October 18, 2023 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend: Dr. Moynihan, Ms. Olson, 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 July 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 Department is working with the Commissioners to sign off on DURB recommended protocols for, January 2023, and April 2023, and July 2023. - The DHS Commissioner's office is reviewing the recommended changes for the reappointment and replacement of DURB members. - The proposed dates for 2024 DURB meetings was presented and are as follows: Wednesday, January 24, 2024 Wednesday, April 17, 2024 Wednesday, July 17, 2024 Wednesday, October 16, 2024 Board members did not have any objections to these dates.
Old Business		
(A) Proposed addendum to Biologic Receptor Modifiers (BRMs) for plaque psoriasis protocol	Approved	The Board reviewed a proposed addendum to the BRMs for plaque psoriasis protocol. For the record and consistency, Dr. Emenike informed the Board about two changes not shown on the addendum: a. At the suggestion of Dr. McMahon, a dermatologist who reviewed the protocol, methotrexate and cyclosporine were removed from criterion #5 as required conventional treatment to try prior to BRMs

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(B) Risk Evaluation and Mitigation Strategy (REMS) program in institutions		b. American Academy of Dermatology's recommendation for the use of topical steroids as first line therapy was inserted as part of criterion #5. The Board recommended approval of the protocol. As a follow up to a question at the July meeting, Mr. Vaccaro explained the application of the REMS program in a hospital or institutional setting. Dr. Gochfeld also explained her personal experience with the REMS program when prescribing clozapine (Clozaril®), a medication used for schizophrenia.
New Business		
(A) Proposed protocol for Kanuma (sebelipase)	Approved	The Board reviewed a proposed protocol for Kanuma, a product indicated for the treatment of patients with lysosomal acid-lipase deficiency (LAL-D). The Board recommended approval of the protocol.
(B) Proposed protocol for Vyjuvek (beremagene geperpavec)	Approved	The Board reviewed a proposed protocol for Vyjuvek, a product indicated for the treatment of dystrophic epidermolysis bullosa (DEB). Dr. Marcus raised concern about the difficulty of finding a dermatologist that specialize in DEB as specified in criterion #5. Dr. Swee was equally concerned about restricting treatment to just dermatologists and suggested "a physician specializing in the treatment of DEB." Dr. Daniel, with Krystal Biotech, the manufacturer of Vyjuvek informed the Board that although the patients had multiple problems that involved other specialties, the primary care for the condition is given by dermatologists. The Board resolved to change criterion #5 to read: medication is prescribed by or in consultation with a dermatologist. The Board recommended approval of the protocol pending update of this section in the final copy.
(C) Proposed addendum for Duchenne Muscular Dystrophy protocol	Approved	The Board reviewed a proposed addendum for Duchenne Muscular Dystrophy products protocol. Dr. Swee enquired about criteria #10 which excluded the use of Elevidys with other exon-skipping therapies (Exondys 51, Vyondys 53, Viltepso, and Amondys 45). Dr. Basoff, with Sarepta Therapeutics explained that these products can be used prior to gene therapy, with Elevidys, if they are eligible but has to be discontinued prior to. Dr. Marcus asked if there is any detriment to using either

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<tr><td></td><td></td><td>product together. Dr. Basoff responded that there has been no studies of concomitant use in humans. He also requested a change to criterion # 2d. After a protracted discussion, Dr. Swee, in the interest of time, invited Dr. Lind to share his thoughts about the suggested changes with him and they will send their final verbiage to the Secretary to update the protocol. Ms. Kimberly Powers a public attendee gave a testimony to the Board about her son's positive experience with gene therapy.
The Board recommended approval of the protocol pending changes to criteria #2, 6, and 10.</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 2nd 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>0.7</td><td>7</td><td>7</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>39</td><td>9</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>40</td><td>16</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>36</td><td>13</td></tr>
<tr><td>UHC</td><td>1</td><td>48</td><td>17</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>35</td><td>8</td></tr>
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NF = Non formulary
Dr. Swee expressed concern over United Healthcare (UHC) and Amerigroup's high denial rates. The Board will continue to look for explanations.
Dr. Marcus commented on the high denial rate (21.9%) for FFS on the ulcer drugs/antispasmodics/anticholinergic category. He wondered if it was recorded incorrectly. Dr. Emenike promised that the MEP department will look at the numbers again.

The Board reviewed a summary of their actions from previous meetings (October 2022 thru July 2023).
There were no comments.</td></tr>
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<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>August 2023</td><td>$13,459,511</td><td>$13,847,607</td></tr>
<tr><td>MCOs</td><td>July 2023</td><td>$118,177,244</td><td>$163,723,951</td></tr>
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<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:
1. Opioid National Drug Code and Oral MME Conversion File Update
2. Long COVID Symptoms May Emerge Months After Infection
3. Dementia Risk Linked With Cumulative Heartburn Med Use, Analysis Suggests
4. Poorer Neighborhoods Linked to Higher Asthma Rates in Kids
5. Certain SSRIs May Increase Arrhythmia Risk in Select Patients
Dr. Swee commented that he does not know why some of these subjects are making news now since they are nothing new.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>None</td></tr>
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