DURB Meeting Summary
July 16, 2025

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Moynihan, Ms. Olson, Dr. Barberio, Dr. Lind (ex-officio), Dr. Slim (ex-officio) Unable to attend: 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 meeting: In compliance with chapter 231 of the Public Law of 1975, notice of this meeting was given by way of the filings in the Trenton Times, Star Ledger, and Atlantic City Press.
Review of Minutes	Approved	Minutes from April 23, 2025, 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 signed off on the DURB-recommended protocols from the April 2025 meeting. - The Department is working with the Commissioners to review and sign off on the State Fiscal Year (SFY) 2024 Annual Report. - In response to an inquiry by the Board during the April 2025 meeting pertaining to tianeptine use in the Medicaid population, the Department informed the Board there is no utilization for this drug based on claims data. The drug is not approved in the United States.
Old Business		
(A) Utilization Trends of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors, Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist and GLP-1/Glucose-	Continue to monitor	The Board reviewed utilization reports for GLP-1 receptor agonists and GLP-1/GIP agonists, SGLT-2 inhibitors and CGRP inhibitors. Dr. Swee requested the utilization trends be presented in a different format to better display the differences. Dr. Agrawal stated the Department will work on changing how the utilization trend information is presented.

Issue	Action	Notes
Dependent Insulinotropic Polypeptide (GIP) Agonist and Calcitonin Gene-Related Peptide (CGRP) Inhibitors		Dr. Swee stated the CGRP inhibitors' utilization is stable and does not need to be presented to the Board.
(B) Updated Protocol for Attention-Deficit Hyperactivity Disorder (ADHD) for Children <6 years old		The Board reviewed an updated version of the Attention-Deficit Hyperactivity Disorder (ADHD) for Children <6 years old protocol with the recommended addition of the word significant to the continuation of therapy criteria pertaining to side effects. There was no further discussion.
(C) Updated Protocol for Spravato® (esketamine)		The Board reviewed an updated version of the Spravato® (esketamine) protocol. Dr. Swee recommended updating the monitoring criteria post administration with the addition of the word appropriately. There was no further discussion.
New Business		
(A) Updated Protocol for Transthyretin-mediated Amyloidosis (ATTR) Products	Recommended	The Board reviewed a proposed addendum to the protocol for the ATTR products. The update added Attruby®, a new drug approved by the Food and Drug Administration (FDA). In addition, the protocol was updated to include a new indication for Amvuttra®. The Board recommended approval of the protocol.
(B) Updated Protocol for Imcivree® (setmelanotide)	Recommended	The Board reviewed a proposed addendum to the protocol for Imcivree. The criteria was updated to allow use in patients 2 years of age and older and the Centers for Disease Control and Prevention (CDC) definition of obesity was included. In addition, Dr. Swee recommended the continuation of therapy criteria be updated with the removal of a specific percentage reduction in body mass index (BMI) and be replaced to accept any reduction in BMI in one year compared to baseline BMI. The Board recommended approval of the protocol with the suggested update.
(C) Updated Protocol for Paroxysmal Nocturnal Hemoglobinuria (PNH) Products	Recommended	The Board reviewed a proposed addendum to the PNH products protocol. The continuation of therapy criteria was updated to include decrease or normalization in reticulocyte count from pre-treatment level. In addition, the absence of unacceptable toxicity from the drug criteria was removed as it does not assess response to PNH treatment. Dr. Agrawal stated protocols for biologic drugs will also cover respective biosimilars and their related indications and dosages.

Issue	Action	Notes
		The Board recommended approval of the protocol.
(D) Updated Protocol for Chimeric Antigen Receptor (CAR) T Cell Products	Recommended	The Board reviewed a proposed addendum to the protocol for CAR T Cell products. In June 2025, the FDA no longer requires the Risk Evaluation and Mitigation Strategies (REMS) for CAR T cell drugs. The protocol was updated to remove the REMS criteria. The protocol was updated to include the statement covering biosimilars and their related indications and dosages for their respective reference biologic drugs. Jay Patel a pharmacist with Bristol Myers Squibb stated Abecma labeling was updated from trial of four or more prior lines of therapy to trial of at least two prior lines of therapy. The protocol criteria was updated to at least two prior lines of therapy for Abecma. The Board recommended approval of the protocol with the updated information Dr. Jay Patel provided.
(E) Updated Protocol for Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) and GLP-1RA/Glucose-Dependent-Insulinotropic-Polypeptide (GIP) Agonists for Type 2 Diabetes	Recommended	The Board reviewed a proposed addendum to the protocol for GLP-1RA and GLP-1RA/GIP products. The protocol was updated to include the statement covering biosimilars and their related indications and dosages for their respective reference biologic drugs. The following two indications were added to the protocol: reduce the risk of major adverse cardiovascular events and reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-state kidney disease and cardiovascular death. The criteria pertaining to these two indications are aligned with the updated 2025 Diabetes Guidelines. Discussion took place around the need for including the statement for coverage of biosimilars and contraindications criteria in each protocol. Dr. Swee questioned if the type of documentation required for requests to reduce the risk of sustained eGFR and kidney disease would be an attestation from the physician. Pinali Agrawal stated the documentation would need to include labs showing the patient has chronic kidney disease. Similarly in response to Dr. Swee regarding the requirement to obtain A1c levels, Pinali Agrawal stated the A1c would be collected for initial requests only for documentation of a diabetes diagnosis. Dr. Swee asked to confirm if the criteria is still requiring trial of metformin despite the American Diabetes Association's (ADA) recommendation that patients do not need to start with metformin therapy. Pinali Agrawal stated the metformin criteria still applies.

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td></td><td></td><td>The Board recommended approval of the protocol.</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 the 1st Quarter 2025 prior authorization (PA) denial report for FFS and MCOs. Dr. Swee stated Fidelis' denial percentage for the non-formulary category is an outlier when compared to the other MCOs. The Department is working with Fidelis to identify reasons for the outlying denial percentages. Dr. Swee mentioned the denials in the clinical criteria not met category is worrisome as it can include requests where prescribers did not respond with the appropriate clinical information. Pinali Agrawal stated clinical criteria not met category can include any of the following: missing information, missing diagnosis, not an approved indication, off-label use not supported by the compendia, duplicate therapy, and drug-drug interaction.</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 (April 2025). Dr. Swee expressed his appreciation to the Department for obtaining approvals for all the Board approved protocols through April 2025.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for April 2025 (FFS) and March 2025 (MCOs) was provided for review. Drug expenditures during the reporting period are noted below:
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total for All Drugs</th></tr>
<tr><td>FFS</td><td>April 2025</td><td>$ 2,450,955*</td><td>$ 2,733,071*</td></tr>
<tr><td>MCOs</td><td>March 2025</td><td>$ 82,146,911</td><td>$117,827,004</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
</table>
Dr. Swee and Dr. Marcus noted that the total monthly drug expenditures are millions of dollars. Dr. Swee also stated that despite applicable drug rebates, the total spend is still high. Dr. Swee stated drugs like insulin are surprisingly always at the top of the list based on amount paid. Addressing naloxone on the top drugs report, Dr. Barberio stated it is</td></tr>
</table>

Issue	Action	Notes
		dispensed in certain situations where there is an increase in the risk of an opioid overdose such as, but not limited to, the following: receiving opioid doses ≥90 MME/day or taking opioids with benzodiazepines.
4. Medication Information		Medical information was provided with links for further reading on the topics below: 1. Discontinuation glucagon-like peptide-1 receptor agonists and body habitus: A systemic review and meta-analysis 2. Antiretroviral postexposure prophylaxis after sexual, injection drug use or other nonoccupational exposure to HIV-CDC recommendations, United States, 2025 3. Genitourinary syndrome of menopause: AUA/SUFU/AUGS guideline 2025 4. Phase 3 trial of semaglutide in metabolic dysfunction-associated steatohepatitis
Follow-up items:		1. Update utilization charts and continue to monitor