October 20, 2021 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 14, 2021 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		- Protocols recommended by the Board in the October 2020, January, April, and July 2021 meetings are being reviewed by the Commissioners. This also includes the DURB annual report for SFY 2020. - The DHS Commissioner is also reviewing the recommended changes for the reappointment and replacement of members that have left the Board. - The Division has hired a new transcriptionist, Lisa Bradley, for the DURB meetings. - The State's chief pharmacist, Zankhana Desai has been working with the MCOs to update the prior authorization denials report. - The proposed dates for the DURB 2022 meetings are as follows: Wednesday, January 19 Wednesday, April 20 Wednesday, July 13 Wednesday, October 19 - The DURB annual report for SFY 2021 is in the packet for the Board members to review and send suggested changes to the Secretary, Sam Emenike, by November 30, 2021,

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		- Special thanks to Dr. Lind, Zankhana Desai, Ed Vaccaro, Dave Franks, and Beth Bailey for their help in putting the report together. - On behalf of the Board, Dr. Swee welcomed Ms. Lisa Bradley to the DURB meetings. He also extended his gratitude to Zankhana for her efforts in revising the DUR PA denials report template.
Old Business		
Updated DUR PA denials report		Deferred to January 2022 meeting.
New Business		
(A) Addendum for Duchenne muscular dystrophy drugs	Approved	The Board reviewed a proposed addendum for the protocol for Duchenne muscular dystrophy drugs. Changes: a. Added a new product, Amondys 45® (casimersen) that was FDA-approved in February 2021 b. Changed the name of the protocol to "Duchenne muscular dystrophy products". The Board recommended rewording criterion #6 to read: "patient's kidney function will be evaluated before and during treatment as required by medication's label" The Board recommended the protocol
(B) Proposed protocol for Aduhelm® (aducanumab)	Approved	The Board reviewed a proposed protocol for Aduhelm® (aducanumab) a product indicated for the treatment of Alzheimer's disease. Dr. Gochfeld recommended that the range for the Mini-Mental State Exam (MMSE) should be changed to 24-29 from proposed 24-30. The Board requested explanation from Biogen's liaison, Mr. Tanner Odom, who was at the meeting. He explained that other assessment tools were used in combination with MMSE and it would not be a problem to change it as the Board recommended. The Board recommended the protocol contingent on changing the MMSE range to 24-29.

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(C) Proposed protocol for Bronchitol® (mannitol)	Approved	The Board reviewed a proposed protocol for Bronchitol® (mannitol) indicated as an add-on treatment for cystic fibrosis. Dr. Marcus was concerned about the use of the word "oral" to describe the route of inhalation of bronchodilator required prior to use. Dr. Emenike informed the Board that "oral inhalation" used in the protocol was straight out of the drug label. The Board recommended the protocol contingent on removing the word "oral" to avoid confusion.
(D) Proposed protocol for Imcivree® (setmelanotide)	Approved	The Board reviewed a proposed protocol for Imcivree® (setmelanotide), a product indicated for the treatment of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency. Dr. Swee wanted to know the prevalence of this disease in New Jersey. Dr. Emenike promised to research that information and bring back to the Board. The Board recommended the protocol.
(E) Proposed protocol for Stromectol® (ivermectin)	Approved	The Board reviewed a proposed exclusion protocol for Stromectol® (ivermectin). Due to increased utilization for possible treatment of COVID-19, which is not approved by the FDA or CDC, the State proposed to limit the quantity to the amount needed for the treatment of approved indications. The Board recommended the exclusion protocol with a request that the State also send out a "Dear Prescriber Letter" alerting providers about the warnings from professional organizations against the use of ivermectin for the treatment of COVID-19 also referred to as SARS-CoV-2 infection. Dr. Gochfeld abstained from the vote.
DURB Annual Report for SFY 2021		The DURB annual report for SFY 2021 was sent earlier to the Board members to review with a request to send suggestions, corrections to the Secretary by November 30, 2021. This would allow enough time for commissioners review, approval, and publication in the NJ Register.

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></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 State is working with the MCOs to revise the current prior authorization (PA) denial report comparing all MCO plans and FFS. The new report template has been sent to the Board members and will be reviewed at the January 2021 meeting. At the meantime, the Board was presented with data for the quarter using the old template.
The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 2nd quarter 2021 are shown 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>12</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>41</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>34</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>42</td></tr>
<tr><td>UHC</td><td>0.9</td><td>48</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>48</td></tr>
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The Board reviewed a summary of actions from previous meetings (October 2020 thru July 2021).
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 2021 (FFS)/July 2021 (MCOs) was provided for review. Dr. Marcus commented on charge(s) for vaccine in the physician administered drugs report. Ms. Desai informed him that the charge(s) are only for administration fees. Drug expenditure is noted below.

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>August 2021</td><td>$9,715,452</td><td>$10,250,129</td></tr>
<tr><td>MCOs</td><td>July 2021</td><td>$95,698,728</td><td>$136,135,289</td></tr>
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4. Medication Information		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. Monoclonal Antibody Therapy for COVID-19 in New Jersey e. Lilly COVID-19 Antibody Therapies Access Update: Limitations of Authorized Use Modified by FDA. A list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized
5. Referenced Materials		Updated protocols returned for Board members review of their suggested changes: A. Addendum for Duchenne muscular dystrophy products – approved October 2021 B. Protocol for Aduhelm® (aducanumab) – approved October 2021 C. Protocol for Bronchitol® (mannitol) – approved October 2021
Follow up items:		A. Review of utilization of drugs/products with DURB-recommended protocols B. Prevalence of obesity due to the genetic conditions proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency in New Jersey C. "Dear Prescriber Letter" on the use of ivermectin