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| MinutesDrug Utilization Review Board MeetingDATE: 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

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| * Aripiprazole
* Clonidine
* Lyrica
* Lantus
* Methylphenidate
 | * Harvoni
* Oxycodone
* Guanfacine
* Risperidone
* Botox
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* 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

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_