Minutes
Drug Utilization Review Board Meeting
DATE: December 11, 2019

Meeting Purpose: Quarterly Drug Utilization Board Meeting
Meeting opened at 6:00 p.m. by Timothy Fensky RPh

Attendance: Melissa Coyle, PharmD; Timothy Fensky, RPh; James Gagnon, RPh, PharmD; Lori Lewicki, RPh; Greg Low, RPh, PhD; Sarah M McGee, MD; Julita Mir, MD; Karen Ryle, MS, RPh; Christy Stine, MD, PhD

Absent: Colleen Labelle, MSN, RN-BC, CARN; Laura Spring, MD; Michael Thompson, MD

Agenda Items:
- Welcome and Introductory Remarks
- Introduction of New Board Members
- Guest Forum
- Biosimilar Update: Pipeline Trends and Regulatory Updates
- PARP (Poly [ADP-ribose] polymerase) Inhibitors Quality Assurance Analysis
- Infectious Disease Hot Topics: New Trends in Hepatitis C Virus and Human Immunodeficiency Virus Treatment
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Clinical Team Update
- List of Documents and Exhibits

Agenda Item	Discussion	Conclusions/Follow Up
Introduction of New Board Members	Welcoming New Members of the DUR Board • Dr Mylissa Coyle • Dr James Gagnon • Dr Julita Mir	**Follow Up** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Pharmaceutical Representative Testimony • Dr Elizabeth Lubelcczyk	**Follow Up** Informational/Advisory
Action	Discussion • Dr Elizabeth Lubelcczyk presented testimony on nasal glucagon on behalf of Lilly Pharmaceuticals.	**Conclusion** The board reviewed and accepted the recommendation.

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Medical Representative Testimony • Dr Frank Nagy	**Follow Up** Informational/Advisory
Action	Discussion • Dr Frank Nagy presented testimony on liquid glucagon on behalf of Xeris Pharmaceuticals.	**Conclusion** The board reviewed and accepted the recommendation.

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion to approve the minutes for June and September was made by Christy Stine, MD, and seconded by Karen Ryle, MS, RPh.	**Follow Up** Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Biosimilar Update: Pipeline Trends and Regulatory Updates	**<u>Biosimilar Update: Pipeline Trends and Regulatory Updates by Dr Tasmina Hydery</u>** The update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical biosimilar pipeline agents that are newly marketed or in late-stage development.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussion • Provided an overview of regulatory updates for biosimilars. • Evaluated the current approval and marketing status of biosimilars in the United States. • Discussed MassHealth management strategies for biosimilars. • Recognized the barriers to biosimilar uptake and utilization. • Reviewed real-world clinical data to support biosimilar utilization. Findings Biosimilar • Are highly similar to reference product by analyzing structure, function, purity, chemical identity, and bioactivity, e.g., minor differences in inactive components. • Interchangeable: additional studies to show same clinical result as reference product and can be substituted for reference product without prescriber involvement. Questions • Dr Low is aware of prescriber skepticism about biosimilars, but in theoretical ways, he is not concerned about it. • Dr Ryle commented that additional studies are required on making biosimilars interchangeable. She asked if the manufacturers are pursuing this. • Dr Hydery responded that with the interchangeability there are going to be more costs associated with those studies. • Dr Low believes one company has done a study, but he does not remember which company did it. • Dr Hydery stated that the FDA released a report about a week prior to the DUR Board meeting about having interchangeable insulin more readily available, so there is more work that needs to be done. • Dr Ryle inquired about the suffix, i.e., the four letters of the medications: is that assigned by the drug manufacturers or the FDA? • Dr Low responded that the drug company can propose the four-letter suffix.	**Conclusion** The board reviewed and accepted the recommendation.

	The FDA can approve the suffix but they can also reject if it is not as random as it needs to be. • Mr Fensky stated that the Board of Pharmacy is not the appropriate body to approve substitution where there is a regulatory body for safety, the FDA. The Board of Pharmacy is basically putting the regulations in place that are given to us by statute and ensuring public safety.	

Agenda Item	Discussion	Conclusions/Follow Up
PARP (Poly [ADP-ribose] polymerase) Inhibitors Quality Assurance Analysis	**PARP (Poly [ADP-ribose]polymerase) Inhibitors Quality Assurance Analysis by Dr Kaelyn Boss** This overview was an evaluation of current medical literature. Dr Boss provided a brief overview of guideline recommendations in this disease state.	**Follow Up** Informational/Advisory

Action	Discussion
	• Reviewed PARP inhibitors and their FDA-approved indications.
	• Discussed Massachusetts Medicaid (MassHealth) prior authorization (PA) criteria for PARP inhibitors.
	• Reviewed current utilization and PA requests.
	• Reviewed cost data and other insurance coverage for PARP inhibitors.
	
	Findings
	• First QA analysis of PARP inhibitors
	  ○ Utilization of Lynparza (olaparib) and Rubraca (rucaparib) resulted in a total amount spending of $820,380 over a six-month period.
	• A total of 25 PAs received for 15 members
	  ○ Absolute denial rate of 0% over a six-month period
	• EBM review conducted
	  ○ Current criteria compared against FDA-approved indications and NCCN guideline recommendations.
	  ○ No changes recommended to criteria.
	• Lynparza (olaparib) 50mg capsule became obsolete in POPS
	  ○ This strength/dosage form will be removed from the internal guidelines.
	• The updates to information regarding PARP inhibitors will be published with the next MassHealth Drug List rollout.
	
	Questions
	• Dr Stine inquired about the denial rate being zero, and the necessity of completing a Prior Authorization form.
	• Dr Boss responded that as these are expensive options and per recommendations of NCCN guidelines, this requires at least one prior therapy line.
		Conclusion
		The board reviewed and accepted the recommendation.

Agenda Item	Discussion	Conclusions/Follow Up
Infectious Disease Hot Topics: New Trends in Hepatitis C Virus and Human Immunodeficiency Virus Treatment	**<u>Infectious Disease Hot Topics: New Trends in Hepatitis C Virus and Human Immunodeficiency Virus Treatment by Dr Pavel Lavitas</u>** This overview was an evaluation of current medical literature and newly approved agent's. Dr Lavitas provided a brief overview of guideline recommendations in these disease states.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Reviewed current management of hepatitis C virus direct-acting antivirals (DAAs).
	• Summarized recent changes to Hepatitis C treatment guidelines.
	• Discussed trends in recent drug approvals for human immunodeficiency virus (HIV) infection.
	• Estimated US prevalence of HCV infection: 3.5 million people
	  o MA prevalence: 200,000+ people
	  o MA incidence: 7,000 to 9,000 people per year
	  o Distribution changed from baby boomers to < 40 years old
	• Treatment goal is HCV eradication, preventing complications and liver related deaths.
	• Oral DAA are costly, but highly effective and recommended for most patients.
	• On October 3, 2019 Descovy (FTC/TAF) was approved for PrEP in men and transgender women only.
	  o Truvada (FTC/TDF) approved for PrEP in 2012
	  ▪ Generic(s) expected after September 30, 2020
	  o Fewer bone and renal side effects vs Truvada
	• Slow historical uptake of PrEP
	  o ~1.1 million people have an indication for PrEP
	  o 40,000 people are infected with HIV every year
	  o PrEP uptake 8,768 (2012) to ~200,000 (2019)
	• On May 9, 2019 Gilead promised to donate Truvada (FTC /TDF) for PrEP to the CDC.
	  o 200,000 uninsured will gain access at no cost x 11 years.
	  ▪ Cost to government: $200 for 30 tablets
	  ▪ Pharmacy chains to donate dispensing/counseling
	  o Gilead plans to transition PrEP business to Descovy (FTC/TAF).
	• DHHS is suing Gilead for patent infringement related to PrEP patents held by DHHS.
		Conclusion
		The board reviewed and accepted the recommendation.

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	**<u>MassHealth Drug List (MHDL) Update given by Dr Arthur Lam</u>** An MHDL overview was presented and included new additions, changes in Prior Authorization (PA) status, and related attachment updates implemented with the October publication rollout.	**<u>Follow Up</u>** Informational/Advisory
Action	• This presentation was tabled until the next DUR Board meeting.	**<u>Conclusion</u>** The board reviewed and accepted the recommendation.

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	**<u>The MassHealth Update was presented by Dr Paul Jeffrey.</u>** The MassHealth Update was a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, and public health.	**<u>Follow Up</u>** Informational/Advisory

Action	MassHealth Update
	• Welcomed new board members.
	• There will be two Mass General Law public hearings for regulations concerning pharmaceutical pricing, with the two agencies involved in the application of the law.
	  ○ EOHHS held the first hearing on Friday, December 13, 2019, giving MassHealth the authority to set the threshold price and negotiate directly with manufacturers.
	  ○ Health Policy Commission (HPC) concerning pricing matters referred to the HPC
	• Pharmacy Program Regulation Updates
	  ○ Hearing scheduled for Friday December 20, 2019
	  ○ Proposal has three parts
	  ▪ Implementation requirement of 90-day supply (currently optional);
	  ▪ Direction to pharmacies and pharmacists where a patient opts to pay for a drug where the drug is not payable under MassHealth rules; and
	  ▪ Clause to allow MassHealth to exclude purchase of certain
		<u>Conclusion</u>
		The board reviewed and accepted the recommendation.

	drugs under the 340b program. Questions • Dr Ryle inquired about rebates for 340b drugs. • Dr Jeffrey stated that MassHealth may ask CMS to reconsider rebates for 304b drugs in a more formal way. He noted that CMS has a new Deputy Director of the Division of Pharmacy, Cindy Denmark, who was a 25-year director of pharmacy in the state of Delaware. Dr Jeffrey also stated that MassHealth is in conversations with CMS to allow rebates on 340b drugs. Dr Ryle noted that pharmacists understand the retail pharmacy costs of drugs and the revenue associated, but not rebates.	

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	**Quarterly Operational Statistics presentation given by Dr Patricia Leto** DUR Operational Overview statistics associated with Prior Authorization (PA) review, PA response, and Call Center metrics.	**Follow Up** Informational/Advisory
Action	Discussion • This presentation was tabled until the next DUR Board meeting.	**Conclusion** The board reviewed and accepted the presentation.

Agenda Item	Discussion	Conclusions/Follow Up
Clinical Team Update	**Clinical Team Update by Dr Mark Tesell** The Clinical Team Update will include an overview of projects and accomplishments of the clinical pharmacist team of the MassHealth Drug Utilization Review Program.	**Follow Up** Informational/Advisory
Action	Discussion • This presentation was tabled until the next DUR Board meeting.	**Conclusion** The board reviewed and accepted the presentation.

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____