date because it is going to be done manually and, therefore, very labor intensive. - The Inflation Reduction Act will have no impact on the State's Medicaid population.
Old Business		
Ivermectin utilization report (January – November 2022)		The Board reviewed a follow-up report for ivermectin utilization for the period of January 2022 to November 2022. They concluded that utilization was down in the State in terms of being used incorrectly. They decided there will be no need for further reports. Dr. Swee however urged the Board to keep an eye on an ivermectin case in a Wisconsin court, which he hopes gets thrown out.
Calcitonin Gene-Related Peptide (CGRP) antagonists utilization report		The Board reviewed a utilization report for calcitonin gene-related peptide (CGRP) used in the treatment of migraines. They had requested the report at the last meeting to ensure that utilization was keeping up with the current trend as first line medications for migraine. The report showed a 42 percent increase in claims between 2021 and 2022. The Board recommended obtaining a future report to ensure that utilization continues to trend upwards.
Semaglutide utilization report		The Board reviewed a utilization report for glucagon-like peptide 1 (GLP-1) receptor agonists used in type 2 diabetes. At the previous meeting, the Board had raised concern about the use of semaglutide products for weight loss. The report showed an overall increase in this drug class. The State however found no supportive evidence to demonstrate the use of unapproved GLP-1 agonist for weight loss. The State also informed the Board that prior authorization requirements and quantity limits was put in place to ensure these products were used only for diabetes management. The Board did not discount the benefit of weight management in T2D; however, the State had informed them of the need for some administrative changes prior to implementation of payment of claims for that disease state.
Summary of suggested changes to proposed protocols		The Board reviewed changes that they suggested for the protocols they recommended at the last meeting. One was for GLP-1 receptor agonists where criterion #3 was modified to read: patient has/had suboptimal response to

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		metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons". The other was for cholic acid (Cholbam) protocol where the Board recommended removal of criterion #1 in the continuation of therapy requiring lab values from prescribers.
New Business		
(A) Proposed addendum for Spinal Muscular Atrophy (SMA) products protocol	Approved	The Board reviewed a proposed addendum to the Spinal Muscular Atrophy (SMA) protocol. The updates included addition of a new product, Evrysdi (risdiplam), to this class and changing the name to SMA protocol to cover two other products, Spinraza (nusinersen) and Zolgensma (onasemnogene abeparvovec) which previously had separate protocols. The Board recommended the protocol
(B) Proposed addendum to Imcivree protocol	Approved	The Board reviewed a proposed addendum to Imcivree (setmelanotide) protocol. The update was the addition of a new indication for patients with monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS). The Board recommended the protocol.
(C) Proposed addendum to GLP-1 agonists for T2D protocol	Approved	The Board reviewed a proposed addendum to glucagon-like peptide-1 receptor agonists for type 2 diabetes protocol. The update was to include a criterion that would exclude patients with established atherosclerotic cardiovascular disease (ASCVD) from trial and failure of metformin prior to treatment with these products. This change was made to be in line with the recent guidelines from the American Diabetes Association. The Board recommended the protocol.
(D) Proposed addendum to Dupixent® protocol for atopic dermatitis	Approved	The Board reviewed a proposed addendum to the protocol for Dupixent (dupilumab). The update was to remove the criterion that required the trial and failure of immunosuppressant therapy prior to the use of Dupixent. The Board recommended the protocol.
(E) Proposed protocol for Gattex®	Approved	The Board reviewed a proposed protocol for Gattex (teduglutide), a product used for the treatment of short bowel syndrome (SBS). Ms. Olson suggested the removal of "adult" in the background section to be consistent with the rest of the protocol. The Board recommended the protocol with the suggested change.

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>(F) Proposed protocol for Hyftor®</td><td>Tabled</td><td>The Board reviewed a protocol for Hyftor (topical sirolimus), a product used for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older. The Board was concerned about the drug label's requirement to "complete all age-appropriate vaccinations" prior to treatment with Hyftor. Dr. Moynihan suggested that for drugs that interfere with vaccines, the medication is given ahead of time or held till after the vaccination. Dr. Lind suggested that conflict would be difficult to avoid with series of core vaccines due at ages 11 and 12. Dr. Marcus suggested that as a topical agent, absorption may not be enough to interfere with vaccinations. The Board decided to table the protocol until the manufacturer, Nobelpharma, can provide more information that will clarify this issue.</td></tr>
<tr><td>Informational Highlights/Reports</td><td></td><td></td></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report

2. Summary of DURB Actions/Recommendations</td><td>Continue to monitor.</td><td>The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 3rd 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>6</td><td>6</td></tr>
<tr><td>Aetna</td><td>0.8</td><td>39</td><td>9</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>38</td><td>14</td></tr>
<tr><td>Horizon</td><td>0.7</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>0.8</td><td>45</td><td>18</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>31</td><td>9</td></tr>
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NF = Non formulary
The Board reviewed a summary of their actions from previous meetings (January 2022 thru October 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 October 2022 (FFS) and November 2022 (MCOs) was provided for review.</td></tr>
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<tr><td></td><td></td><td>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>November 2022</td><td>$11,868,293</td><td>$12,224,856</td></tr>
<tr><td>MCOs</td><td>October 2022</td><td>$112,315,948</td><td>$157,532,370</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links for reference. The COVID-19 information, although with similar subjects to previous meetings, are frequently updated sources:
1. Wisconsin Supreme Court to hear ivermectin treatment use
Dr. Swee expressed his concern about this case where a patient’s family is suing the hospital to have a patient treated with ivermectin in spite of the physician and hospital’s objections.
2. FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use
3. The TikTok trend that triggered a diabetes drug shortage
4. COVID-19 Vaccines information</td></tr>
<tr><td>Follow up items:</td><td></td><td>A. CGRP antagonists for migraine utilization report - update
B. Study of Imcivree in Hispanic and Latino population – report from Dr. Heller (Rhythm Pharmaceutical)
C. MCO data on PA denials</td></tr>
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