July 19, 2023 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Moynihan, Dr. Barberio, Ms. Olson, Dr. Lind (ex-officio) Unable to attend: Dr. Marcus, 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, the Star Ledger and Atlantic City Press.
Review of Minutes	Approved	Minutes from April 19, 2023, 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 protocol for April 2022 and October 2022. - The Department is working with the Commissioners to also sign off on DURB recommended protocols for , January 2022, and April 2023. - The DHS Commissioner's office is in contact with NJ PHARMA (Pharmaceutical Association) regarding potential replacement of a board member. We are awaiting information on the future appointee. - Dr. Lind informed the Board that the Department of Health is working on a replacement for their representative who was lost six years ago. - Dr. Swee pointed out that not all Board members have been contacted by professional associations in support of reappointment. - The Board raised no concerns about the medical necessity forms for Skysona and Zynteglo which they reviewed.

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Old Business		
(A)MCO response to PA denials report	Continue to monitor	Dr. Swee commented on the variances between the response times among the Managed Care Organizations (MCOs).
(B) MCOs churn rate request report	Continue to monitor	The Board reviewed the churn rate report for the MCOs. Dr. Swee observed that it has dropped substantially which is good for the patients and healthcare. The Board requested that this should be an annual report.
(C) Leqembi and Aduhelm utilization report		There was no utilization for these products from 2022 thru June 2023. The Board recommended to keep the review on its future meeting agenda.
(D)Report for non-formulary denials for antidiabetic medications	Continue to monitor	The Board reviewed a prior authorization denials report (by therapeutic class) of antidiabetics. Dr. Swee commented on the differences in non-formulary status of some of the medications. He announced that the Board will review the formulary of the MCOs to determine why one in six or one in seven patients are denied medications due to non-formulary issues.
(E) Hemgenix use in pediatric patients		The Board reviewed a letter from CSL Behring, the manufacturer of Hemgenix, explaining that they had not done any studies on pediatric patients. Dr. Swee announced that the Board is in the process or reaching out to pediatric and family physician groups to see what they are doing about that and will update the public when that information is available.
(F) Calcitonin gene-related peptide (CGRP) inhibitors utilization	Continue to monitor	The Board reviewed a utilization report for CGRP inhibitors. The report showed overall utilization of 29% and 2% for FFS and MCOs respectively. The Board requested another report in six months.
(G) Summary of DURB suggested changes to proposed Livmarli protocol		The Board reviewed their suggested changes for proposed Livmarli protocol. They had no further comments.

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New Business		
(A) Proposed protocol for CAR T-cell products	Approved	The Board reviewed a proposed protocol for chimeric antigen receptor (CAR T-cell) products. These products are used as targeted, personalized therapy that contains patients' analogous T cells reengineered to fight cancer. Dr. Swee had questions about the process of delivering the medical necessity forms and contacting the prescribing physicians at institutions, especially with the temporary nature of residents and fellows. Dr. Emenike responded that the same process as in the outpatient will apply. He doubted that this class of medications will be prescribed by residents. Ms. Olson wondered who should be enrolled in the Risk Evaluation and Mitigation Strategy (REMS) program, the hospital or prescriber. Mr. Vaccaro informed the Board that he will provide information at the next meeting that will give the Board an understanding of REMS-related billing and other processes involved. The Board recommended the protocol
(B) Proposed protocol for Qalsody	Approved	The Board reviewed a proposed protocol for Qalsody (tofersen), a product indicated for the treatment of Amyotrophic Lateral Sclerosis (ALS) in adults. Dr. Swee requested Dr. Moynihan's opinion on Medicaid's reimbursement for the product. She responded that they pay for similar products used for ALS. The Board recommended the protocol.
(C) Proposed addendum for biologic respond modifiers (BRMs) protocol	Tabled	The Board reviewed a proposed addendum for BRMs used in the treatment of plaque psoriasis protocol. Dr. Moynihan enquired about the process if a patient also had psoriatic arthritis, or other overlapping diseases. Dr. Emenike responded that the State will honor the claim if there are no other clinical issues. Dr. Swee wondered what protocol would be applied. Dr. Emenike explained that the protocol was intended for plaque psoriasis due to the constant exposure to direct-to-consumer advertising but did not foresee a problem with occasional overlaps. Dr. Gochfeld was concerned that since this is not a life-threatening illness, the requirement for one conventional drug trial prior to use of the BRMs was too low a hurdle. Dr. Swee also felt that only 3 months trial of topical corticosteroids was a low threshold too. He and Dr. Moynihan suggested seeking guidance from a dermatologist. Dr. Lind suggested that the leniency in the protocol may not be an issue since the MCO's

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>formularies could limit use. The Board however decided to proceed with the dermatology consult.
The protocol was tabled for the next meeting.</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 1st quarter 2023 are shown below.
<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th><th>% w/o NF*</th></tr>
<tr><td>FFS</td><td>0.6</td><td>7</td><td>7</td></tr>
<tr><td>Aetna</td><td>1</td><td>37</td><td>13.2</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>36</td><td>16</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>36</td><td>12</td></tr>
<tr><td>UHC</td><td>1</td><td>45</td><td>16</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>33</td><td>10</td></tr>
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NF = Non formulary
Dr. Swee again expressed concern over United Healthcare's (UHC) high denial rate. There was no further comments from board members.

The Board reviewed a summary of their actions from previous meetings (July 2022 thru April 2023).
There were no comments.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for May 2023 (FFS) and April 2023 (MCOs) was provided for review.
Drug expenditures 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>May 2023</td><td>$11,158,169</td><td>$11,509,968</td></tr>
<tr><td>MCOs</td><td>April 2023</td><td>$115,944,192</td><td>$160,723,222</td></tr>
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4. Medication Information		Medical information was provided with links for further reading on the topics below: 1. Weighing the Consequences of Weight-Loss Drugs 2. FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults 3. House Passes Bill to Address Fentanyl Overdoses 4. COVID-19 Vaccines information
Follow-up items:		A. Present the MCOs churn rate report annually B. Present the CGRP utilization report in 6 months C. Billing and REMS process in inpatient environment (Ed Vaccaro.) D. MCO formulary comparison report