January 15, 2025, DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Ms. Olson, Dr. Lind (ex-officio), Dr. Slim (ex-officio). Unable to attend: Dr. Barberio and Mr. Schafer
Dr. Swee's pre-meeting announcement		Dr. Swee called the meeting to order by reading the following statement as required for the first annual meeting of the Board: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the following filings: • On January 6, 2025, it was posted to the DHS/DMAHS website and published in the NJ Register at 54 N.J.R. 2410(a) • On December 17, 2024, it was published in the Atlantic City Press, the Bergen Record, the Camden Courier Post, the Newark Star-Ledger, and the Trenton Times. • It was sent to the Local Medical Assistance Customer Centers and County Social Service Agencies to be posted in an area accessible to both employees and the general public. • It was also sent to the Statehouse Press Office
Review of Minutes	Approved	Minutes from October 16, 2024, 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 review and sign off on DURB-recommended protocols for July and October 2024 meetings. - The DURB annual report for SFY 2024 was updated with feedback received from Board members and will be sent to the Commissioners for review and sign off.

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		- Response from Genentech to the Board's question from the October 2024 meeting regarding the age limit for PiaSky® was discussed.
Old Business		
(A) Utilization Trends of Bupropion, GLP-1/GIP Agonists, SGLT-2 Inhibitors, and CGRP Inhibitors	Continue to monitor	The Board reviewed utilization reports for bupropion, GLP-1/GIP agonists, SGLT-2 inhibitors and CGRP inhibitors. Dr. Swee requested ongoing reports to monitor utilization for GLP-1/GIP agonists, SGLT-2 inhibitors, and CGRP inhibitors. Ms. Olson expressed satisfaction in the way the reports were created.
(B) Expansion of Antidiabetic Denials	Continue to monitor	The Board reviewed a detailed Medicaid MCOs antidiabetic drugs denials report for the second quarter (April- June) of 2024. Dr. Elizabeth Bailey, with the State's Pharmacy unit, called attention to a typo under Horizon's section, missing incomplete information, the correct number is 444. Dr. Swee emphasized the importance of the report shared and requested the Board continue to monitor.
(C) Examples of Clinical Criteria Not Met Denials (Antidiabetics)		The Board reviewed examples of clinical criteria not met denials for antidiabetic agents. This information was previously requested by the Board to review the disparity of denials among the MCOs. Dr. Bailey explained that not all the MCOs distinguish their denied claims between clinical criteria not met and incomplete information. Dr. Swee expressed concern with the potential that some of the incomplete information denials may be due to the MCOs not contacting the appropriate caregiver or poor communication with the provider.
New Business		
(A) Proposed addendum to the protocol for Ingrezza® (valbenazine)	Recommended	The Board reviewed a proposed addendum to the protocol for Ingrezza® (valbenazine). The two major updates were to include all vesicular monoamine transporter 2 (VMAT2) inhibitors used in the treatment of tardive dyskinesia and Huntington's chorea and remove the prescriber restriction. The two new additional products are Austedo® (deutetrabenazine) and Xenazine® (tetrabenazine). The Board recommended approval of the protocol.
(B) Proposed protocol for Alopecia Areata products	Recommended	The Board reviewed a proposed protocol for alopecia areata. Dr. Marcus recommended adding syphilis to the examples listed in criterion number three due to its increased incidence. Dr. Jihad Slim concurred with Dr. Marcus' recommendation. The Board recommended approval of the protocol.

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(C) Proposed protocol for Lyfgenia™ (lovotibeglogene autotemcel)	Recommended and continue to monitor	The Board reviewed a proposed protocol for Lyfgenia™ (lovotibeglogene autotemcel), a product indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. Dr. Marcus recommended offline to add the black box warning to the protocol. Dr. Swee expressed concern about the difference in the number of vaso-occlusive events (VOEs) between Lyfgenia and Casgevy which potentially may be due to the inclusion criteria of the clinical studies. Dr. Swee requested to reevaluate approval criteria for this protocol if requests are received below the recommended number of VOEs. The Board recommended approval of the protocol pending the addition of the black box warning.
(D) Proposed protocol for Casgevy® (exagamglogene autotemcel)	Recommended and continue to monitor	The Board reviewed a proposed protocol for Casgevy® (exagamglogene autotemcel), another product indicated for the treatment of sickle cell disease with recurrent vaso-occlusive crises or transfusion-dependent β-thalassemia. The Board recommended offline to add the criterion for the product to be administered at a Qualified Treatment Center. Dr. Dalia Hanna addressed a panel member's offline inquiry about why the Casgevy protocol did not require the product to be administered at a Qualified Treatment Center like the protocol for Lyfgenia. This criterion will be added to the protocol. Dr. Swee requested to monitor requests and utilization for Lyfgenia and Casgevy. The Board recommended approval of the protocol with the additional criteria for the product to be administered at a Qualified Treatment Center.
DURB Annual Report	Approved	Dr. Hanna expressed appreciation for the feedback and updates received from the Board concerning the DURB Annual Report for SFY 2024. She explained the department will be sending the report to the Commissioners for their review and sign-off. The Board will be notified when the report is published in the State Register. Dr. Swee also requested the Board be notified if there are any updates to the report as a result of the Commissioners' review.
Informational Highlights/Reports		

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>1. Fee-for-Service/MCO Prior Authorization Report</td><td>Continue to monitor</td><td>The Board reviewed the 3rd Quarter 2024 prior authorization (PA) denial report for FFS and MCOs.

Dr. Swee mentioned new PA regulations effective 1/1/2025, to improve timing of decisions for PA requests. He expressed concerns about the high rate of denials for ADHD medications. Dr. Marcus explained the disparity in percentages related to ADHD medications could potentially be associated with the MCOs formulary coverage of these products.

Dr. Hanna suggested restructuring this denial report to assist the Board with their review and oversight of FFS and MCO denials. Dr. Swee suggested continuing to review the top therapeutic categories and the activity associated with those denials.</td></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (January 2024 thru October 2024). Dr. Swee expressed his appreciation to the department for their quick turnaround to the Board’s requests.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for November 2024 (FFS) and October 2024 (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>November 2024</td><td>$ 2,388,384*</td><td>$ 2,704,425*</td></tr>
<tr><td>MCOs</td><td>October 2024</td><td>$ 115,966,998</td><td>$ 164,917,315</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
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Dr. Swee commented on the cost of insulin regardless of the government efforts to reduce their costs. He also inquired about what percentage is the MCOs total spend for drugs from their total expenditures. Dr. Thomas Lind indicated he would need to obtain this information from the State’s fiscal department.</td></tr>
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4. Medication Information		Medical information was provided with links for further reading on the topics below: 1. Scripts for GLP-1, SGLT2 Drugs on the Rise in Type 1 Diabetes Patients 2. Old Drugs, New Tricks: The Power of Medication Repurposing 3. Real-World Study Confirms RSV Vaccine's, Arexvy and Abrysvo, Protective Power for Seniors 4. Shorter Course of Antibiotics Works for Bloodstream Infections 5. Study: OUD Patients More Likely to Stay on Methadone Than Buprenorphine/Naloxone 6. Cephalosporin May Hold Potential for Early Syphilis Dr. Swee commented that the CDC released new guidelines regarding syphilis. Dr. Slim confirmed the guidelines were for the use of doxycycline for postexposure prophylaxis which has helped slow down the rate of incidences.
Follow-up items:		1. Provide utilization reports for GLP-1/GIP agonists, SGLT2 inhibitors, and CGRP inhibitors to continue to monitor. 2. Provide utilization reports for Lyfgenia and Casgevy, as well as monitor if requests go beyond twelve months. 3. Provide reports to review top PA denials by therapeutic categories 4. Provide the percentage of MCOs total drug expenditure