July 17, 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), 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 laws of 1975, notice of this meeting was given by way of filings in the Trenton Times, Star Ledger, and Atlantic City Press.
Review of Minutes	Approved	Minutes from April 17, 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 Commissioners have signed off on DURB-recommended protocols for, July 2023, and October 2023 meetings. • The Department is now working with the Commissioners to sign off on the DURB-recommended protocols for January 2024 and April 2024. • The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that no longer participate in the meetings.
Old Business		
(A) NJ Medicaid MCO Churn rate trend (2023-2024 YTD) (B) Updated Ingrezza protocol	Continue to monitor Recommended	The Board reviewed a Medicaid MCOs churn rate report for YTD 2023-2024. Dr. Swee commented that it'd be nice if it was a little less, but is stable, nonetheless. The Board reviewed an updated version of the protocol for Ingrezza with the changes they recommended: • Revised section A, criterion #3 to read: Medication is prescribed by or in consultation with a neurologist, psychiatrist, "or a specialist in the field at treating this disease state".

(C) Updated Egrifta protocol	Recommended	• Revised section B, criterion #3 to read: Use with caution in patients with depression, agitation, psychosis. • Revised section B, criterion #4 to read the same as section A, #3 above. The Board reviewed an updated version of the protocol for Egrifta with the changes they recommended: • Delete criterion #4e (waist circumference) • Delete criterion #6 requiring waist circumference for men and women • In continuation of therapy: delete patient response by the assessment of waist circumference from criterion #3 The Board recommended the protocol with the changes.
(D) Updated DAAs for HCV protocol	Recommended	The Board reviewed an updated version of the protocol for DAAs for HCV with the changes they recommended: • Replace "null responder" with "reinfected" in section B, criterion #3
(E) Updated Zurzuvae protocol	Recommended	The Board reviewed the updated version of the protocol for Zurzuvae for HCV with the changes they recommended: • Add "provider with planned follow up" The Board recommended approval of the protocol with the changes.
New Business		
(A) Proposed addendum to the protocol for Dupixent (dupilumab)	Recommended	The Board reviewed a proposed protocol for Dupixent which consolidated all the approved indications, atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), eosinophilic esophagitis, and prurigo nodularis. The Board recommended approval of the protocol.
(B) Proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors	Recommended	The Board reviewed a proposed addendum to the protocol for calcitonin gene-related peptide (CGRP) inhibitors. The addendum was to remove step therapy requirements for migraine prevention as recently recommended by the American Headache Society. Dr. Swee requested a utilization report for these products every other meeting to ensure there is "continued" increase in use. The Board recommended approval of the protocol with the changes.

(C) Proposed addendum to the protocol for Vyjuvek (beremagene geperpavec)	Recommended	The Board reviewed a proposed addendum for the protocol for Vyjuvek. The addendum was to: a. Emphasize that the medication will be applied only to open wounds b. Wound size is required with request to guide dosing c. Treatment is only for 24 weeks pending further evaluation The Board recommended approval of the protocol with the changes.
(D) Proposed addendum to the protocol for Duchenne Muscular Dystrophy products	Recommended	The Board reviewed a proposed addendum to the protocol for Duchenne Muscular Dystrophy products. The addendum was to: • Consolidate the products indicated for this disease state by adding Emflaza (deflazacort), which was a solo protocol approved in 2020 and Agamree (vamorolone). • Remove the requirement that only ambulatory patients qualified for Elevidys. Ms. Kathrin Kucharski, with medical affairs at Sarepta informed the Board that the sites that do Elevidys infusion have the capability to weigh the patients in wheelchairs. She also added that the dose is packed at a maximum dose of 70kg. The Board then decided to delete criterion #4 in continuation of therapy section which states: for dose increases, the member's weight must be received. Ms. Olson suggested changing criterion #6 in criteria for approval section from "prescribed by or in consultation with a pediatric/adult neurologist or a physician who is an expert in the treatment of DMD and other neuromuscular disorders to ". . . pediatric/adult neurologist or a specialist who is an expert in the treatment of DMD." Dr. Swee countered that there are other neuromuscular disorders. The Board decided to only change "physician" to "specialist" in the sentence. The Board recommended approval of the protocol with the change.
(E) Proposed protocol for Qelbree	Recommended	The Board reviewed a proposed protocol for Qelbree, a product indicated for the treatment of attention deficit hyperactive disorder (ADHD). Dr. Marcus expressed concern that the protocol required two step therapy process before Qelbree is made available to the patient. The Board decided to delete criterion #3 which required patients to have a history of failure, intolerance, or contraindication to atomoxetine, clonidine, or guanfacine.

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<tr><td>(F) Proposed protocol for Wegovy to reduce the risk of major adverse cardiovascular events (MACE)</td><td>Recommended</td><td>The Board recommended approval of the protocol with the change. Dr. Slim abstained.

The Board reviewed a proposed protocol for Wegovy, indicated to reduce the risk of major adverse cardiovascular events (MACE). Dr. Marcus expressed concern about the requirement for consultation with a cardiologist or vascular specialist. Dr. Emenike explained that although the State does not require this for other indications for GLP-1 agonists, it is required in this case because of the special circumstances (prior MI, prior stroke, etc.) needed for the use of this product.
Ms. Nikki Patel asked on the chat section how long the initial approval would be. Dr. Emenike responded that the State usually allows 6 months for initial approval.

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 percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 1st quarter 2024 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>0.8</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>45</td><td>17</td></tr>
<tr><td>Fidelis</td><td>1.2</td><td>31</td><td>7</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>32</td><td>10</td></tr>
<tr><td>UHC</td><td>1.1</td><td>45</td><td>15</td></tr>
<tr><td>Wellpoint</td><td>0.9</td><td>37</td><td>14</td></tr>
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NF = Non formulary
Note: WellCare is now Fidelis. Amerigroup is now Wellpoint.

Dr. Swee expressed concern about the disparity of denials among the MCOs. He concluded that it must be a formulary issue because he deals with it frequently in his practice – change patients medications due to formulary changes. He also reiterated the Board’s request for denials of diabetic medications by the plans. Dr. Emenike promised to provide the report after obtaining formulary drug information from the MCOs.</td></tr>
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<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of their actions from previous meetings (July 2023 thru April 2024).
Dr. Swee inquired again about the lag time in signing off of the DURB-recommended protocols by the Commissioners. Dr. Lind responded that he cannot make the signatures, but he can move the process along. Dr. Swee asked for Dr. Marcus' input on the top drugs. Dr. Marcus responded that his only concern was the compounding drugs and that has been clarified.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for November 2023 (FFS) and October 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>April 2024</td><td>$5,003,988 *</td><td>$5,434,972 *</td></tr>
<tr><td>MCOs</td><td>March 2024</td><td>$114,010,653</td><td>$162,589,785</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</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. Obesity drugs could bankrupt US healthcare, says Sanders
2. Cell and Gene Therapies: Excitement tempered by reality
3. Scientists Developing Vaccine Against Present and Future COVID Viruses
4. Narcan May Have Moved Over the Counter, but It's Still Underutilized</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Provide a follow up utilization report for calcitonin gene-related peptide (CGRP) inhibitors
2. Provide a denials report antidiabetics.</td></tr>
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