January 24, 2024 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Dr. Barberio, Dr. Moynihan, Ms. Olson, Dr. Lind (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 first annual meeting of the Board: In compliance with Chapter 231 of the public laws of 1975, notice of this meeting was given by way of the following filings: ✓ On December 18, 2023, it was: • Sent to the local Medical Assistance Customer Centers and County Boards of Social Services to be posted in an area accessible to both employees and the general public • Sent to the Statehouse Press Office • Sent to the offices of Legal Services of New Jersey • Sent to a division of Medical Assistance and Health Services (DMAHS)-which maintains a list of interested parties ✓ It was sent to the following newspapers: the Atlantic City Press, the Bergen Record, the Camden Post, the Newark Star-Ledger, the Trenton Times, and it was published on December 22 or 23 (depending on the newspaper) ✓ On December 27, 2023, it was posted on the DHS/DMAHS website ✓ Published in the January 16, 2024, issue of the NJ Register
Review of Minutes	Approved	Minutes from October 18, 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, July 2023, and October 2023 - The DHS Commissioner's office is reviewing the recommended changes for the reappointment and replacement of DURB members.

		Dr. Swee inquired from Dr. Lind why there is a full year of protocols that were recommended by the Board that are not implemented. Dr. Lind responded that the State is trying to get the approvals in a stepwise order. The January protocol is now with the Commissioner of the Department of Health, but he is not sure what the holdup is.
Old Business		
(A) Calcitonin gene-related peptide (CGRP) inhibitors utilization report (2022 vs. 2023)		The Board reviewed a utilization report for calcitonin gene-related peptide (CGRP) inhibitors products for 3rd quarter 2022 versus 3rd quarter 2023. There was 26% increase in the fee-for-service program and 19% increase in the MCO programs.
(B) Updated Duchenne Muscular Dystrophy products protocol	Recommended	The Board reviewed the updated version of the protocol for Duchenne Muscular Dystrophy products protocol. They had approved the protocol at the October 2023 meeting with suggested changes. The Board recommended approval of the protocol as presented.
(C) Updated Vyjuvek protocol	Recommended	The Board reviewed the updated version of the protocol for Vyjuvek. They had also approved the protocol at the October 2023 meeting with suggested changes. The Board recommended approval of the protocol as presented.
New Business		

(A) Proposed addendum to the protocol for CGRP inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) antagonists for the treatment of migraines. The change was the addition of Zavzpret (zavegepant), a new product recently approved by the FDA for the treatment of acute migraine. The Board recommended approval of the protocol.
(B) Proposed addendum to the protocol for PCSK9 inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for the proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. The changes were as follows: 1. Add a 2022 American College of Cardiology (ACC) expert consensus decision pathway (ECDP) recommended LDL-C threshold for ASCVD patients who are at very high risk for subsequent cardiovascular event 2. Add Leqvio® (inclisiran), a recently approved PCSK9 modifier. 3. Change protocol name to "Protocol for the Safe and Efficient Use of PCSK9 Modifiers" - Dr. Marcus expressed concern over criterion #3 (patient is not pregnant). He suggested modifying it to add a risk benefit consideration for the prescriber as recommended by the American Academy of Cardiology. - Dr. Sam Reveron, with Amgen clarified that this was no absolute contraindication. He also commented on the protocol's definition of major cardiovascular risk. Dr. Swee responded that we will keep the definition as is. - Dr. Reveron requested inserting subsection "C" under criterion #8 that allows PCSK9 inhibitors for "patients on maximally tolerated statin who will required >25% further reduction in LDL. Dr. Swee declined inserting specific numbers but deferred to the Medication Exception Program (MEP) staff to make that determination in consultation with the prescriber. - In the section for criteria for reauthorization, Dr. Reveron requested deletion of the 35% reduction in LDL-C requirement. He also requested that the Board consider changing the 30 days required for LDL-C review to 90 days. The Board accepted the change to 90 days but made no recommendation regarding the 35% reduction in LDL-C. - Ms. Suzanne Shugg, a clinical lipid specialist informed the Board that 90 days follow up was better than 30 days for her patients. The Board agreed with that request. The Board recommended approval of the protocol with the changes.

(C) Proposed update to the protocol for Synagis	Recommended	The Board reviewed a proposed update for the protocol for Synagis (palivizumab), a product used for prophylaxis for respiratory syncytial virus (RSV) in pediatric patients. The original protocol was a holdover from a former vendor, First Health. The changes suggested were: Expanded eligibility for 4 additional classes of patients below, and exclusion for Beyfortus. 1. Impaired ability to clear secretions 2. Cystic fibrosis 3. Severe immunodeficiencies 4. Cardiac transplant Dr. Marcus wanted to know the number of patients that are eligible for treatment. Dr. Lind promised to look into that and inform the Board at a later meeting. Dr. Emenike also indicated that he will be looking at the number of patients treated the previous year to give the Board an idea. The Board recommended approval of the protocol.
(D) Proposed addendum to the protocol for Lumizyme	Recommended	The Board reviewed a proposed addendum to the protocol for Lumizyme (alglucosidase alfa), used in the treatment of Pompe Disease. The changes to the protocol were as follows: 1. Add Nexviazyme® (avalglucosidase alfa) 2. Add new product for the treatment of late-onset Pompe disease [Pombiliti® (cipaglucosidase alfa-atga + Opfolda® (miglustat)] 3. Rename protocol to "Pompe disease products protocol" The Board recommended approval of the protocol.
(E) Proposed protocol for Zurzuvae		The Board reviewed a proposed protocol for Zurzuvae (zuranolone), a product approved for the treatment of postpartum depression (PPD). Dr. Gochfeld expressed concern that a pediatrician would

	Recommended	be doing the screening. Dr. Lind responded that they were included as part of the Bright Futures guidelines. Ms. Olson suggested the addition of psychiatric advanced practice nurses, certified nurse midwives, pediatric nurse practitioners, and pediatric advanced practice nurses. Dr. Swee countered that an "appropriate caregiver" would cover these entities. He also wondered if a 17-year-old mother would be treated. Dr. Emenike responded that the State would remove criterion #1 specifying 18 years and older if that is the recommendation of the Board. Dr. Marcus raised concern that a pediatrician would be prescribing Zurzuvae for the mother. Dr. Swee and Dr. Lind pointed out the difficulty of accessing a psychiatrist in the State. Dr. Paul Isikwe, with Biogen, the manufacturer of the product requested that "AND" in criterion #2 be changed to "OR" to accommodate the definition of PPD. The Board agreed. Ms. Olson suggested that it would be better to use the verbiage "appropriate provider" and "appropriate healthcare provider" for the initial and continuation of therapy requirements respectively. Dr. Lind noted that Ms. Jill Krause made a note on the meeting platform's chat board that supporting the Board's appropriate provider verbiage. The Board voted to recommend the protocol with the suggested changes. Dr. Marcus abstained.
Informational **Highlights/Reports**		

1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 3rd quarter 2023 are shown below.
2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of their actions from previous meetings (January 2023 thru October 2023). There were no comments.
3. DHS/DHSS/MCO Programs Top Drugs Report		Top drugs report for November 2023 (FFS) and October 2023 (MCOs) was provided for review. Drug expenditures during the reporting period is noted below:

Plan	(%) PA Requests of claims	Denial (%)	% w/o NF*
FFS	0.8	2	2
Aetna	0.9	36	13
Amerigroup	0.8	38	15
Fidelis Care	1	38	12
Horizon	0.9	32	12
UHC	1	50	17

NF = Non formulary

Note: WellCare is now Fidelis Care.

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>November 2023</td><td>$11,586,337</td><td>$12,080,484</td></tr>
<tr><td>MCOs</td><td>October 2023</td><td>$119,009,542</td><td>$167,889,068</td></tr>
</table>
</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was provided with links for further reading on the topics below:

1. Benefits of Prior Authorizations

2. Poison control centers see surge in calls about weight-loss drugs

3. Longer Use of ADHD Meds May Boost Heart Risk

4. Burnout, Poor Mental Health on the Rise for Healthcare Workers, CDC Says

5. High Blood Pressure in Babies Linked to Adult Atherosclerosis

6. How Much Pain Is 'Enough' to Prescribe Opioids?

7. Reimbursement to Pharmacists for Generic Drugs by Medicare Part D Sponsors

8. 2024 Medicare Part D Stand-Alone Prescription Drug Plans in New Jersey

Dr. Emenike called the attention of the Board to the article on the benefits of prior authorization. Dr. Swee responded that there are two sides to the argument and referenced legislation to cut back on prior authorization recently signed by the Governor.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>Number of pediatric patients in FFS/MCO treated with RSV prophylaxis medication, Synagis</td></tr>
</table>