April 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. Dr. Swee introduced Dr. Jihad Slim, a new member of the Board with the following statement: Dr. Slim is an infectious disease specialist in Newark. He's currently affiliated with St. Michael's Medical Center, and he also oversees the fellowship program at Newark Beth Israel. He has experience treating conditions such as sexually transmitted diseases, hepatitis C, and HIV, among other conditions. He serves as the Medical Director for the New Jersey Department of Health, Division of HIV, STD, and TB Services, and is an ex-officio member of this Board. Welcome, Dr. Slim.
Review of Minutes	Approved	Minutes from January 24, 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 of Health (DOH and Human Services (DHS) to review and sign off on DURB-recommended protocols from July 2023 and January 2024 DURB meetings - The Commissioners have signed off on DURB-recommended protocols for, January 2023, and April 2023 meetings. - The DHS Commissioner is reviewing recommended changes for the appointment and replacement of DURB members that no longer participate in the meetings.

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		- The Board approved an educational newsletter, entitled "Morphine Milligram Equivalence, which was distributed in March 2024
Old Business		
(A) Synagis utilization report (CY2022 vs. CY2023)	Continue to monitor	The Board reviewed a utilization report for Synagis for the CY 2022 versus CY 2023. There were 463 unduplicated recipients and 1,554 claims for 2022 versus 368 unduplicated recipients and 1,159 claims for 2023. The Board concluded that although there was a slight decrease in utilization, it was still going in the right direction.
(B) Updated protein convertase subtilisin kexin type 9 modifiers protocol	Recommended	The Board reviewed the updated version of the protocol for protein convertase subtilisin kexin type 9 (PCSK-9) modifiers. During review at the April meeting, the Board made a couple of suggestions: - Change criterion #3 to read "consider benefit versus risk for pregnant or nursing patients (was "patient is not pregnant") - Change time period for subsequent lab requests from 30 to 90 days The Board recommended approval of the protocol with the changes.
New Business		
(A) Proposed protocol for Ingrezza® (valbenazine)	Recommended	The Board reviewed a proposed protocol for Ingrezza, a vesicular monoamine transporter 2 (VMAT2) inhibitor used for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease. - Ms. Olson suggested changing criterion A3 to read: medication is prescribed by or in consultation with a neurologist, psychiatrist, APN who is a specialist in the field for this disease state. - The Board suggested changing criterion B3 to read: Use with caution in patients with depression, agitation, or psychosis The Board recommended approval of the protocol with the suggested changes.

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(B) Proposed protocol for Egrifta® (tesamorelin)	Recommended	The Board reviewed a proposed protocol for Egrifta, a growth hormone-releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. Dr. Swee had a concern about criterion 4c, documentation of waist circumference. Dr. Slim informed the Board that reduction in waist circumference was one of the primary endpoints during clinical trials but is not considered vital in real life situations. Dr. Barberio also suggested that in her clinic, the prescribers focused on weight but not waist circumference. The Board decided to delete that criterion. The Board recommended approval of the protocol with the suggested change.
(C) Proposed addendum for spinal muscular dystrophy (SMA) products protocol	Recommended	The Board reviewed a proposed addendum for the protocol for SMA products. The addendum is the deletion of criterion #2 (patient has SMA types I, II, III). A neurologist had suggested that this is no longer applicable in modern practice. The other change was to alert prescribers that Spinraza will not be used concomitantly with either Evrysdi or Zolgensma. The Board recommended approval of the protocol.
(D) Proposed addendum to the protocol for DAAs for hepatitis C	Recommended	The Board reviewed a proposed addendum to the protocol for direct acting antiviral (DAA) hepatitis C drugs. The addendum included: 1. Removal of criterion # 6 which read: Initial quantity dispensed will be limited to 14 days dosage units (14-14-28-28 format) 2. Delete Viekira Pak (discontinued January 2019) 3. Restructure protocol to minimize barriers to access Dr. Swee inquired about the current cost of these products in comparison to their debut high cost in 2014. Dr. Emenike responded that they have come down some especially with the availability of the generics. The focus now is how to provide access to the multimillion-dollar products in the market. Dr. Slim suggested changing criterion #3 under treatment experienced patients to read: provide previous history including medication, length of therapy, and whether the patient is a relapser, noncompliant, or reinfected.

April 17, 2024, DURB Meeting Summary

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>(E) Proposed protocol for Zurzuvae</td><td>Recommended</td><td>The Board recommended approval of the protocol with the suggested changes.

The Board reviewed a proposed addendum to the protocol for Zurzuvae.
The addendum was to remove the continuation of therapy section which, follow up research confirmed that the medication will only be given for 14 days. Dr. Marcus suggested to include a plan for follow up after the scheduled treatment. Dr. Gochfeld agreed, saying that medication alone is never enough for depression. The Board agreed to change criterion #3 to read: medication is prescribed by or in consultation with an appropriate healthcare provider with planned follow up.

The Board recommended approval of the protocol with the recommended change.</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 4th quarter 2023 are shown below.
<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th><th>% w/o NF*</th></tr>
<tr><td>FFS</td><td>0.8</td><td>2</td><td>2</td></tr>
<tr><td>Aetna</td><td>0.8</td><td>42</td><td>17</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>38</td><td>17</td></tr>
<tr><td>Fidelis</td><td>1.1</td><td>33</td><td>9</td></tr>
<tr><td>Horizon</td><td>0.8</td><td>32</td><td>11</td></tr>
<tr><td>UHC</td><td>0.9</td><td>49</td><td>17</td></tr>
</table>
NF = Non formulary
Note: WellCare is now Fidelis.

Dr. Swee expressed concern about the denial rates for the non-formulary products. Dr. Marcus also raised concern about the denials of antidiabetics. Dr. Emenike informed the Board that the denials may not necessarily be absolute because the MCOs have formularies (PDLs) and may have approved a similar agent down the road which may not have been captured in the present report. Dr. Swee suggested that</td></tr>
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April 17, 2024, DURB Meeting Summary

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<tr><td></td><td></td><td>for the next report, the antidiabetics be divided into non-formulary and formulary products.</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 2023 thru January 2024).
Dr. Swee inquired about the lag time in signing off of the DURB-recommended protocols by the Commissioners. Dr. Lind responded that the Commissioners have put in lots of efforts in catching up so we are making progress in that area.</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>January 2024</td><td>$4,314,569 *</td><td>$4,674,834 *</td></tr>
<tr><td>MCOs</td><td>December 2023</td><td>$112,698,240</td><td>$ 159,204,807</td></tr>
<tr><td colspan="4">* Less PAAD, ADDP and Sr. Gold</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. Can a Common Diabetes Drug Turn Patients' Urine into Alcohol?
2. Measles' Deadliest Sequelae
3. Highly Potent Statin Stands Out for Diabetes, Cataract Risks</td></tr>
<tr><td>Follow-up items:</td><td></td><td>1. Separate non-formulary antidiabetics from formulary antidiabetics in the next PA denials report
2. Dr. Marcus will send Dr. Emenike some concerns regarding changes in drug rankings from one meeting to the other for review and possible explanations</td></tr>
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