January 19, 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 1st meeting of the year: 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 6, 2021, publication in the New Jersey Register at 53 NJR-2094A; on December 9, 2021, a posting on the Department of Human Services Division of Medical Assistance Health Services website; also on December 9, 2021, it was sent to the local medical assistance customer centers, county boards, statehouse press office, legal services of New Jersey, and an e-mail list of interested parties of the Division of Medical Assistants and Health Services; and on December 15, 2021, it was published in the Atlantic City Press, the Bergen Record, the Camden Courier Post, the Newark Star Ledger, and the Trenton Times.
Review of Minutes	Approved	Minutes from October 20, 2021, 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
		- The Commissioners have signed off on DURB-recommended protocols for January 2020, July 2020, and January 2021. - The Commissioners also have signed off on the DURB annual report for SFY 2020. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - As of November 24, 2021, there were no claims for setmelanotide (Imcivree®), a product used for the treatment of obesity due to impairment of the melanocortin-4 receptor (MC4R) pathway. This information was requested by Dr. Swee at the Board's October 2021 meeting.

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Old Business		
(A) Review of updated DUR PA denials report		Dr. Swee was concerned that after excluding the non-formulary category from the PA denials report, the denial rates for the MCOs were still double, triple the denial rates of the fee-for-service population. He requested that the State work with the MCOs to put together demographic variations report that could help explain the variations in the denial rates.
(B) Review of utilization of drugs/products with DURB-recommended protocols in 2020		The Board reviewed a utilization report products/protocols that they recommended in 2020. Dr. Swee noted that most of the products are very expensive. He requested that the report should be presented for review every six months.
(C) "Dear Prescriber" letter on ivermectin		The Board reviewed a letter they requested to be sent out to prescribers explaining the recent protocol for ivermectin. Dr. Lind, medical director informed the Board that the letter will be sent out after review by the DMAHS director.
New Business		
(A) Addendum for PCSK9 inhibitors protocol	Approved	The Board reviewed a proposed addendum for the protocol for proprotein subtilisin/kexin type 9 (PCSK9) inhibitors. Changes: a. Praluent (alirocumab) – new indication as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. – April 2021 b. Repatha (evolocumab) – approved use in pediatric patients aged 10 and older with heterozygous familial hypercholesterolemia (HeFH) – September 2021 c. Repatha – approved use in pediatric patients aged 10 and older with homozygous familial hypercholesterolemia (HoFH) – September 2021. The Board recommended the addendum.
(B) Addendum for Spravato®	Approved	The Board reviewed a proposed addendum for the protocol for esketamine nasal spray protocol.

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(esketamine) nasal spray protocol		Change: Addition of new indication for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior – July 2021. Dr. Gochfeld noted that she reviewed the protocol. The Board recommended the addendum.
(C) Proposed protocol for Gamifant® (emapalumab-lzsg)	Approved	The Board reviewed a proposed protocol for Gamifant, a product used for the treatment of hemophagocytic lymphohistiocytosis or HLH. Liem Sanderson, PharmD, with Anthem IngenioRx, suggested the protocol should emphasize that indication is for primary HLH only. This change will be made in the final version of the protocol. The Board recommended the protocol.
(D) Proposed protocol for nitisinone products	Approved	The Board reviewed a protocol for nitisinone products (Nityr® and Orfadin®), both indicated for the treatment of tyrosinemia type 1. Dr. Marcus expressed concern about the criterion which called for "consultation with a metabolic disease specialist". The Board compromised by changing the wording to "consultation with an expert in this condition". This change will be made in the final version of the protocol. The Board recommended the protocol.
(E) Proposed protocol for Lucemyra® (lofexidine)	Approved	The Board reviewed a protocol for lofexidine (Lucemyra®), a product indicated for use in medically supervised opioid withdrawal or detoxification. Ms. Olson suggested changing the criterion which called for medication to be prescribed "by or in consultation with a physician specializing in pain management or addiction treatment to "in consultation with a provider or advanced practice nurse specialized in pain management of addiction treatment". Dr. Swee inquired about oversight by a physician. Dr. Barberio countered that she consults a physician named in her protocol when she has a question or problem. The Board changed the criterion to read "medication is prescribed by or in consultation with a provider specializing in pain management or addiction treatment". The Board was concerned about the

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		criterion that required intolerance, inadequate response to clonidine prior to the use of Lucemyra. That criterion was removed, and the change will be reflected in the final version of the protocol. The Board recommended the protocol.
(F) Proposed protocol for Paxlovid (nirmatrelvir/ritonavir)	Approved	The Board reviewed a protocol for Paxlovid®, an oral antiviral recently given emergency use authorization (EUA) by the FDA for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older. The Board recommended the protocol.
(G) Proposed protocol for molnupiravir	Approved	The Board reviewed a protocol for molnupiravir, an oral antiviral also recently given EUA by the FDA for the treatment of mild-to-moderate COVID-19 in adults. The Board recommended the protocol.
Attendee question on DURB-recommended protocols		Mr. Mark Walter had a question about the status of the October 2020 protocols. Dr. Lind informed him that those protocols was still being reviewed. Ms. Desai, the Chief of Pharmaceutical Services followed up by informing the Board that she had been in regular contact with the Department of Health's commissioner's office to check on the status of the protocols. Dr. Swee offered to help expedite the process if needed.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	The State continues to with the MCOs to revise and update the current prior authorization (PA) denial report comparing all MCO plans and FFS. The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 3rd quarter 2021 are shown below. <u>A column has been added to reflect denial rates when non-formulary category is excluded.</u>

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>
<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>0.4</td><td>6.1</td><td>6.1</td></tr>
<tr><td>Aetna</td><td>1.7</td><td>37</td><td>13.4</td></tr>
<tr><td>Amerigroup</td><td>0.8</td><td>38</td><td>18</td></tr>
<tr><td>Horizon</td><td>0.6</td><td>32</td><td>12</td></tr>
<tr><td>UHC</td><td>0.9</td><td>43</td><td>13.3</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>37</td><td>9</td></tr>
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The Board reviewed a summary of actions from previous meetings (January 2021 thru October 2021).
There were no comments.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for August 2021 (FFS)/July 2021 (MCOs) was provided for review. Dr. Marcus commented on charge(s) for vaccine in the physician administered drugs report. Ms. Desai informed him that the charge(s) are only for administration fees. Drug expenditure is noted below.

Reported drug expenditures:
<table>
<tr><th>Plan</th><th>Month Reported</th><th>Top Drugs</th><th>Total</th></tr>
<tr><td>FFS</td><td>November 2021</td><td>$11,317,501</td><td>$11,873,831</td></tr>
<tr><td>MCOs</td><td>October 2021</td><td>$97,713,788</td><td>$138,006,584</td></tr>
</table></td></tr>
<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>
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5. Referenced Materials		Updated protocols returned for Board members review of their suggested changes: A. Addendum for Duchenne muscular dystrophy products – approved October 2021 B. Protocol for Aduhelm® (aducanumab) – approved October 2021 C. Protocol for Bronchitol® (mannitol) – approved October 2021
Follow up items:		A. MCOs to submit explanations for variations in PA denials B. Present annual utilization report for DURB-recommended protocols for review