October 16, 2019 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Moore, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Gooen, Dr. Lind (ex-officio) Unable to attend:, Dr. Moynihan, Mr. Schafer
Public Notice		Dr. Swee read the public notice required for public meetings: In compliance with Chapter 231 of 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 July 17, 2019 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 following DURB-recommended protocols: - Dupilumab (Dupixent®) - Calcitonin gene-related peptides inhibitors for migraine [Aimovig® (erenumab-aooe), Ajovy® (fremanezumab), Emgality® (galcanezumab-gnlm)] - Gout products [Uloric® (febuxostat), Zurampic® (lesinurad), Krystexxa® (pegloticase) DXC's MEP is working on implementing these protocols. • Awaiting commissioners' signatures for the following protocols: - Hereditary angioedema (HAE) products - Urea cycle disorder products - Chelating agents used in the treatment of Wilson's disease, Cystinuria, and severe, active rheumatoid arthritis - Zolgensma® (onasemnogene abeparvovec-xioi) • The DURB annual report for SFY 2019 was presented. Board members were informed to review the content and send any comments to the Secretary on or before November 30, 2019. • Update on board members reappointment/replacement: - There was nothing new to report on this subject

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		• Proposed meeting dates for 2020 DURB meetings: - Board members reviewed and approved proposed meeting dates for 2020 listed below: - Wednesday, January 22 - Wednesday, April 22 - Wednesday, July 15 - Wednesday, October 21 - Dr. Marcus wanted to be sure that the title for the chelating agents was changed as discussed during the July meeting. As reflected in the "Referenced Materials" section, the title for the protocol was changed from "Proposed Protocol for Chelating Agents" to "Protocol for Cuprimine® (penicillamine) and Syprine® (trientine) Used in the Treatment of Wilson's Disease, Cystinuria, and Severe, Active Rheumatoid Arthritis". - Dr. Gooen asked about the status of the Medication-Assisted Treatment (MAT) streamlining. She was informed that prior authorization was removed from most MAT products and a newsletter was sent out outlining that process.
Old Business		
WellCare and Amerigroup breakdown of "Other Category" in the quarterly PA Denials Report		The Board reviewed a follow-up report provided by WellCare and Amerigroup explaining the breakdown of the "other category" in the Prior Authorization Denial Report. Aharon Levi, PharmD, with Amerigroup explained that 52 out of the 53 denials in "other category", were non-covered benefits while one was a non-formulary claim. He noted that he will be having a meeting with the reporting team refine the process. The reported denial, (34), in the second quarter was also in the wrong category and has been fixed. Ashraf Sunesara, PharmD, with WellCare also explained the Plan's breakdown of "other category" to the Board.

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New Business		
(A) Proposed protocol for hereditary transthyretin-mediated amyloidosis (hATTR) products	Approved with suggested changes	The Board reviewed a proposed protocol for Transthyretin-mediated Amyloidosis (ATTR) products. They expressed concern about not having an expert to guide them in their decision making process regarding the protocol. Dr. Swee volunteered to contact the Medical Society of New Jersey to enquire about specialist(s) in the disease that could help in this area. The Board recommended changing the criterion on prescriber specialty from "Medication is prescribed by or in consultation with a neurologist or cardiologist" to "Medication is prescribed by or in consultation with a neurologist, cardiologist, or a specialist in the treatment of ATTR". They approved the protocol pending this update. Dr. Gooen suggested revisiting the protocol for future updates. Dr. Swee agreed that all four protocols should be revisited to monitor utilization and other issues.
(B) Proposed protocol Elaprase® (idursulfase)	Approved	The Board reviewed a proposed protocol for Elaprase® (idursulfase), another risk corridor drug. They were informed that the protocol for this product, used for the treatment of mucopolysaccharidosis II or MPS II was reviewed and approved by a geneticist, Dr. B. Pletcher. The Board approved the protocol.
(C) Proposed protocol for Gaucher disease products	Approved with suggested changes	The Board reviewed a proposed protocol for Gaucher disease products. This protocol was also reviewed by Dr. Pletcher who suggested including geneticists as required specialty for consulting and/or prescribing this product. She also suggested removing the part of the criterion that required a patient to fail treatment with enzyme replacement therapy (ERT) prior to initiation of substrate replacement therapy (SRT). The Board agreed, recommending that the entire criterion #4 requiring that "Patient is intolerant to enzyme replacement therapy" be stricken from the protocol. They also recommended adding a geneticist as one of the specialties involved in the use of these products.
(D) Proposed protocol for Cablivi® (caplacizumab-yhdp)	Approved	The Board reviewed and recommended a protocol for Cablivi®, a product used for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP).

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></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 Board reviewed prior authorization (PA) denial report comparing all MCO plans including FFS for the 2nd quarter of 2019. Dr. Swee expressed concern about some of the denials in the 50 percentile. Dr. Marcus suggested introducing a better categorization to make the report more self-explanatory.
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>0.6</td><td>15</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>34</td></tr>
<tr><td>Amerigroup</td><td>1</td><td>26</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>40</td></tr>
<tr><td>UHC</td><td>0.9</td><td>54</td></tr>
<tr><td>WellCare</td><td>0.6</td><td>49</td></tr>
</table></td></tr>
<tr><td>2. Summary of DURB Actions/Recommendations</td><td></td><td>The Board reviewed a summary of actions from previous meetings (October 2018 thru July 2019).</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for July 2019 (FFS)/June 2019 (MCOs) was reviewed.
Dr. Marcus wondered if the drug prices were the reason for the change in ranking of the drugs from one month to the other and hoped that the patients were not being caught in the shuffle. Dr. Moore suggested that the drug shortages and back orders may be contributing to some of the changes in ranking. Dr. Marcus also wondered why lancets and other diabetic, non-drug items were listed on the top drugs report. Mr. Vaccaro explained that some of the MCOs bill these medical supplies as pharmacy services which is now routine in the pharmacy market place.</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Some medical information was presented which included FDA’s widening probe on generic drug impurities.</td></tr>
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Follow up items:		- Board members will review the SFY 2019 DURB annual report and send comments and/or suggestions to the Secretary on or before November 30, 2019. This will facilitate timely publication in the NJ Register. - Dr. Swee will reach out to the Medical Society of New Jersey for possible recommendations for a specialist in the treatment of ATTR. - A utilization report and any available updates on the risk corridor drugs will be presented to the Board at future meetings. - Provide update on nicotine replacement therapy utilization and any information on vaping at the next meeting.