October 16, 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 July 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 January 2024, and April 2024 meetings. • The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that we've lost. • Proposed dates for 2025 DURB meetings was presented for review and approval by board members. The dates are as follows: Wednesday, January 15 Wednesday, April 23 Wednesday, July 16 Wednesday, October 22 Please review these dates and let me or Dr. Swee know if you would like to make changes. If no changes, these dates will be forwarded to the DHS commissioner for approval and publication. Dr. Swee expressed his gratitude to Dr. Lind and the staff who made it possible to have the protocols signed and also for the work they are doing towards the replacement of board members lost by retirement or resignation.

Issue	Action	Notes
Old Business		
(A) MCO antidiabetic drugs denial trend (2023-2024 YTD)	Continue to monitor	The Board reviewed a Medicaid MCOs antidiabetic drugs denials report for the first quarter of (Jan-March 2024). The Board had requested this report to address the overall denials of antidiabetic products. Dr. Marcus wanted an explanation for 60% denial of GLP-1 agonists. Dr. Swee expressed concern that most of this was due to formularies maintained by the plans. Dr. Elizabeth Bailey, with the State's pharmacy unit explained that over half of the denials were formulary related. She went on to explain that for most of the plans, over half of the products in the antidiabetics category were GLP-agonists and given the popularity of these products for weight loss, it was not surprising to have the observed rate of denials since weight loss products are not part of NJ Medicaid covered benefits. She also told the Board that the denials for non-GLP-1 agonists denials is much smaller than appears in the PA denials report. Twenty-five percent of denials in this category were eventually reversed or approved. Dr. Swee emphasized that the Board would like to keep an eye on the formulary component and inclusion of the eventual approval rate in the report would also be welcome.
(B) CGRP inhibitors report (4th quarter 2022 vs. 2023)	Continue to monitor	The Board reviewed a calcitonin gene-related peptide (CGRP) inhibitors utilization report comparing the 4th quarter of 2022 with the same quarter in 2023. There was a 33% overall increase in utilization in 2023 versus 2022. Dr. Swee expressed satisfaction in the trend and requested review of this report in the next couple of meetings.
(C) Updated addendum to protocol for DMD products	Recommended	The Board reviewed an updated version of the protocol for Duchenne Muscular Dystrophy products with the changes they recommended at the last meeting. There was no further discussion.
(D) Updated Qelbree® protocol	Recommended	The Board reviewed an updated version of the protocol Qelbree® with the changes they recommended at the last meeting. There was no further discussion.

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New Business		
(A) Proposed addendum to the protocol for ATTR products	Recommended	The Board reviewed a proposed addendum to the protocol for transthyretin-mediated amyloidosis (ATTR) products. The major update was the addition of two products, Anvuttra® (vutrisiran) and Wainua® (eplontersen). Dr. Emenike addressed a panel member's question: if a patient is already on Amvuttra®, could also use it for cardiomyopathy? He explained that the packet insert for Amvuttra® is specific for polyneuropathy, but a prescriber has the discretion to use any medication he/she sees fit under specific circumstances. The Board recommended approval of the protocol.
(B) Proposed protocol for IBAT inhibitor products	Recommended	The Board reviewed a proposed protocol for ileal bile acid transporter (IBAT) inhibitor products. The purpose of the protocol was to combine individual protocols that were previously approved by the Board: Bylvay® (odevixibat), 2022, and Livmarli® (maralixibat), 2023. The Board recommended approval of the protocol.
(C) Proposed addendum to the protocol for PNH products	Recommended	The Board reviewed a proposed addendum for the protocol for paroxysmal nocturnal hemoglobinuria (PNH) products. Dr. Emenike addressed a panel member's offline question about the use of these products for neuromyelitis optica. He informed the Board that Soliris® (eculizumab) is considered a first line treatment for this disease and therefore will be covered by the state. Dr. Swee expressed concern about the minimum age for use of PiaSky® (crovalimab) is 13. Dr. Emenike explained that the information in the protocol represented what is in the drug's label. The Board requested more information from the manufacturer regarding the basis for that age choice. The Board recommended approval of the protocol pending further clarification from the manufacturer, Genentech.
(D) Proposed protocol Winrevair®	Recommended	The Board reviewed a proposed protocol for Winrevair™ (sotatercept-csrk), a product indicated for the treatment of pulmonary arterial hypertension (PAH).

Issue	Action	Notes
		Dr. Emenike addressed a panel member's offline question about criterion number 5: could a patient fulfill the requirement by using 2 medications from the same category? He explained that it would be more efficient to use one from two different categories to explore the different mechanisms of action. Dr. Swee requested Dr. Moynihan's input regarding Medicare's approach to this step therapy options. Dr. Moynihan responded that they would only do that only on review. Dr. Swee further requested consultation with a cardiologist or pulmonologist, or a specialist in this disease state to help the Board understand the rationale behind the step therapy. Ms. Olson informed the Board that from her research, the product will be an add-on for patients at higher risk of hospitalization/death, or not responding to therapy but would not require discontinuation of other conventional therapies. The Board recommended approval of the protocol pending more information from specialists.
(E) Summary of protocols to be retired	Continue to monitor	The Board reviewed a list of protocols (28) recommended by the State to be retired. The protocols were in the following categories: • Protocols that have been updated since first introduced (16) • Protocols that were only applicable to the General Assistance (GA) population, which no longer exists (3) • Protocols that no longer require prior authorization (5) • Protocols that have low PA requests and high approval rates (4) Dr. Swee expressed appreciation for the State considering this approach to the protocols and hoped that this will be an ongoing process.

<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</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 2nd 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>0.9</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>1.0</td><td>46</td><td>15</td></tr>
<tr><td>Fidelis</td><td>1.1</td><td>35</td><td>7</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>34</td><td>12</td></tr>
<tr><td>UHC</td><td>1.2</td><td>41</td><td>14</td></tr>
<tr><td>Wellpoint</td><td>0.9</td><td>41</td><td>16</td></tr>
</table>
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 mentioned formularies to be a major factor and probably monoclonal antibodies. He said that this is not good for physicians and PAs.
• Dr. Marcus raised concern about the clinical criteria not met (CCNM) category.
• Dr. Emenike explained that for FFS, the high percentage could be related to the lower denominator of the patient population in comparison to the MCOs.
• Dr. Lind also explained that the number is high because FFS does not have non-formulary denials.
• Dr. Reut Ghodsi, with the State’s pharmacy unit explained that the high FFS denial rates is related to not receiving requested information from the providers therefore prompting closing of the claim as a denial. She suggested creating another bucket for that category.
• Dr. Swee suggested a category called “information not available”. It is worth noting here that that a category called “incomplete information” already exists but does not have enough claims to make the reporting threshold.

The Board requested more details on the CCNM category.</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 (October 2023 through July 2024).
There was no discussion on this section.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2024 (FFS) and June 2024 (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</th></tr>
<tr><td>FFS</td><td>July 2024</td><td>$4,216,990 *</td><td>$4,628,767 *</td></tr>
<tr><td>MCOs</td><td>June 2024</td><td>$107,949,726</td><td>$152,594,619</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</td></tr>
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Dr. Marcus had a question why Vivitrol® was injected by the physician but appeared on the top drugs list. Dr. Reut Ghodsi responded that it is typically dispensed from a pharmacy to the provider’s office therefore making it a pharmacy claim.</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. Legit Ozempic® Sales Soar While Counterfeits Put Patients in Danger

2. Medicare Unveils First 10 Negotiated Drug Price

3. FDA Approves First Emergency Allergy Nasal Spray

Dr. Swee wanted to know if the new nasal spray was on the market. Ms. Desai, the State’s pharmacy chief responded that it is loaded on the State’s drug system and will be a covered benefit, but pricing information is not available yet.</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Provide a more detailed information on the denials of antidiabetics, including eventual approval data

2. Provide follow up utilization report for calcitonin gene-related peptide (CGRP) inhibitors to show trend</td></tr>
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Follow-up items:		3. Approach Genentech, the manufacturer of PiaSky® for clarification on the minimum age of use at 13 4. Consult a cardiologist, pulmonologist or specialist in PAH to provide clarity on the State's step therapy approach in the protocols 5. Provide examples of CCNM denials 6. Consider an educational newsletter for providers on the CCNM category