January 20, 2021 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 first meeting of the year announcement		Dr. Swee called the meeting to order by read the following statement as required for the Board's first meeting of the year: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of filings. The distribution methods used to circulate the public notice were as follows: ✓ 1/8/21 – Emailed to DMAHS email list ✓ 1/4/21 – Published in NJR at 53 NJR (86)b ✓ 12/23/20 – Posted in newspapers: Bergen Record, Newark Star-Ledger, Trenton Times, Camden Courier Post, and Atlantic City Press ✓ 12/8/20 – Filed with Secretary of State Office
Review of Minutes	Approved	Minutes from October 28, 2020 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 the DURB annual report for SFY 2019. It was published in the NJ Register inviting comments until February 19, 2021 - The Division is working with the Department to sign off on the DURB-recommended protocols at the July and October 2020 meetings. This includes: a. Varubi (rolapitant) b. Vyondys 53 (golodirsen) c. Cryopyrin-associated periodic syndrome (CAPS) products d. Spravato (esketamine)

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		For October 2020: a. Vimizim (elosulfase alfa) b. Naglazyme (galsulfase) c. Mepsevii (vestronidase alfa-vjbk) Also awaiting signature for the SFY 2020 DURB annual report. - Carol Johnson, commissioner of NJ department of health services (DHS), has resigned effective January 15, 2021, to join the Biden-Harris administration's White House COVID-19 response team. - Dr. Linda Gooen no longer resides in NJ and has therefore resigned her position as a member of the DURB. - July 2019 through January 2020 protocols were signed off by the Commissioners.
Old Business		
A. United Healthcare Clinical Criteria Not Met (CCNM) denials report		The Board reviewed a report on CCNM denials that they requested from United Healthcare (UHC) plan. Dr. Swee indicated that the report did not address the Board's concern: breakdown of unclassified denials into defined categories. Ms. Mona Kripalani, UHC's regional pharmacy manager promised to take the ask back to her reporting team and update the report information provided.
B. Addendum to opioid protocol	Approved pending update of criterion #7	The Board reviewed an addendum to the opioid protocol originally approved in October 2018. There were two proposals: (a) Reduce maximum daily dose for opioid tolerant patients from 120 MME (morphine milligram equivalent) to 90 MME as recommended by the CDC. (b) Emphasize co-prescribing of naloxone under specified circumstances.

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		Dr. Marcus questioned the rationale behind encouraging naloxone use only for this group of patients and not everyone. Dr. Emenike explained that it will not be practical or efficient to provide naloxone for every opioid prescription. Dr. Marcus then recommended that it should be made available to the patients' family members. The Board decided to adopt Ms. Olson's suggestion and modify criterion #7 to read: "Naloxone prescription is provided or offered to patient/patient's family or caretaker especially in the following situations. ."
New Business		
(A) Proposed protocol for Daraprim® (pyrimethamine)	Approved	The Board reviewed a proposed protocol for pyrimethamine, a product indicated for the treatment of patients with toxoplasmosis. The intent of the protocol is to ensure that the prescribers are using the combination drugs suggested by treatment guidelines. It also recommends that more cost-effective therapy such as the use of trimethoprim/sulfamethoxazole, also suggested in these guidelines is tried first where there are no contraindications. Dr. Marcus wanted the State to investigate the availability of a liquid formulation for this product. He also wondered if there were children in our population that needed the liquid dosage form. Dr. Emenike promised to investigate these issues and update the Board at the next meeting. The Board recommended the protocol.
(B) Proposed protocol for Increlex® (mecasermin)	Approved	The Board reviewed a proposed protocol for mecasermin, a product indicated for the treatment of patients with primary severe insulin-like growth factor-1 (UGF-1) deficiency. The Board recommended the protocol.
(C) Proposed protocol for exclusion for Victoza® (liraglutide)	Approved	The Board reviewed a proposed exclusion protocol for liraglutide (Victoza), indicated as an adjunct treatment to diet and exercise in patients with type 2 diabetes mellitus. The intent of the protocol is to ensure that the dosing of Victoza is not greater than the manufacturer's/FDA labeling which is unique for this indication. Dr. Swee raised concern that the State covered claims for some weight loss programs including surgery but not weight loss medications.

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<tr><td></td><td></td><td>Dr. Moynihan suggested that prescribers could justify use by providing literature as allowed in one of the protocol's criteria. Dr. Marcus compared this to the benefits of coverage for smoking cessation. Mr. Vaccaro informed the Board that under federal regulations for Medicaid programs, weight loss products are prohibited from coverage. The Board considered generating a letter to the legislature.
Ms. Mary Beth Fox, a representative with Nova Nordisk informed the Board that there is a bill in congress called "Treat and Reduce Obesity Act" that shows recognition in CMS that obesity is a chronic disease that needs treatment. She promised to send a copy of the bill to the Board.
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>The Board reviewed prior authorization (PA) denial report comparing all MCO plans including FFS for the 3rd quarter of 2020.
There were no comments regarding the report.
Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below:

<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.5</td><td>13</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>44</td></tr>
<tr><td>Amerigroup</td><td>0.5</td><td>37</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>44</td></tr>
<tr><td>UHC</td><td>0.8</td><td>50</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>45</td></tr>
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<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of actions from previous meetings (October 2019 thru October 2020).</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2020 (FFS)/August 2020 (MCOs) was provided for review.
Reported drug expenditures:
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>November 2020</td><td>$9,771,297</td><td>$10,933,902</td></tr>
<tr><td>MCOs</td><td>October 2020</td><td>$86,894,107</td><td>$124,694,755</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links to:
a. COVID-19 Vaccines information
b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
c. New Jersey COVID-19 Information Hub</td></tr>
<tr><td>5. Referenced Materials</td><td></td><td>Updated protocols returned for Board members review included:
1. Opioid protocol (approved October 2018)
2. Update to Vimizim approved protocol – change of criterion #3
3. Update to Naglazyme approved protocol – change of criterion #3
4. Update to Mepsevii approved protocol – change of criterion #3</td></tr>
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Follow up items:		- United Healthcare will provide a description of their denials and categorize them for clarity. - Dr. Marcus wanted to know if there is an official source for liquid pyrimethamine for children and if there is utilization in this population. Dr. Emenike will investigate these and update the Board. - Ms. Fox with Novo Nordisk will provide a copy of "Treat and Rescue Obesity Act" bill currently pending in the US Congress. (received) - Drs. Marcus and Gochfeld wanted the Board to work on a system to alert NJ physicians on the use of monoclonal antibodies for qualified COVID-19 patients.