Minutes
Drug Utilization Review Board Meeting
DATE: December 14, 2016

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 PM by Chair, Sarah McGee.

Attendance: Adam Bard Burrows, M.D.; Timothy Fensky, R.PH.; Joel Goldstein, M.D.; Sarah M. McGee, M.D.; Audra Meadows, M.D., MPH; Christy Stine, M.D.; Arthur Yu-Shin Kim, M.D.

Absent: Leslie Fish, Pharm.D.; Sophie McIntyre, Pharm.D.; Karen Ryle, M.S., R.PH

Agenda Items:
I. Welcome and Introductory Remarks
II. Public Comment
III. Clinical Items Update
IV. Multiple Sclerosis Agents Quality Assurance Analysis
V. Clinical Team Annual Review
VI. Opioid Dependence Therapy Quality Assurance Analysis
VII. Pipeline Update
VIII. MHDL Update
IX. DUR Operational Update
X. MassHealth Update
XI. Androgen Therapy Assurance Analysis *(Time permitting)*

Agenda Item	Discussion	Conclusions/Follow Up
Review of Minutes	• Motion to accept September 14, 2016 minutes	**Follow Up:** **N/A**
Action	• Motion accepted	**Conclusions:** N/A

Agenda Item	Discussion	Conclusions/Follow Up
Public Comment	Thomas Carattini, Medical Managed Care Director for Sanofi Genzyme • Discussed Lemtrada® (alemtuzumab) Joey Sturgeon, Managed Markets National Accounts Director for Silvergate Pharmaceuticals • Discussed Qbrelis® (lisinopril)	**Follow Up:** **Informational**

	Heidi Belden, Medical Director for Tris Pharma • Discussed Dyanavel XR® (amphetamine)	

Agenda Item	Discussion	Conclusions/Follow Up
Clinical Items Update	• Discussed updated US Preventative Services Task Force (USPSTF) recommendations for statin use for the primary prevention of CVD in adults ➢ Published on November 15, 2016 ➢ Benefits of statin therapy are weighed against harms • US Surgeon General's Report: Facing Addiction in America ➢ Classifies addiction as a chronic illness requiring compassion and understanding vs. a moral failure ➢ Provides statistics on the impact of the addiction epidemic ➢ Genetic and environmental factors as well as early initiation of substance use are associated with substance use disorder	**Follow Up: Informational**

Agenda Item	Discussion	Conclusions/Follow Up
Multiple Sclerosis Agents Quality Assurance Analysis	Discussion • Provided an overview of pathogenesis, complications and treatments for multiple sclerosis (MS) • Explained the historical management of the class • Analyzed trends and changes in recent utilization • Presented an overview of prior authorization (PA) requests for MS agents • Recommended changes to MassHealth clinical criteria	**Follow Up: Informational**
Action	Conclusions and Recommendations • Utilization Data o From March 1, 2016 through August 31, 2016, there were a total of 1,330 paid claims for 327 unique utilizers totaling $6,447,324 • PA requests o Total of 71 PA requests including 57 approvals and 14 denials o All PA requests evaluated demonstrated appropriate use of the current clinical guideline • Recommendations o At this time no changes are recommended to the MassHealth Clinical Criteria	**Conclusion:** Proceed with recommendations as stated.

Agenda Item	Discussion	Conclusions/Follow Up
Clinical Team Annual Review	Discussion • Reviewed clinical projects and accomplishments for fiscal year 2016 • Summarized and quantified new drug reviews, guidelines, and proposals ➢ 69 New drug reviews (NDRs) ➢ Clinical Guidelines o 81 evidence-based medicine (EBM) updates ➢ 54 QAs resulting in guideline clarification and change in PA status ➢ 5 clinical proposals • Discussed progress related to MassHealth clinical initiatives ➢ 1,998 total cases sent to clinical review • Provided an overview of contributions of pharmacy practice residents and students on the DUR rotation ➢ Resident posters at Academy of Managed Care Pharmacy and AMCP Managed Care & Specialty Pharmacy Annual meetings ➢ Student rotations o Affiliated with 8 schools of pharmacy o Produces 1 QA, 4 NDRs, 7 escalated clinical review cases, 7 pipeline updates • Presented an overview of disseminated work related to the MassHealth pharmacy program • Described trends in clinical projects	**Follow Up: Informational**

Agenda Item	Discussion	Conclusions/Follow Up
Opioid Dependence Therapy Quality Assurance Analysis	Presentation • Reviewed the historical and current management of the therapeutic class • Analyzed the current utilization of the therapeutic class and impact of preferred product designation upon utilization trends • Examined prior authorization (PA) requests for the opioid dependence and reversal agents ➢ There were 1,509 prior authorization requests for opioid drugs from April 1 to September 30, 2016 o 903 approvals • Provided recommendations to enhance the quality of the PA review process	**Follow Up: Informational**
Action	Discussion • Quality Assurance Analysis revealed appropriate review of opioid dependence requests • Preferred product market share of 94% • PA requirement for continuation of Suboxone® (buprenorphine/naloxone film) > 16 mg/day and ≤ 24 mg/day remains appropriate • Most members with a denial for a non-preferred buprenorphine/naloxone agent	**Conclusion:** Proceed with proposed recommendations as stated.

	filled Suboxone® (buprenorphine/naloxone film) after denial • Evzio® (naloxone auto-injection) criteria can be updated. ➢ Ask for clinical rational to establish medical necessity of the auto-injection formulation, as it pertains to the caregiver. o Outreach to the prescriber will be conducted upon denial to inform of products available without a PA to ensure members are provided with an appropriate alternative.	

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	Discussed Updated Agents • Sofosbuvir/velpatasvir/voxilepravir ➢ Proposed indication: Genotype 1-5 HCV infection ➢ 4 phase III clinical trials ➢ NDA submitted December of 2016 • Niraparib ➢ Proposed indication: Platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer ➢ NDA submitted November of 2016 o Decision expected in the first half of 2017 o Supported by data from the phase III ENGOT-OV16/NOVA trial	**Follow Up: Informational**

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	Discussed new drug additions and changes that will go into effect on January 9, 2017 • There will be 11 new drugs and 7 new generics added • Four drugs will have quantity limit changes • Four drugs will change to require prior authorization • Three drugs will be added to the Brand Name Preferred Over Generic list.	**Follow Up: Informational**

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	Presentation was deferred until next meeting.	**Follow Up: N/A**

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	Discussion • $8 billion waiver allows MassHealth to restructure the delivery system (11/15/16) ➢ $1.8 billion will aid in transforming the way services are paid for o From a traditional service model to an ACO model launched on 12/1/16 o Pay providers to provide total care of patients • ACO models to launch over the next year ➢ Direct contract between the provider organization and the PCC plan (or fee for service population) ➢ Direct contract with the ACO and an MCO, one of our Managed Care partners ➢ Contract between MassHealth and an ACO/MCO collaborative (Hybrid model) • Pharmacy priorities ➢ CMS Covered Outpatient Drug Rule o Proposal for new method to reimburse pharmacies o Regulations in place by 4/1/17 o Submit a state plan by June 30, 2017 ➢ Decrease budget costs o 95% of the drugs that come to market require prior authorization o Additional supplemental rebates with new procurement for 7/1/17 o Change regulations around brand named drugs vs generic to allow for Brand Name Preferred Over Generic List ➢ 340B Reimbursement policy update ➢ Re-procurement of claims processor o Launch of new Xerox contract which expires June 30, 2018	

Meeting adjourned at 8:00 PM.

Respectfully submitted,

Vincent Palumbo
DUR Program Director