October 28, 2020 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Gooen, Dr. Moynihan, Dr. Lind (ex-officio) Unable to attend: Mr. Schafer
Review of Minutes	Approved	Minutes from July 15, 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		- All DURB-recommended protocols from July 2019 through January 2020 were signed off by the Commissioners. These include: a. Hereditary angioedema (HAE) products b. Urea cycle disorder products c. Chelating agents used in the treatment of Wilson's disease, Cystinuria, and severe, active rheumatoid arthritis d. Zolgensma® (onasemnogene abeparvovec-xioi) For October 2019: a. Hereditary transthyretin-mediated amyloidosis (ATTR) products b. Elaprase® (idursulfase) c. Gaucher disease products d. Cablivi® (caplacizumab-yhdp) For January 2020: a. Fabry disease products b. Lambert-Eaton Myasthenic Syndrome products c. Strensiq®(asfotase) - The Commissioners also signed off on the DURB Annual Report for SFY 2019. This will be forwarded for posting in the NJ Register. - Board members have received the preliminary copy of the DURB Annual Report for SFY 2020. They were instructed to review and send comments to the Secretary on or before November 30, 2020.

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		- Proposed DURB meeting dates for 2021 was listed in the meeting packet for board members to review and comment. The dates are listed below: Wednesday, January 20 Wednesday, April 21 Wednesday, July 14 Wednesday, October 20 - There were no updates for board members appointment and re-appointments. Dr. Swee wanted to know the status of a NJ proposed legislative action that was going to reaffirm the Board's existence with the additional requirements to report conflicts of interest on a quarterly basis. Dr. Lind responded that there has been no further updates on this issue.
Old Business		
A. United Healthcare Clinical Criteria Not Met (CCNM) report		Dr. Mimo Odebiyi with United Healthcare (UHC) informed the Board that the Plan's prior authorization team is still working on getting some examples of denials in this category Dr. Swee requested that UHC should work on getting the report to the Board in 30 days. Dr. Odebiyi agreed to do so.
B. Review of buprenorphine utilization for pain		The Board reviewed a report on buprenorphine utilization for the 2018 and 2019 calendar year. The purpose of the report was to see how much buprenorphine was being used for pain. The report showed that in 2018, 156 patients (7.2% of patients) received buprenorphine for pain for 146 days. In 2019, there were 250 patients (9%) for 130 days. Three hundred and twenty (15%) of patients used this product for substance abuse disorder in 2018 for 167 days while 548 (19%) used it for 156 days for the same diagnosis. Board members expressed concern about the number of patients without medical claims who received this product (1,595 and 1,959) in 2018 and 2019 respectively. Mr. Ed Vaccaro, R.Ph., explained that due to lack of access to network providers, some of the patients pay cash for their medication

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		assisted treatment (MAT) products, a class that buprenorphine belongs. Dr. Marcus suggested that the Board should get more involved in reviewing the use of drug products without adequate follow up or prior medical claims. Dr. Barberio informed the Board that she is an X-wavered buprenorphine prescriber and her team follows up with their patients but many prescribers do not accept insurance hence the lack of medical claims in the State's records.
C. Addendum for Calcitonin Gene-Related Peptide (CGRP) antagonists protocol	Approved	The Board reviewed a proposed addendum for calcitonin gene-related peptide (CGRP) protocol that was approved in April 2019. The addendum incorporated recent guidelines published by the American Headache Society. Dr. Moynihan expressed concern about the various choices of migraine medications recommended to be used prior to the CGRPs. Dr. Swee expressed similar sentiments. The Board voted to recommend the protocol. Dr. Swee abstained.
New Business		
(A) Proposed protocol for Vimizim® (elosulfase)	Approved pending update of criterion #3	The Board reviewed a proposed protocol for elosulfase, a product indicated for the treatment of patients with Mucopolysaccharidosis type IVA also referred to as Morquio A syndrome. Dr. Swee was concerned that the Medication Exception Program (MEP) team will not be able to interpret the labs, tests requested as part of the criteria and suggested that it was unnecessary to include that criterion. Dr. Emenike explained that MEP already has such reviews in place through medical necessity forms and refers to literatures and guidelines to help them to interpret the tests or labs. Dr. Moynihan, a Rheumatologist, informed the Board that in her position as Medicare medical director for the west coast, they allow similar claims to go through without much scrutiny except for unusual situations. Mr. Currie, pharmacy director for Horizon said that for their plan, some of the requests in the protocols are more for validation that the drug therapy is working. Mr. Vaccaro supported Dr. Swee's suggestion for a progress note-based report where the prescriber will include results of some tests if necessary. The Board approved the protocol pending rewording of criterion #3.

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<tr><td>(B) Proposed protocol for Naglazyme® (galsulfase)</td><td>Approved pending update of criterion #3</td><td>The Board reviewed a protocol for galsulfase, a product indicated for the treatment of patients with Mucopolysaccharidosis VI also called Maroteaux-Lamy syndrome. The discussion about the tests/labs criterion is also applicable to this protocol so the Board approved the protocol pending update of the criterion.</td></tr>
<tr><td>(C) Proposed protocol for Mepsevii® (vestronidase alfa-vjbk)</td><td>Approved pending update of criterion #3</td><td>The Board reviewed a protocol for vestronidase alfa-vjbk), a product indicated for the treatment of patients with Mucopolysaccharidosis VII also referred to as Sly syndrome. They approved the protocol with similar changes as the previous two.</td></tr>
<tr><td>Draft of DURB Annual Report for SFY 2020</td><td></td><td>The DURB annual report for SFY 2020 will be reviewed by board members and comments sent to the Secretary by November 30, 2020. Final version will be sent to DHS assistant commissioner for review, then on to the DHS and DOH commissioners for sign off.</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 2nd 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>12</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>42</td></tr>
<tr><td>Amerigroup</td><td>1.2</td><td>30</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>41</td></tr>
<tr><td>UHC</td><td>0.6</td><td>53</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>39</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 (July 2019 thru July 2020).</td></tr>
<tr><td></td><td></td><td></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>July 2020</td><td>$10,263,903</td><td>$10,933,902</td></tr>
<tr><td>MCOs</td><td>August 2020</td><td>$83,639,315</td><td>$119,672,681</td></tr>
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<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided a link to:
a. FAQs for Pharmacists on Naloxone Co-prescribing
b. metformin ER recall updates.</td></tr>
<tr><td>COVID-19 Drugs Utilization write up</td><td></td><td>The Board formed a subcommittee to work on a paper about the various drugs used relative to COVID-19 therapy. They will be reviewing the utilization of these products. The subcommittee will be made up of Dr. Swee, Dr. Marcus and Dr. Gooen.</td></tr>
<tr><td>Follow up items:</td><td></td><td>- United Healthcare will provide examples to explain their process for determining clinical criteria not met (CCNM) category (in 30 days)
- The Board’s subcommittee work on COVID-19-related products.
- Update criterion #3 of the enzyme replacement products reviewed – Vimizim, Naglazyme, and Mepsevii.</td></tr>
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