April 21, 2021 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 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
Secretary's Report		- Protocols recommended by the Board in the July and October 2020 meetings, and in the January 2021 meeting are being reviewed by the Commissioners. - Reappointment and replacement of DURB members that have resigned is being assessed by the Department. - Sarah Adelman has been appointed as DHS Acting Commissioner. Her predecessor, Carole Johnson, accepted a position with the Biden administration. - United Healthcare (UHC) is still working with their IT team to produce a report that will address the Board's concern for the Plan's high denial rate. - In reference to Dr. Marcus request at the last meeting. The State investigated the use of liquid pyrimethamine (not commercially available) for children and found that there was no claim for this dosage form in this population in the past year. - Ms. Fox with Novo Nordisk provided more information on a bill progressing in the US congress: "Treat and Reduce Obesity Act". This information was forwarded to the DURB members.

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Old Business		
United Healthcare Clinical Criteria Not Met (CCNM) denials report		Dr. Swee expressed concern in the amount of time United Healthcare is taking to provide the report the Board requested two meetings prior. This is in reference to the quarterly PA denials report.
New Business		
(A) Proposed protocol for Korlym® (mifepristone)	Approved	The Board reviewed a proposed protocol for mifepristone, a product indicated for the treatment of patients with Cushing's syndrome who have type 2 diabetes mellitus (T2D) or glucose intolerance and have failed surgery or are not candidates for surgery. The intent of the protocol is to ensure that they meet the aforementioned criteria and do not have any contraindications, also outlined. Dr. Moynihan asked what the State's response would be if a patient chooses not to have surgery. Dr. Swee responded that that would fall under the criterion that "patient is not a candidate for surgery" for reasons such as religion, fear, etc. The Board recommended the protocol.
(B) Proposed protocol for Juxtapid® (lomitapide)	Approved	The Board reviewed a proposed protocol for lomitapide, a product indicated as an adjunct to a low-fat diet and other lipid-lowering treatments to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). The intent of the protocol is to ensure that lomitapide is not used in patients who have hypercholesterolemia but not related to HoFH. Dr. Swee wanted an explanation of REMS (Risk Evaluation and Mitigation Strategy) to which lomitapide is associated. Dr. Emenike explained that the patient and prescriber are required to be registered in the program for monitoring purposes. Ms. Olson further clarified that the prescriber must demonstrate that he/she understands why the product is on the REMS program as well as providing data on the patient's treatment. The Board recommended the protocol.

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(C) Proposed protocol for exclusion for cystic fibrosis transmembrane conductance regulator (CFTR) products	Approved	The Board reviewed a proposed protocol for cystic fibrosis transmembrane conductance regulator (CFTR) modulators. These products include Kalydeco® (ivacaftor), Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor), Trikafta® (elexacaftor/tezacaftor/ivacaftor). The purpose of the protocol is to ensure that appropriate mutation testing is done, the prescriber is a specialist in CF, a pulmonologist, or in consultation with one, among others. Dr. Swee wanted to know if a pediatric patient started on one of the products indicated for pediatric use would need to switch to another product indicated for adult patients as they get older. Dr. Marcus responded that there would be no need to switch if the current product is working. Dr. Lind confirmed that identified mutation would drive the choice of product used. Dr. Moynihan wondered if continuation of therapy would depend predominantly on pulmonary improvement. Dr. Emenike responded that any patient improvement from baseline would suffice. The Board recommended the protocol.
Informational Highlights/Reports		
1. Fee-for-Service/MCO Prior Authorization Report	Continue to monitor.	The Board reviewed prior authorization (PA) denial report comparing all MCO plans including FFS for the 4th quarter of 2020. Dr. Swee commented on the differences in the numbers presented and wondered why this is so if the Plans are attending to the same patient population. Dr. Marcus pointed out the identical numbers for WellCare's "duration exceeded" and "excessive dose" data. He also expressed concern about Horizon's "huge" number of incomplete information. Sam Currie, R.Ph., director of pharmacy at Horizon explained that their model was different hence the large numbers. Horizon, he said, works with the pharmacists at the point of sale rather than with the prescribers, who initiate the PA process in other models. This process ultimately causes some of the PA requests to fall out of the contract timeframe with the State. However,

<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>this model saves the prescriber a lot of time in the long run. Ed Vaccaro, R.Ph. explained Horizon's process through a practicing pharmacist's standpoint.
Dr. Marcus requested that Horizon provide examples that would better explain their PA process. Dr. Swee also reiterated the need for Horizon to provide these examples to help the Board understand the process.
Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below:

<table>
<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.5</td><td>12</td></tr>
<tr><td>Aetna</td><td>0.7</td><td>41</td></tr>
<tr><td>Amerigroup</td><td>1.5</td><td>33</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>44</td></tr>
<tr><td>UHC</td><td>0.8</td><td>51</td></tr>
<tr><td>WellCare</td><td>0.7</td><td>47</td></tr>
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The Board reviewed a summary of actions from previous meetings (January 2020 thru January 2021).
Dr. Swee inquired about the possibility of the Acting Commissioner attending and speaking to the Board at one of the meetings. Dr. Lind responded that considering her workload, it could be a difficult ask but will forward the invitation. He also mentioned that she is aware and have discussed the Board's recruitment issues.</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for January 2021 (FFS)/December 2020 (MCOs) was provided for review. Drs. Swee, Marcus and Gochfeld lamented 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>January 2021</td><td>$11,473,227</td><td>$12,110,030</td></tr>
<tr><td>MCOs</td><td>December 2020</td><td>$90,044,905</td><td>$129,305,683</td></tr>
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4. Medication Information		Medical information was presented which provided a links to: a. COVID-19 Vaccines 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. Board members discussed COVID-19 vaccine availability and distribution issues. They also discussed the availability of monoclonal antibodies for the treatment of COVID-19 patients in New Jersey.
5. Referenced Materials		Updated protocols returned for Board members review included: 1. Addendum to opioid protocol (change in criterion #7 to include the word "especially") 2. Exclusion protocol for Victoza (change of word "limitations" to "exclusions")
Follow up items:		- United Healthcare will provide an updated report on incomplete information in the denials report - The State will prepare a report for the Board on utilization of high cost drugs to be reviewed at the April 2022 meeting - The State will discuss "no surgery" option for patients considered for Korlym® therapy with MCO partners - Horizon will provide examples that explain their incomplete information process - Dr. Lind will extend a DURB meeting invitation to the DHS Acting Commissioner.