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:
I. Welcome and Introductory Remarks
II. Guest Forum
III. Clinical Items Update
IV. Minutes
V. Abuse Deterrent Opioids Clinical Update
VI. Pipeline Update
VII. Hepatitis C Clinical Update
VIII. MassHealth Update
IX. MHDL Update
X. DUR Operational Update
XI. Asthma and Allergy Monoclonal Antibodies QA

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

Agenda Item	Discussion	Conclusions/Follow Up
Clinical Items Update	Pharmacy News	**Follow Up** Informational
Action	**Discussion** • Victoza (liraglutide) o On August 25, the FDA approved Victoza (liraglutide) for reduction in the	**Follow Up** N/A

	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.	

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.	

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.
		<u>Conclusion</u>
		Informational

Agenda Item	**Discussion**	**Conclusions/Follow Up**
Pipeline Update	Pipeline Update Presentation	**<u>Follow Up</u>** 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)
	  ○ <u>Proposed indication</u>: 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.
		<u>Conclusion</u>
		Informational

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.

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
		Conclusion
		Informational

	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	

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

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
		<u>Conclusion</u>
		Informational

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.	**<u>Follow Up</u>** 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: _____