# October 18, 2017 DURB Meeting Summary

| Issue | Action | Notes |
|---|---|---|
| Roll Call | | Present: Dr. Swee, Dr. Zanna (ex officio), Dr. Gooen, Dr. Marcus, Dr. Barberio, Ms. Olson, Dr. Lind (ex officio)<br>Unable to attend: Mr. Schafer, Dr. Gochfeld, Dr. Moynihan, Dr. Moore |
| Public Notice | | Dr. Swee read a public notice required at each meeting: 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 August 10, 2017 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 | | • Still awaiting the Commissioners signatures for DURB annual summary for SFY 2016.<br>• The Commissioners have signed off on DURB- approved protocols for Exondys®, Emflaza® and Spinraza®.<br>• United Healthcare changed their format for presenting "directed interventions" category on the denials report.<br>• We were informed that the reappointment and appointment of DURB members will now be initiated next year as it was not reviewed by the Senate during this session.<br>• Proposed dates for 2018 DURB meetings are:<br>- Wednesday, January 10<br>- Wednesday, April 18<br>- Wednesday, July 18 and<br>- Wednesday, October 17<br><br>The DURB annual report for SFY 2017 is included in the Board members meeting packets. Please review; send comments/suggestions to Sam Emenike by November 30, 2017. |
| **Old Business** | | |
| (a) Update on approved pediatric protocols for Sovaldi® and Harvoni® | | The Board was presented with updated copies of sofosbuvir (Sovaldi®) and ledipasvir (Harvoni®) protocols for the treatment of hepatitis C in pediatric patients. The Board had requested changes (removal of the requirement for fibrosis stage 2 or METAVIR score of F2) from the original version. |

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<table>
<tr><th>Issue</th><th>Action</th><th>Notes</th></tr>
<tr><td>(b) Dentists opioid utilization review report from Medicaid Fraud division<br><br>(c ) PCSK9 utilization review</td><td></td><td>In 2016, the Board requested that Medicaid Fraud Division (MFD) investigate 22 Medicaid recipients who received more than 30 days of opioids from dentists in 2015. An excerpt from MFD's report provided by Vira Jaskir, R.Ph., the investigator was presented to the Board and is listed in the table below:
<table>
<tr><td>Recipients</td><td>Findings</td></tr>
<tr><td>7</td><td>Wrong prescriber information submitted by pharmacies</td></tr>
<tr><td>7</td><td>Clinical justification provided by prescribers</td></tr>
<tr><td>3</td><td>Referral was made to Pennsylvania DEA regarding this prescriber</td></tr>
<tr><td>2</td><td>Recipients referred to MCO's lock-in unit due to multiple scripts filled at multiple pharmacies</td></tr>
<tr><td>1</td><td>Prescriber is on the NJ Department of Treasury Consolidated Debarment Report</td></tr>
<tr><td>1</td><td>Prescriber is a specialist doing oral cancer research</td></tr>
<tr><td>1</td><td>32 days of opioid with antibiotics. No further opioid prescribed</td></tr>
</table>
Dr. Marcus expressed concern about the first category – wrong prescriber information. Mr. Vaccaro explained that MFD verified that the errors may have been due to the prescriber not providing the correct National Provider Identifier (NPI) number or the pharmacist using the incorrect one. There is a movement to make the NPI the standard provider ID in 2018. This should prevent or reduce these types of incidents. Dr. Gooen suggested that some form of education may be needed for pharmacists to reinforce the need to use the correct NPI or ID numbers.<br><br>The Board reviewed a 2017 utilization report for proprotein convertase subtilisin/kexin type 9 or PCSK9 inhibitors. A summary of that report is shown below.<br>FFS and MCOs Without Part D and TPL
<table>
<tr><td>Claims</td><td>Recipients</td><td>Quantity</td><td>Payments</td></tr>
<tr><td>44</td><td>17</td><td>88</td><td>$48,750</td></tr>
</table>
FFS and MCOs With Part D and TPL
<table>
<tr><td>Claims</td><td>Recipients</td><td>Quantity</td><td>Payments</td></tr>
<tr><td>484</td><td>143</td><td>1040</td><td>$170,193</td></tr>
</table></td></tr>
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| | | Dr. Marcus had a question about how the products were made – prefilled syringes or other dosage form, and ease of use. Mr. Banket with Amgen, the manufacturer of one of the products, Repatha, explained that the available dosage forms are mostly prefilled and could be used routinely. |
| **New Business** | | |
| (A) Proposed update to protocol for direct acting antivirals (DAAs) used in hepatitis C therapy | Approved | The Board reviewed an updated protocol for direct acting antivirals (DAAs) used in the treatment of chronic hepatitis C infection. This protocol was originally approved in June 2016. Included in the updated version are:<br>- The need for the assessment of patient for coinfection with hepatitis B (HBV) prior to initiating hepatitis C therapy and after treatment.<br>- Assessment of polymorphisms when using regimens that require such testing.<br>- The Addition of two new products: sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) and glecaprevir/pibrentasvir (Mavyret®), to the list of DAAs.<br><br>Dr. Swee inquired about the responsibility for reviewing the HBV tests and was assured that the pharmacists at MEP will continue to do that as part of their PA review. |
| (B) Proposed protocol for safe and efficient use of opioid induced constipation products | Tabled for next meeting | The Board reviewed a proposed protocol for use of opioid induced constipation (OIC) products. Dr. Marcus expressed concern about direct-to-consumer advertisements for these products in the middle of an opioid epidemic. Ms. Olson indicated that use in oncology is minimal. The Board however, wanted some changes made to the protocol and tabled it for the next meeting. Dr. Swee requested a report to show if there is evidence of misuse of the products – patients using them with no history of opioids. Dr. Barberio pointed out that for billing purposes, hospice care should be differentiated from palliative care and these needed to be separated out in the protocol. |

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| (C) Proposed protocol for the safe and efficient use of cerliponase alfa (Brineura®) | Approved | The Board reviewed a proposed protocol for cerliponase alfa (Brineura®), a recently FDA approved medication for treatment to slow loss of walking ability (ambulation) in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2). Dr. Gooen inquired about the possibility of children being brought into NJ from other states (who did not approve this product) to be treated here. Mr. Vaccaro assured her that Early and Periodic Screening, Diagnostic and Treatment (EPSDT), a Medicaid requirement makes that unnecessary. |
| (D) Tenofovir disoproxil versus tenofovir alafenamide | | Dr. Swee shared an email from Dr. Steven Levin, a renowned expert in AIDS. Dr. Levin was worried that some of the MCOs are denying payment for the new formulations of tenofovir containing alafenamide or TAF versus the older formulations containing disoproxil. The MCO representatives responded that they had both products on their formularies and any possible denials may have been due to drug-related problems – duplication, drug-drug interactions, etc. Dr. Swee promised to send Dr. Levin a note and request specific denials. |
| (E ) DURB annual report for SFY 2017 | | Dr. Swee reminded board members to review the annual report in their packet and make suggestions/recommendations. |
| **Informational Highlights/Reports** | | |
| 1. Fee-for-Service/MCO Prior Authorization Report | Continue to monitor. | The Board reviewed prior authorization denial report comparing all MCO plans including FFS for the 2nd quarter of 2017. Dr. Swee was concerned that United Healthcare's (UHC), response to previous request mixed two separate causes – denials and non-formulary. He would prefer that these be separated. Mr. Verba, with UHC promised to work with his team to separate out the non-formulary denials from those that would have bypassed the PA process had they met the other clinical criteria.<br>Percentage of prior authorization requests relative to total claims and denials associated with the PAs are listed below: |

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<tr><td>Plan</td><td>(%) PA Requests of claims</td><td>Denial (%)</td></tr>
<tr><td>FFS</td><td>0.6</td><td>17</td></tr>
<tr><td>Aetna</td><td>0.5</td><td>40</td></tr>
<tr><td>Amerigroup</td><td>0.9</td><td>27</td></tr>
<tr><td>Horizon</td><td>1</td><td>34</td></tr>
<tr><td>UHC</td><td>0.9</td><td>49</td></tr>
<tr><td>WellCare</td><td>0.9</td><td>46</td></tr>
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</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 2016 thru August 2017).</td></tr>
<tr><td>3. DHS/DHSS/MCO Programs Top Drugs Report</td><td></td><td>The Board reviewed August 2017 report for the top drugs, by dollar amount, claims count, service units and category for fee-for-service plan. This was compared to the report for April 2017. They also reviewed May 2017 report for MCO top drugs. Dr. Marcus again raised a previous concern about a claim for hereditary angiodema product which seemed to be the same amount (20 units) in each report. Dalia, Hanna, PharmD, with Molina, explained that 20 units did not necessarily mean that the patient was getting 20 doses.</td></tr>
<tr><td>4. Medication Information</td><td></td><td>Some medical information were discussed</td></tr>
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| **Follow up items:**<br>(a) Protocol for opioid induced constipation drugs | | (a) The Board requested further review and update of the protocol. They wanted the indications to be separated out for clarity. |
| (b) Tenofovir disoproxil versus tenofovir alafenamide denials | | (b) Dr. Swee will obtain specific information from Dr. Levin to help determine the reason(s) for the denials. |
| (C ) United Healthcare directed intervention denials report | | (c) Mr. Verba with UHC will work with his team to determine how to provide a further breakdown of the directed intervention category. |