April 20, 2022, DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Moynihan, 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 Board's meetings: 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 January 19, 2022, 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
		Ruchi Banker, PharmD, with Gainwell Technologies presented the Secretary's report and other agenda items. - The Department is working with the Commissioners to sign off on DURB-recommended protocols for: October 2020, April 2021, July 2021, October 2021, and January 2022. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - Dr. Swee requested that Dr. Lind comment on the delayed sign off for the October 2020 protocols. Dr. Lind responded that the protocols are with the Department of Health, and he had sent the most recent reminder a week ago but had not received a response.
Old Business		
Review of updated protocols from the previous meeting.		Dr. Swee requested that going forward, changes made in DURB-recommended protocols should be presented as old business. At the meantime, he requested that Sam Emenike, PharmD, update the Board with the changes that were made. Those changes were as follows:

		For Gamifant® - Dr. Liem Sanderson (Anthem IngenioRx) suggested including the word "primary" as part of the diagnosis criterion (#1) for hemophagocytic lymphohistiocytosis (HLH). "Weight must be received" was changed to "weight will be monitored" for criterion #5. For Nitisinone products – Criterion #4 was changed from "prescribed by or in consultation with a metabolic disease specialist" to " . . in consultation with a prescriber with expertise in this condition". For Lucemyra® - Ms. Olson and Dr. Barberio suggested changing criterion #4 from "medication is prescribed by or in consultation with a physician specializing in pain management or addiction treatment" to ". . .with a prescriber specializing in pain management or addiction treatment". - The Board recommended deleting criterion #5 which read: "patient has tried and has inadequate response or intolerance, contraindication to oral clonidine or clonidine patch for opioid withdrawal".
New Business		
(A) Proposed protocol for Hetlioz® (tasimelteon)	Approved	The Board reviewed a proposed protocol for Hetlioz, a product indicated for the treatment of non-24 sleep-wake disorder. Dr. Marcus enquired why patients under 16 years of age would be required to take the liquid formulation if they can take the capsule. The Board also wanted to know why adult size teenagers, e.g., 15-year-olds could not take the capsule if they can. The Board recommended the protocol pending obtaining information from the drug manufacturer regarding these questions.
(B) Proposed protocol for cysteamine products	Approved	The Board reviewed a proposed protocol for cysteamine products, Cystagon (cysteamine bitartrate) immediate release capsules and Procysbi (cysteamine bitartrate) delayed release capsules. Both are indicated for the treatment of nephropathic cystinosis. The Board recommended the protocol.

(C) Proposed protocol for Revcovi® (elapegademase-lvlr)	Approved	The Board reviewed a protocol for Revcovi, a product indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID). Dr. Swee was concerned that the protocol was asking the treating prescriber for "details of the diagnosis". Dr. Emenike explained that the medication necessity form sent to the prescribers only requires attestation from them that they confirmed the diagnosis based on peer-reviewed guidelines (which lists these genetic or lab data) needed prior to treating the disease state. No further details are required of them from the department. He promised to talk to the State's MCO partners and update the Board with their input on the subject. Ed Vaccaro, R.Ph., with Gainwell Technology informed the Board that another reason for requesting attestation from the prescribers is to deter fraudulent claims. Dr. Barberio suggested changing the word "physician" in criterion number 2 to "provider". Dr. Swee responded that since the information will ultimately come from a physician, the criterion should be left as is. The Board recommended the protocol.
(D) Proposed protocol for Luxturna® (voretigene neparvovec-rzyl)	Approved	The Board reviewed a protocol for Luxturna, a product indicated for the treatment of retinal dystrophy. There were no comments. The Board recommended the protocol.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	Dr. Swee again voiced his concern about the burden that prior authorization placed on providers. He also pointed to the disparity in the denial rates among the MCOs and when compared to fee-for-service rates. His hope that the rates would decrease after the non-formulary denials were excluded from the calculation did not materialize. He is therefore looking forward to data that will be provided by the State in coming meetings to explain these differences.

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<td>2. Summary of DURB Actions/Recommendations</td>
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<td>The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 4th quarter 2021 are shown below.

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<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th><th>%W/O NF</th></tr>
<tr><td>FFS</td><td>0.7</td><td>7.3</td><td>7.3</td></tr>
<tr><td>Aetna</td><td>0.9</td><td>33.3</td><td>11.4</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>34.2</td><td>18</td></tr>
<tr><td>Horizon</td><td>0.6</td><td>33.2</td><td>13</td></tr>
<tr><td>UHC</td><td>0.8</td><td>44</td><td>14.4</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>27.3</td><td>8</td></tr>
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The Board reviewed a summary of their actions from previous meetings (April 2021 thru January 2022).
There were no comments.</td>
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<td>3. DHS/DHSS/MCO Programs Top Drugs Report</td>
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<td>Top drugs report for January 2022 (FFS)/December 2021 (MCOs) was provided for review. Dr. Marcus commented on charge(s) for oseltamivir (Tamiflu®) on the report given the low rate of influenza during the reporting period. He also wondered about the absence of the new oral COVID-19 drugs (Paxlovid and molnupiravir) in the report. He was informed that it was too early and moreover a utilization report targeting the two drugs was not done, yet. He requested that the State publish a (quick) newsletter to help providers understand the place of these medications in the fight against COVID-19.

Other discussions by the Board:
- The surge in omicron variant, BA.2 nationwide
- The need to treat patients early if positive for COVID-19
- Possibility of new federal laws having an impact on the price of insulin
- Use of monoclonal antibodies over the new oral medications when patients visit the hospital after positive test for COVID-19</td>
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- The presence of ivermectin on the drugs report despite FDA assertion of its ineffectiveness in COVID-19. (ivermectin has other approved indications)

Ms. Desai, the State's pharmacy services chief informed the Board that their recommended newsletter on ivermectin was distributed to providers early in the week.
Drug expenditure during the reporting period is noted below:

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<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>January 2022</td><td>$11,017,583</td><td>$11,486,068</td></tr>
<tr><td>MCOs</td><td>December 2021</td><td>$101,478,644</td><td>$143,708,498</td></tr>
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<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links to some COVID-19 guides. Although with similar subjects to previous meetings, these are frequently updated sources:
a. COVID-19 Vaccine information
b. Information for Clinicians on Investigational Therapeutics for Patients with COVID-19
c. New Jersey COVID-19 Information Hub
d. Know Your Treatment Options for COVID-19 - FDA</td></tr>
<tr><td>5. Referenced Materials</td><td></td><td>Updated protocols returned for Board members review of their suggested changes:
A. Proposed protocol for Gamifant® (emapalumab-lzsg) – approved January 2022
B. Proposed Protocol for Nitisinone products – approved January 2022
C. Proposed protocol for Lucemyra® (lofexidine) – approved January 2022</td></tr>
<tr><td>Follow up items:</td><td></td><td>A. Obtain information why patients under 16 are required to take liquid Hetlioz if they can take the pills.
B. Discuss with MCOs the need to request details of diagnosis in protocols
C. MCOs to provide explanations for variations in PA denials
D. Prepare an educational newsletter for new oral medications for COVID-19
H. Investigate uses for ivermectin in drugs report</td></tr>
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