January 22, 2020 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 about the NJDURB meetings required for the first meeting of the year: The distribution methods used to circulate the public notice are noted below: • Sent to the local Medical Assistance Customer Centers and County Boards of Social Services to be posted in an area accessible to both employees and the general public; Sent to the Statehouse Press Office; (December 5, 2019) • Sent to the offices of Legal Services of New Jersey; (December 5, 2019) • Sent to a Division of Medical Assistance and Health Services (DMAHS)-maintained list of Interested Parties; (December 5, 2019) • Sent to the following newspapers for publication: the Atlantic City Press, the Bergen Record, the Camden Courier Post, the Newark Star-Ledger, and the Trenton Times. The notice was published on December 16, 2019. • Was posted on the DHS/DMAHS website December 11, 2019 •Published in the January 6, 2020 issue of the NJ Register at 52 N.J.R. 80(a).
Review of Minutes	Approved	Minutes from October 16, 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		• Awaiting commissioners' signatures for the following DURB-recommended protocols: - Hereditary angioedema products - Chelating agents used in the treatment of Wilson's disease, cystinuria, and severe, active rheumatoid arthritis DHS commissioner had a concern about the Zolgensma protocol which is still being resolved. • Other outstanding protocols are: - Hereditary transthyretin-mediated amyloidosis (ATTR) products - Elaprase® - Gaucher disease products

Issue	Action	Notes
		- Cablivi® Dr. Swee made a comment about his long tenure with the Board (since 1996) and the Board's philosophy of making recommendations based on our state's and local needs but not allowing examples from other states (even though taken into consideration) to override those recommendations. He anticipates that the Board will continue with this philosophy. • The DURB annual report for fiscal year 2019 is going through the approval levels and should be signed off any day now. • Dr. Swee informed the Board that his efforts to contact a specialist in the treatment of ATTR and other inherited diseases in the State were unsuccessful. The Board may have to rely on outside input for their deliberations. • There is no update from the State regarding reappointments and replacement of Board members.
Old Business		
Update on Nicotine Replacement Therapy products utilization		The Board reviewed report on the utilization of nicotine replacement therapy (NRT) products for SFY 2017, 2018 and 2019. - Overall utilization seemed to be steady. There were 28% more claims in 2018 than 2017, and 27% more in 2019 over 2018. Most of the change was in cost of the products 6% and 123% respectively, which seemed to be driven by one product – varenicline or Chantix®. - Slight decline in the utilization of bupropion/Zyban - Ms. Olson wondered what percentages of smokers are in each plan and how to ascertain that they are getting access to NRT products. There was no further discussion on this.

January 22, 2020 DURB Meeting Summary

Issue	Action	Notes
New Business		
(A) Proposed protocol for Fabry disease products (Fabrazyme®, Galafold®)	Approved	The Board reviewed a proposed protocol for Fabry disease products. The Board was informed that Dr. Pletcher, a geneticist and Associate Professor of Pediatrics and Medicine at Rutgers New Jersey Medical School reviewed and gave her consent for this protocol. Dr. Gooen expressed concern about the use of one of the products, Galafold® (migalastat), in severe renal impairment. That caution is part of the protocol. The Board approved and recommended the protocol.
(B) Proposed protocol for Lambert-Eaton Myasthenic Syndrome products (Firdapse®, Ruzurgi®)	Approved	The Board reviewed a proposed protocol for Lambert—Eaton Myasthenic Syndrome (LEMS) products. The Board approved and recommended the protocol. Dr. Swee enquired from the audience if anybody had knowledge of any treatment center dealing with or has encountered any of these rare diseases – Fabry disease and LEMS. Sam Currie, R.Ph., Pharmacy Director at Horizon NJ Health responded that although the numbers are small, Horizon has had patient representation for both protocols. He also informed the Board that both protocols are consistent with what Horizon has in place.
(C) Proposed protocol for Strensiq®	Approved	The Board reviewed a protocol for Strensiq® (asfotase alfa), a drug used for the treatment of perinatal/infantile and juvenile-onset hypophosphatasia. The Board approved and recommended the protocol. During this review, Sam Emenike, PharmD, shared some epidemiology data with the Board: - Fabry disease – Prevalence: 1 in 40, 000 to 60,000 males. Incidence: 3,230 males, and 4,483 females for a total of over 7,000. (Source: National Fabry Disease Foundation). - LEMS – Prevalence: 2.8 million worldwide; 400 in the United States. (Source: National Organization for Rare Disorders). - Perinatal/infantile and juvenile-onset hypophosphatasia – Prevalence: 1 in 100,000. (Source: Orphanet Journal of Rare Diseases, 2007 Incidence: Not known Dr. Marcus was curious about the financial impact of a patient using one of these products on the State's drug cost. The Board spent some time discussing the various costs of some of the products reviewed.

January 22, 2020 DURB Meeting Summary

<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 3rd quarter of 2019. Dr. Swee called on Olawemimo Odebiyi, PharmD, Regional Pharmacy Manager for United Healthcare to explain the Plan's highest rate of denials for the "clinical criteria not met" (CCNM) category. She promised to run a report, do some analysis and present to the Board at the next meeting. Mr. Currie, explained the difference between Horizon's model, which although has a high CCNM category, has a different approach to resolving the PA denials. Dr. Swee also expressed concern about the high number of non-formulary denials for Horizon and UHC. He requested that Mr. Currie work with Ed Vaccaro, R.Ph., on a report that explains how often Horizon contacted prescribers to resolve CCNM and non-formulary medications PAs.
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>14</td></tr>
<tr><td>Aetna</td><td>0.6</td><td>37</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>1</td><td>56</td></tr>
<tr><td>WellCare</td><td>0.6</td><td>49</td></tr>
</table>
</td></tr>
</table>

January 22, 2020 DURB Meeting Summary

Issue	Action	Notes
2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of actions from previous meetings (January 2019 thru October 2019).
3. DHS/DHSS/MCO Programs Top Drugs Report		Top drugs report for September 2019 (FFS)/August 2019 (MCOs) was reviewed. The Board discussed the $2.4 million spent on one product, Biktarvy, a recent entry into the market for the treatment of AIDS infection. Mr. Vaccaro stated that fee-for-service could do better with some of the drug costs if a formulary was in place. Dr. Marcus wondered about the public health programs that are distributing naloxone and who were paying for it. Mr. Vaccaro suggested that there's usually grant money involved. Dr. Marcus also wondered why none of the drugs used for the treatment of cystic fibrosis appears in the top drugs list even though they very expensive. Mr. Vaccaro suggested that this may be because the State has a CF program thus the cost is not reflected in fee for service drugs list. He informed the Board that this information is available online and promised to verify same and update them at a future date. Dr. Gochfeld expressed concern about the cost of chlorpromazine and risperidone, drugs that have been available for a while. She wanted to know what other states are doing to rein in the rising cost of these life-long medications for psychiatric patients. Dan Flores, with Amgen Pharmaceuticals volunteered to provide a lecture on health economics.
4. Medication Information		Some medical information was presented which included HHS guide for clinicians on the appropriate dosage reduction or discontinuation of long-term opioid analgesics.
Follow up items:		- United Healthcare will provide a report that explains why their clinical criteria not met (CCNM) category is high - Amerigroup will provide a similar report on CCNM - Mr. Currie and Ed Vaccaro will collaborate on a report on how often Horizon contacted prescribers to resolve CCNM and non-formulary drugs prior authorization requests - Mr. Vaccaro will provide information on possible grants for CF patients treatment program - Dr. Flores with Amgen will provide educational material on health economics to the Board.

January 22, 2020 DURB Meeting Summary