July 15, 2020 DURB Meeting Summary

Issue	Action	Notes
Roll Call		Present: Dr. Swee, Dr. Gochfeld, Dr. Marcus, Ms. Olson, Dr. Barberio, Dr. Gooen, Dr. Moynihan, Dr. Lind (ex-officio) Unable to attend: Mr. Schafer
Review of Minutes	Approved	Minutes from January 22, 2020 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 for July 2019: a. Hereditary angioedema (HAE) products b. Urea cycle disorder products c. Chelating agents used in the treatment of Wilson's disease, Cystinuria, and severe, active rheumatoid arthritis d. Zolgensma® (onasemnogene abeparvovec-xioi) For October 2019: a. Hereditary transthyretin-mediated amyloidosis (ATTR) products b. Elaprase® (idursulfase) c. Gaucher disease products d. Cablivi® (caplacizumab-yhdp) For January 2020: a. Fabry disease products b. Lambert-Eaton Myasthenic Syndrome products c. Strensiq®(asfotase) Also outstanding for signatures: DURB Annual Report for SFY 2019 Dr. Swee wondered if the pandemic was the reason for the delay in signing of these protocols. Dr. Emenike responded that he could see the pandemic affecting the January protocols and the annual report but had no explanation for the earlier protocols, July and October, 2019. The DHS commissioner had a concern about the Zolgensma protocol but that was being resolved through the Medical Director's

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		office. Dr. Lind informed the Board that he sent a reminder about the outstanding protocols to the Commissioner's office so they are aware of the situation. He is working with the Commissioner's office to resolve the issues. - Regarding a concern raised by Dr. Marcus at the previous meeting about cystic fibrosis drugs payments, Mr. Vaccaro, informed the Board that the Department of Health has a cystic fibrosis program that processes claims under a generic identifier for recipients. That could explain why the claims are not showing up in the top drugs report. - Dr. Sandra Moore, a member of the Board resigned recently. Her resignation letter was forwarded to Lynn Koch, the State's boards reappointment, appointment coordinator.
Old Business		
A. United Healthcare Clinical Criteria Not Met (CCNM) report		The Board reviewed a report from United Healthcare (UHC) which addressed a previous request from the Board concerning their high clinical criteria not met (CCNM) category on the denials report. Dr. Odebiyi, with UHC explained that they follow the State's protocol and claims that do not meet the threshold are denied for CCNM. Dr. Swee requested that UHC provide some examples of these denials to ensure that the plan's interpretation of "medically necessary" claims is the same as the prescriber's interpretation. Regarding Dr. Marcus' concern about non-FDA approved indications, Dr. Odebiyi explained that they have peer-to-peer conversations between the Plan's medical director and the physicians which usually results in terms that is best for the patient. She will provide examples of these reviews, decisions at the next meeting.
B. Amerigroup Clinical Criteria		Dr. Levi with Amerigroup explained that most of the plan's denials in this category are due to step therapy for drugs like proton pump inhibitors and are resolved by reaching out to the prescriber when necessary.

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Not Met (CCNM) report		
C. Horizon resolution rate for CCNM and non-formulary drugs PA requests		The Board reviewed a report from Horizon which had updated their previous number for CCNM from 4, 484 to 2,493 after double checking their data.
D. Addendum to Dupixent® (dupilumab) protocol	Approved	The Board reviewed an addendum for dupilumab protocol which was approved in April 2019. The update was the removal of criterion #7 (Patient will not use Dupixent® concomitantly with other biologics [e.g., Nucala (mepolizumab), Xolair (omalizumab), Rituxan (rituximab), etc. indicated for atopic dermatitis]). None of the products listed is indicated for atopic dermatitis. The Board recommended the addendum. Dr. Gooen enquired why other indications for dupilumab were not included in the addendum. She was informed that for now, the addendum addressed previous approval (atopic dermatitis) and other indications will be reviewed at a future date if necessary.
E. Addendum to Emflaza® (deflazacort) protocol	Approved	The Board reviewed an addendum for deflazacort protocol which was approved in August 2017. The updates were changes to criterion #2 (The patient is ≥ 5 years of age) which was changed to: the patient is ≥ 2 years of age according to new guidelines. And, criterion for #3 (Inadequate response, intolerance, or contraindication to a 6 month trial of prednisone at the optimal dose of 0.75 mg/kg/day). This was changed to: Patient has had a 3 month trial of prednisone at the optimal dose of 0.75mg/kg/day unless the patient has experienced an inadequate response, intolerance, or has a contraindication to therapy (intolerance includes, but is not limited to weight gain, behavioral disturbance, growth

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		restriction, pubertal delay, and vertebral fractures). The purpose of the change is to reduce trial period with prednisone.
F. Addendum to PCSK9 inhibitors	Approved	The Board reviewed an addendum for proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors. The change was the addition of a criterion that allows use for secondary prevention to the products, Praluent (alirocumab) and evolocumab (Repatha) according to recent guidelines. That criterion is: To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease. The purpose is to increase access.
New Business		
(A) Proposed protocol for Varubi® (rolapitant)	Approved	The Board reviewed a proposed protocol for rolapitant, a product indicated for use in combination with other antiemetic agents in adults for the prevention of nausea and vomiting associated with chemotherapy. Dr. Gooen suggested the addition of alert from the FDA regarding allergic reaction to the product including that for patients allergic to soybean oil. Ms. Olson commented that the product will likely be rarely used and will be with strict chemo protocols when used. The Board approved and recommended the protocol.
(B) Proposed protocol for Vyondys 53® (golodirsen)	Approved	The Board reviewed a proposed protocol for golodirsen, a product indicated for the treatment of Duchenne muscular dystrophy (DMD). Dr. Swee raised concern about how patients renal function will be monitored as stated in one of the criteria. He was informed that a medical necessity form will be sent to prescribers to obtain baseline renal function test and follow ups after that. The Board approved and recommended the protocol.
(C) Proposed protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) products	Approved pending addition of off-label language	The Board reviewed a proposed protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) products which include rilonacept (Arcalyst®), canakinumab (Ilaris®) and anakinra (Kineret®). Dr. Moynihan, expressed some concern conveyed to her by some immunologists and geneticists who requested flexibility in the eligible age used in the treatment guidelines. She wanted the flexibility verbiage to be included in the protocol. She was informed that such off-label use would have

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		to be discussed with the prescribers on a case-by-case basis but not necessarily written into the protocol. Dr. Swee requested that a language informing prescribers that the flexibility is available would be welcome. Dr. Emenike promised to discuss with the MCO team and agree on appropriate language. Mr. Currie, director of pharmacy at Horizon informed the Board that since there is no distinct off-label policy developing one could be considered. The Board approved and recommended the protocol pending addition of such language.
(D) Proposed protocol for Spravato® (esketamine)	Approved pending update of step therapy trial duration	The Board reviewed a proposed protocol for esketamine nasal spray, a product indicated for use in treatment-resistant depression in conjunction with an oral antidepressant. Dr. Gochfeld informed the Board that the current protocol was much more user friendly than the one sent to her to review in April. She however wondered why there was no criterion requiring use or consultation with a psychiatrist or a mental health nurse practitioner. Dr. Swee pointed out that access to psychiatrists for the Medicaid population was limited making it more difficult for patients. The Board requested that criterion #3 which requires documentation of failure or intolerance for at least "4 weeks" each to at least 2 antidepressants (prior to using esketamine) be changed to "3 weeks" to give the prescriber more flexibility. The Board approved and recommended the protocol pending the change in duration of trial period. Dr. Gochfeld abstained from the vote.
Proposed Newsletter on Medication-Assisted Treatment (MAT)	Approved	The Board reviewed a proposed educational newsletter on medication-assisted treatment (MAT). The purpose of the newsletter is to explain the benefits and risks associated with the MAT program medications and address the issues surrounding requests to remove prior authorization for these medications. Dr. Marcus questioned a recommendation by a Substance Abuse and Mental Health Services Administration (SAMHSA) consensus panel (mentioned in the newsletter) that it is prudent to transition patients who require long-term treatment from buprenorphine to buprenorphine/naloxone after induction. He argued that the presence of naloxone was to deter abuse via injection and therefore encouraged

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>Top (25) Drugs Utilization Review (2017-2019)</td><td></td><td>that it be used when appropriate for pain. Dr. Emenike pointed out that for the purpose of the newsletter, buprenorphine by itself is discouraged for long-term maintenance therapy in MAT. Buprenorphine/naloxone which is indicated only for substance abuse treatment is encouraged. Dr. Hanna informed the Board that in practice there was not much claims for buprenorphine/naloxone for pain but rather buprenorphine is being used more in those situations. Dr. Marcus requested that a utilization review of buprenorphine for pain to ensure there is no diversion.

Top 25 drugs used during the period of 2019 and 2019 was included in the packet.</td></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 4th quarter of 2019.
There were no comments regarding the report.
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>14</td></tr>
<tr><td>Aetna</td><td>0.5</td><td>41</td></tr>
<tr><td>Amerigroup</td><td>0.7</td><td>30</td></tr>
<tr><td>Horizon</td><td>0.9</td><td>41</td></tr>
<tr><td>UHC</td><td>1</td><td>57</td></tr>
<tr><td>WellCare</td><td>0.6</td><td>47</td></tr>
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Medication Information: 1. Protocol for the use of investigational drugs for the treatment of COVID-19		Protocol introduced in March 2020 as guidance for the use of hydroxychloroquine (HCQ), chloroquine (CQ), and lopinavir-ritonavir (Kaletra®) was included in the packet.
2. Reversal of Protocol for the treatment of COVID-19		The FDA reversed its emergency use authorization (EUA) for HCQ in June 2020. The reversal of the above protocol was introduced as an addendum.
3. Coronavirus (COVID-19) treatment Hub (URL)		A link with information to most recent COVID-19 treatments and updates was included in the packet.
2. Summary of DURB Actions/Recommendations		The Board reviewed a summary of actions from previous meetings (October 2019 thru January 2020).

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<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>Top drugs report for January 2020 (FFS)/December 2019 (MCOs) was provided for review.

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 2020</td><td>$13,077,495</td><td>$14,122,318</td></tr>
<tr><td>MCOs</td><td>December 2019</td><td>$80,037,005</td><td>$115,417,402</td></tr>
</table></td></tr>
<tr><td>4. Medication Information</td><td></td><td>Medical information was presented which provided a link to metformin ER recall updates.</td></tr>
<tr><td>Follow up items:</td><td></td><td>- United Healthcare will provide examples to explain their process for determining clinical criteria not met (CCNM) category
- The State will work with the MCOs to develop an additional language to be inserted into the CAPs protocol or to be used for off-label use in protocols
- The State will provide a report on the utilization of buprenorphine for pain</td></tr>
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