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| Minutes  Drug Utilization Review Board Meeting  DATE: 9/13/2017 |  |

**Meeting Purpose:** Quarterly Open Board Meeting

Meeting opened at 6:00 P.M. by Chair, Timothy Fensky.

**Attendance:** Timothy Fensky, R. PH.; Leslie Fish, Pharm. D.; Joel Goldstein, M.D.; Colleen Labelle, MSN RN-BC CARN; Lori Lewicki, R. PH.; Greg Low, R. PH.; Sarah M. McGee, M.D.; Sophie McIntyre, Pharm.D.; Christy Stine, M.D.; Arthur Yu-shin Kim, M.D.

**Absent:** Audra R. Meadows, M.D.; Therese Mulvey, M.D.; Karen Ryle, M.S., R.PH.; Michael Thompson, M.D.;

**Agenda Items:**

1. Welcome and Introductory Remarks
2. Guest Forum
3. Clinical Items Update
4. Minutes
5. Abuse Deterrent Opioids Clinical Update
6. Pipeline Update
7. Hepatitis C Clinical Update
8. MassHealth Update
9. MHDL Update
10. DUR Operational Update
11. Asthma and Allergy Monoclonal Antibodies QA

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Guest Forum** | Jennifer McNary   * Spoke about Exondys. | **Follow Up**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Clinical Items Update** | Pharmacy News | **Follow Up**  Informational |
| **Action** | **Discussion**   * Victoza (liraglutide)   + On August 25, the FDA approved Victoza (liraglutide) for reduction in the risk of major adverse CV events in adults with T2DM and established CV disease. * Jardiance (empagliflozin)   + Jardiance (empagliflozin) was approved in December 2016 for the reduction in the risk of CV death in adults with T2DM and established CV disease.   + Guidelines favor the use of both agents in long-standing uncontrolled T2DM and established CV disease.   + Metformin remains the initial therapy. * Cost-effectiveness of PCSK9 Inhibitors Analyses Suggest Drugs May Be Overpriced. | **Follow Up**  N/A |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Review of Minutes** | Motion to accept the June 14, 2107 minutes as written. | **Follow Up**  N/A |
| **Action** | Minutes were accepted. |  |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Abuse Deterrent Opioids Clinical Update** | **Discussion**   * Review the concept of abuse-deterrent opioid formulations (ADFs). * Discuss the types of studies that are required for a manufacturer to obtain abuse-deterrent labeling for a product. * Identify the ADFs that are currently approved and their mechanisms of abuse-deterrence. * Summarize the Evidence Report on ADFs prepared by the Institute of Clinical and Economic Review (ICER). * Review the ongoing work of the Massachusetts Drug Formulary Commission * Formulated to meaningfully deter abuse of the opioid. * According to the Food and Drug Administration (FDA) ADFs may be categorized by the following methods: * Physical/Chemical Barrier * Agonist/Antagonist Combination * Aversive Technology * Delivery System Resistant to Manipulation * New Molecular Entity/Prodrugs * Combination of Methods * Other Novel Approaches | **Follow Up**  Informational |
| **Action** | **Conclusions**   * ADFs are effective options for the treatment of pain * May have the potential to reduce abuse, based upon surrogate endpoints * Postmarket studies confirming ADFs reduce abuse in the community are limited, and available data is mixed. * Abuse and diversion of the ADF typically decrease * Abuse may shift from the ADF to other opioids/heroin * Changes in heroin abuse rates ranged from -11% to +100% after OxyContin (oxycodone extended-release) reformulation * Study with 11% decrease in heroin abuse showed 191% increase in oxymorphone extended-release abuse. * Widespread adoption of ADFs is likely to substantially increase healthcare costs, according to ICER. * Massachusetts is currently taking steps to encourage the increased use of ADFs, as a result of Chapter 258 of the Acts of 2014. | **Conclusion**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Pipeline Update** | Pipeline Update Presentation | **Follow Up**  Informational |
| **Action** | **Discussion**   * Fitusiran   + Proposed Indication: Treatment of Hemophilia A or B   + Potential Impact     - Approximately 20 million patients living with hemophilia in US     - Hemophilia management is based on factor replacement that requires frequent IV infusion and is associated with extremely high costs.     - Promoting production of thrombin may reduce frequency of bleeds, reducing need for replacement therapy.   + Projected market entry     - A specific timeline is not available. * Luxturna™ (voretigene neparvovec)   + Proposed indication: Treatment of vision loss due to confirmed biallelic RPE65-mediated IRD   + Potential impact     - Approximately 3,300 patients with RPE65-mediated IRDs in the US     - BioPharm Insight reports amortized payment models may be used due to significant costs.     - Awarded Orphan Drug, Breakthrough Therapy designations   + Projected market entry     - An FDA decision is expected by January 12, 2018. | **Conclusion**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Hepatitis C Clinical Update** | **Discussion**   * Provide an overview of hepatitis C treatment. * Provide highlights of prescribing information and clinical trial data for the novel hepatitis C agents. * Discuss relevant clinical and economic considerations. * Propose recommendations for managing novel hepatitis C agents. | **Follow Up**  Informational |
| **Action** | **Conclusion**   * New agents address gaps in hepatitis C treatment   + Prior failure of DAA   + Severe renal impairment * Offer shorter treatment duration for many patients. * Ribavirin-free treatment options are needed in   + Decompensated cirrhosis   + Post-liver transplant * Careful screening for drug interactions will continue to be necessary.   **Recommendation**   * Review updated treatment guidelines when they become available. * Monitor the utilization of the newer agents. * Entertain cost proposals from manufacturers to select one or more hepatitis C product as preferred. | **Conclusion**  Proceed with recommendations as stated. |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **MassHealth Update** | MassHealth Update | **Follow Up**  Informational |
| **Action** | **MassHealth Update**   * Re-procure managed-care organization contracts. * Procure accountable-care organizational (ACO) contracts   + Six ACOs are participating in pilot for direct contract with MassHealth PCC   + Target date is March 1, 2018 * Budget remains concern   + Newly approved and pipeline agents (e.g., orphan drugs) are escalating cost at unsustainable rate.   **Pharmacy Program**   * Pricing   + Implementing updated pricing regulations mandated by CMS which will modify reimbursement to pharmacies * Regulations changes in process   + Dispensing fee on Medicaid Prescriptions was $10.02, amendment filed with State Plan to reduce fee to $9.02   + Waiver 1115 posted on website:     - Establish closed formulary     - Establish specialty pharmacy network   + Possible updates to 340B Program * Procurement of supplemental rebate   + Currently reviewing bids * Abuse Deterrent Opioids   + Convening a workgroup to take a step forward to manage opioids in Massachusetts * Pediatric Behavioral Health Medication Initiative   + Working with foster care population and Department of Youth and Families | **Conclusion**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **MHDL Update** | MassHealth Drug List (MHDL) Updates | **Follow Up**  Informational |
| **Action** | Discussed new drug additions and changes that will go into effect on September 25, 2017   * There will be seven new drugs added to the drug list. * Six will require PA and one will not. * One drug will change to require prior authorization. * Four drugs will be removed from the Brand Name Preferred to Over Generic list. * Three drugs will be added to the Brand Name Preferred Over Generic list. * Four drugs will be removed from the Over-the-Counter Drug list. * Eight drugs will be added to the Over-the-Counter Drug list. | **Conclusion**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **DUR Operational Update** | Quarterly Operational Statistics | **Follow Up**  Informational |
| **Action** | * Prior Authorization (PA) Requests – average 7,500 per month, FY 91,000 over all * Call Volume – 7,500 calls per month, peak September 2016 with 8,092 calls * Abandonment rate about 1.5%   + Industry standards is about 5% * Average answered call wait time – 9 seconds * Overall call time for answered calls – 3 minutes and 52 seconds * Goal under 4 minutes * Refill too soon (40%) and prior authorization required (36%) were majority of calls for pharmacy edits * Appeals average 10 to 11 per month * Provider outreach * Average over 8 to 10% over all the PA volume * Top 10 medications  |  |  | | --- | --- | | * Aripiprazole * Clonidine * Lyrica * Lantus * Methylphenidate | * Harvoni * Oxycodone * Guanfacine * Risperidone * Botox |  * PA turn-around time during business hours * Goal is 24 hours * 59% done in 6 hours * 99.9 within 24 hours * PA turn-around time during non-business hours * 85% done in 6 hours * 99% within less than 9 hours | **Conclusion**  Informational |

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| **Agenda Item** | **Discussion** | **Conclusions/Follow Up** |
| **Asthma and Allergy Monoclonal Antibodies QA** | **Discussion**   * Discuss background information on the various asthma & allergy monoclonal antibodies and their use in clinical practice. * Evaluate recent utilization and cost data for MassHealth members. * Present a brief overview of the current prior authorization (PA) criteria and review the randomly selected cases. * Review historical comparison of utilization from last QA evaluation. * Discuss recommendations to current MassHealth clinical criteria. | **Follow Up**  Informational |
| **Action** | **Conclusion:**   * No recent guideline updates for CIU, GINA (2017)- asthma * Guidance for absolute blood eosinophil count threshold   + NICE: 300 cells/μL (Nucala) and 400 cells/μL (Cinqair)   + Clinical trials: 150 cells/μL (Nucala) and 400 cells/μL (Cinqair)   + Levels may be affected by systemic corticosteroid use   + Varying units reported by labs * Update PA form to ask for weight. * Recertifications changed from two years to one year. | **Conclusion**  Proceed with recommendations as stated. |

Meeting adjourned at 8:03 P.M.

Respectfully submitted by: Vincent Palumbo, Director of DUR

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