April 19, 2023 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Dr. Barberio, Dr. Lind (ex-officio) Unable to attend: 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 January 25, 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 July 2022. - The Department is working with the Commissioners to also sign off on DURB recommended protocols for , April 2022, October 2022, and January 2023. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. Dr. Swee asked Dr. Lind why there was an out of order approval by the commissioners for July 2022 but not for April 2022's protocol. Dr. Lind responded that the Department had asked the same question but will follow up and have an answer for the Board at the next meeting.
Old Business		
(A)Nobelpharma response regarding Hyftor protocol.		The Board reviewed a response from Nobelpharma, in reference to a question about concomitant use of their product, Hyftor (sirolimus) topical gel with routine vaccination. The Board concluded that due to lack of evidence that topical sirolimus accumulated systemically, there should be no concern about concomitant use with vaccination and therefore do not need the criterion in the protocol.

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(B) Hyftor proposed protocol	Approved	The Board recommended the protocol.
(C) Rhythm Pharmaceutical's update on Imcivree.		The Board reviewed a response from Rhythm Pharmaceutical's Dr. Heller in reference to Dr. Swee's question on including Hispanics/Latinos when determining BMI used in their studies with the drug Imcivree (setmelanotide). In her report, Dr. Heller cited some studies by the company that included this population.
Summary of DURB suggested change for Gattex (teduglutide) protocol		At the last meeting, the Board suggested deleting the word "adult" in the background section of the Gattex protocol. This change was made and presented as follow up to the Board.
New Business		
(A) Proposed protocol for Skysona	Approved	The Board reviewed a proposed protocol for Skysona (elivaldogene autotemcel), a product used to slow the progression of neurology dysfunction in patients with early, active cerebral adrenoleukodystrophy (CALD). Dr. Marcus wanted to know how the State would confirm the capabilities of the sites where the product will be used and if they will comply with the protocol. Dr. Emenike informed him that prescribers are required to complete a medication necessity form (MNF) prior to use. These forms when completed are attestation that they are meeting the protocol requirements. Dr. Marcus suggested that the MNF should be shared with the Board for their input. The Board recommended the protocol
(B) Proposed protocol for Zynteglo	Approved	The Board reviewed a proposed protocol for Zynteglo (betibeglogene autotemcel), a product used for the treatment of patients with beta-thalassemia who require regular red blood cell transfusions. They also requested to review the MNF for this product. The Board recommended the protocol.
(C) Proposed protocol for Hemgenix	Approved	The Board reviewed a proposed protocol for Hemgenix (etranacogene dezaparvovec), a product used for the treatment of adults with hemophilia B. The Board was concerned that the treatment was not extended to patients under the age of 18. The product's package insert however states that "the safety and

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		efficacy of Hemgenix in pediatric patients have not been established". The Board requested a follow up with CSL Behring or NJ American Academy of Pediatrics to provide information on how the product could be used for a younger population. Dr. Lind suggested that the drug company may provide information on ongoing studies on pediatric patients aimed at expanding the coverage in the future. The Board recommended the protocol.
(D) Proposed protocol for Leqembi	Approved	The Board reviewed a proposed Leqembi (lecanemab-irmb), a product used for the treatment of Alzheimer's disease. Dr. Gochfeld expressed concern about the product because there is evidence that, it not only may not work, but also could cause harm. She suggested that the highest possible barriers be set for use of the product. Dr. Swee acknowledged her concern but felt there will not be lots of patients eligible for the product because the barriers are already there. Dr. Moynihan informed the Board that as a monoclonal, CMS has an NCD (National Coverage Determination) 200.3, which requires the patient to be in a CMS-approved study to be eligible for treatment. Dr. Swee requested a report on utilization of Leqembi in three months. The Board recommended the protocol. Dr. Gochfeld objected.
(E) Proposed protocol for Livmarli	Approved	The Board reviewed a proposed protocol for Livmarli (maralixibat), a product used for the treatment of cholestatic pruritus in patients with Alagille syndrome. Dr. Marcus was concerned that a pediatrician was not listed as eligible prescriber or consultant for a product indicated for 3 months and older patients. Dr. Lind pointed out that the criterion says, "in consultation with", which means that a pediatrician could prescribe in consultation with a hepatologist, gastroenterologist, or a specialist in Alagille syndrome. After discussion, the Board agreed to amend the criterion to read: "Medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or other specialist with experience in the treatment of the disease". The Board recommended the protocol pending the change and presentation of the updated version at the next meeting.

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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 percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 4th quarter 2022 are shown below.
<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td><td>% w/o NF*</td></tr>
<tr><td>FFS</td><td>0.6</td><td>8</td><td>8</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>39</td><td>12</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>36</td><td>14</td></tr>
<tr><td>Horizon</td><td>0.7</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>0.7</td><td>44</td><td>17</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>30</td><td>9</td></tr>
</table>
NF = Non formulary
Dr. Swee expressed concern that United Healthcare's (UHC) denial rate was higher than the other plans. Ms. Kripalani, the Pharmacy Director for UHC informed the Board that as a ratio of total claims processed, UHC's has the lowest denial rate. She also said that her team is working to reduce the total prior authorization burden on prescribers.
Dr. Marcus pointed out the high rate of denials of antidiabetics. Dr. Emenike responded that the denials in that category may be more related to non-formulary products but not necessarily antidiabetics in general. The Board requested a report on denials of this category for the next meeting.

The Board reviewed a summary of their actions from previous meetings (April 2022 thru January 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 January 2023 (FFS) and December 2022 (MCOs) was provided for review.
Dr. Swee referred to the cost, ranking of insulin in the report while reminding the State of their promise that this cost will go down because of the Inflation Reduction Act. Dr. Emenike pointed out that pricing related to the IRA was</td></tr>
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Drug expenditure 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>January 2023</td><td>$15,001,393</td><td>$15,460,557</td></tr>
<tr><td>MCOs</td><td>December 2022</td><td>$112,278,270</td><td>$158,134,726</td></tr>
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</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links for reference and further reading.
1. Effect of Higher-Dose Ivermectin for 6 Days vs Placebo on Time to Sustained Recovery in Outpatients With COVID-19
2.The Ethics of Clinical Research Managing Persistent Uncertainty
3. Are High Costs of Newer Diabetes Drugs Deterring Eligible Patients?
4. Docs Push Ivermectin for Flu
5. COVID-19 Vaccines information</td></tr>
<tr><td>Follow-up items:</td><td></td><td>A. Dr. Lind will verify and inform the Board the reason for out of order approvals of the recommended protocols by the Commissioners
B. Provide medication necessity forms (MNF) for Skysona and Zynteglo for board review
C. Obtain information from CSL Behring, the manufacturer of Hemgenix and/or NJ Pediatric Association on how to make use of the product in a younger population
D. Provide a report on Leqembi utilization at the next meeting
E. Provide a report on non-formulary denials of antidiabetic products</td></tr>
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