July 14, 2021 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Moynihan, Dr. Lind (ex-officio) Unable to attend Mr. Schafer, Dr. Barberio
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 April 21, 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
Secretary's Report		- The Commissioners have signed off on the July 2020 DURB recommended protocols - Protocols recommended by the Board in the October 2020, January, April, and July 2021 meetings are being reviewed by the Commissioners. This also includes the DURB annual report for SFY 2020. - The DHS Commissioner is reviewing the recommended changes for the reappointment and replacement of DURB members. - Denise Sweet, has resigned as the transcriptionist for the DURB. The Division is working towards hiring a new transcriptionist for the October meeting. - The State is yet to determine if the October meeting will be live or virtual. This information will be provided as soon as it is available.
Old Business		
A-United Healthcare Clinical Criteria Not Met (CCNM) denials report		Sam Emenike, PharmD, informed the Board that, Zankhana Desai, R.Ph., Chief, Pharmaceutical Services DHS, is working with the Plans to revise and update the prior authorization report. The Board decided to table discussion on the submitted reports by UHC and Horizon until the next meeting.

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B-Horizon examples of incomplete information denials resolution		See UHC above
New Business		
(A) Addendum for DAA for HCV protocol	Approved	The Board reviewed a proposed addendum for the protocol for direct-acting antivirals (DAAs) for hepatitis C. One of the addenda was to remove prescriber restrictions requested by Dr. Robert Eilers, Medical Director of Mental Health and Addiction Services for the State. The other addendum was the deletion of discontinued medications from the protocol. The Board recommended the protocol.
(B) Addendum for Dupixent® (dupilumab)	Approved	The Board reviewed a proposed addendum for Dupixent protocol. Changes: a. December 2020: Updated age to 6 years and older based on FDA approved indication (was 12 years and older). b. Removed date of trial requirement from criterion #6. The Board recommended the protocol.
(C) Addendum for Vyondys® (golodirsen)	Approved	The Board reviewed a proposed addendum for Vyondys protocol. Change: Added Viltolarsen (Viltepso®) – FDA-approved in August 2020 The Board was informed that this protocol will be renamed "Duchenne Muscular Dystrophy" protocol to accommodate another recently FDA-approved product, Amondys 45 and possibly future products. The Board recommended the protocol.
(D) Addendum for Epidiolex® (cannabidiol)	Approved	The Board reviewed a proposed addendum for Epidiolex protocol. Changes: a. Addition of new indication for Tuberous Sclerosis Complex (TSC) – July 2020 b. Eligibility age changed from 2 to 1 year of age The Board recommended the protocol.

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(E) Addendum for Cablivi® (caplacizumab)	Approved	The Board reviewed a proposed addendum for Cablivi protocol. Change: Addition of new diagnosis: thrombotic microangiopathy (TMA) The Board approved the protocol.
(F) Proposed protocol for Cabenuva® (cabotegravir/rilpivirine) injectable	Approved	The Board reviewed a proposed protocol for Cabenuva injectable, a long-acting (once a month) product indicated for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed. Paul Amato, PharmD, with ViiV Healthcare, requested that the Board consider rewording the criterion on lead-in therapy. Ms. Olson suggested, and the Board agreed, to change the wording to read: "According to the prescriber, the patient has completed, or will complete, and is tolerating or will tolerate approximately one month of therapy (lead-in) with Vocabria (cabotegravir tablets) + Edurant (rilpivirine tablets". This was intended to remove delays and allow prescribers to procure Cabenuva® prior to the patient completing the one-month oral therapy. Mr. Eric Sherr, also with ViiV, questioned the need for the protocol which he perceived as "restrictive". Dr. Swee explained that the protocol was a product of a collaborative effort with the State's MCO partners and was fair. The Board recommended the protocol with the change above.
(G) Proposed protocol for biologic response modifier products	Approved	The Board reviewed a proposed protocol for biologic response modifiers used in the treatment of plaque psoriasis. This includes the following products: Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Ilumya (tildrakizumab), Otezla (apremilast), Remicade (infliximab), Siliq (bradalumab), Skyrizi (risankizimab-rzaa), Stelara (ustekinumab), Taltz (ixekizumab) and Tremfya (guselkumab). Dr. Emenike informed the Board about Dr. Moynihan's help in obtaining review of the protocol by a dermatologist with the New Jersey Dermatology Society (NJDS). Dr. Swee raised a concern that the need for consultation with a dermatologist for renewal of scripts could limit access to care. The Board agreed to require consultation only for initial prescriptions. Dr. Moynihan however suggested that the NJDS be alerted of this change. The Board agreed to do that and recommended the protocol.

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>Proposed protocol for Lumizyme® (alglucosidase alfa)

Proposed protocol for Myalept® (metreleptin)</td><td>Approved

Approved</td><td>The Board reviewed a proposed protocol for Lumizyme, a product indicated for patients with Pompe disease or acid alpha-glucosidase (GAA) deficiency.
The Board recommended the protocol.

The Board reviewed a proposed protocol for Myalept, a product indicated as an adjunct to diet as replacement therapy for complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.
The Board recommended 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

2. Summary of DURB Actions/Recommendations</td><td>Continue to monitor.</td><td>As mentioned earlier, the Board tabled discussions on prior authorization (PA) denial report comparing all MCO plans and FFS for the next meeting.
The percentage of prior authorization requests relative to total claims and denials associated with the PAs for the 1st quarter 2021 are listed below:

<table>
<tr><th>Plan</th><th>(%) PA Requests of claims</th><th>Denial (%)</th></tr>
<tr><td>FFS</td><td>0.5</td><td>13</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>40</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>39</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>44</td></tr>
<tr><td>UHC</td><td>0.9</td><td>46</td></tr>
<tr><td>WellCare</td><td>0.8</td><td>50</td></tr>
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The Board reviewed a summary of actions from previous meetings (July 2020 thru April 2021).
There were no comments.</td></tr>
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<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for April 2021 (FFS)/March 2021 (MCOs) was provided for review. Drs. Swee, Marcus and Gochfeld commented on the presence of insulin in the top drugs report. Dr. Marcus also mentioned pyrimethamine, an old drug that received a huge price increase.

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>April 2021</td><td>$10,721,922</td><td>$11,325,420</td></tr>
<tr><td>MCOs</td><td>March 2021</td><td>$100,992,663</td><td>$117,616,651</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided links to:
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. Monoclonal Antibody Therapy for COVID-19 in New Jersey
e. New: Sotrovimab – Emergency Use Authorization (EUA) granted for the Treatment of COVID-19

Dr. Gochfeld wanted to have further discussion on the availability of inexpensive products for COVID-19 used in other countries but ignored by the FDA in favor of multimillion dollar industry products.</td></tr>
<tr><td>5. Referenced Materials</td><td></td><td>Updated protocols returned for Board members review:
A. Protocol for DAAs for HCV (last updated and approved July 2018)
B. Dupixent® (dupilumab) protocol (last updated and approved July 2020)
C. Vyondys® (golodirsen) protocol (Approved 2020)
D. Epidiolex® (cannabidiol) protocol (approved January 2019)
E. Cablivi® (caplacizumab) protocol (approved October 2019)</td></tr>
<tr><td>Follow up items:</td><td></td><td>- Review and update the PA denials report</td></tr>
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