Minutes
Drug Utilization Review Board Meeting
DATE: 6/12/19

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 pm by, Timothy Fensky

Attendance: Timothy Fensky, R Ph; Joel Goldstein, MD; Colleen Labelle, MSN, RN-BC, CARN; Greg Low, Rh, PhD; Karen Ryle, MS, R Ph; Christy Stine, MD; Michael Thompson, MD;

Absent: Lori Lewicki, R Ph; Sarah M. McGee, MD; Therese Mulvey, MD;

Agenda Items:
I. Welcome and Introductory Remarks
II. Minutes
III. Pipeline Update Summary
IV. Resident Research Project: Changes in Medical and Pharmacy Utilization Following Initiation of Clozapine in Adults with Treatment-Resistant Schizophrenia in a Medicaid Population
V. Resident Research Project: An Observational Case-Control Study of Risk Factors for Overdose in Members of State Medicaid Program Prescribed Concurrent Benzodiazepines and Opioids
VI. Spravato (esketamine) New Drug Review
VII. MHDL Update
VIII. DUR Operational Update
IX. MassHealth Update
X. Immunoglobulin Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion made by Christy Stine, MD to accept the March 13, 2019, minutes as written.	**Follow Up** N/A
	Minutes for March 13, 2019, were seconded by Joel Goldstein, MD All approved.	

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	Pipeline Update Summary by Dr Pavel Lavitas The Pipeline Update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development.	**Follow Up** Informational/Advisory

Action	**Discussion**
	• Reviewed Givosiran – RNAi Therapeutic Agent treating ALA1S
	  ○ Treatment of AHP
	• Reviewed Luspatercept – Erytheroid Maturation Agent
	  ○ Treatment of very low to intermediate-risk MDS-associated anemia requiring RBC transfusions
	  ○ Treatment of β-thalassemia-associated anemia requiring RBC transfusions
	
	Findings
	• Givosiran
	  ○ Completion of the rolling NDA submission to the FDA
	  ○ R, DB, PC phase III study (N=94)
	  ○ **Population:** Patients ≥ 12 years of age with AHP and ≥ 2 attacks within prior six months
	  ○ **Administration:**
	  • Givosiran 2.5 mg/kg SC monthly
	  • Placebo
	  ○ Projected Market Entry: Late 2019/early 2020
	• Luspatercept
	  ○ FDA accepted BLA for review
	  ○ R, DB, PC phase III MEDALIST study (N=229)
	  ○ **Population:** Adults with very low to intermediate-risk MDS-associated anemia who require RBC transfusions
	  ○ **Administration:**
	  • Luspatercept 1 mg/kg SC every 21 days
	  • Placebo
	  ○ FDA decision is expected by 12/4/19 (β-thalassemia) and by 4/4/20 (MDS)
		Conclusion
		Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project	Resident Research Project: Changes in Medical and Pharmacy Utilization Following Initiation of Clozapine in Adults with Treatment-Resistant Schizophrenia in a Medicaid Population by Dr Mckenzie Taylor This is an overview of a research project by a current pharmacy practice resident.	**Follow Up** Informational/Advisory
Action	**Discussion** • APA defines treatment-resistant schizophrenia as little or no symptomatic response to at least two antipsychotics.* • It is estimated that 16 to 20% of patients with schizophrenia are categorized as treatment-resistant. • The rate of clozapine utilization in these patients is two to three% • Clozaril (clozapine) is the only medication FDA-approved for treatment-resistant schizophrenia. • The primary objective of this retrospective analysis was to assess the changes in medical and pharmacy utilization pre-and post-clozapine initiation (index date) in members with TRS. **Findings** • The results of this analysis suggest that the evaluated healthcare utilization and associated costs decreased among select members with schizophrenia following the initiation of clozapine • The mean number of schizophrenia-and mental health-related ED visits and associated costs decreased in the six months following clozapine initiation	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project	<u>Resident Research Project: An Observational Case-Control Study of Risk Factors for Overdose in Members of State Medicaid Program Prescribed Concurrent Benzodiazepines and Opioids by Dr Kaelyn Boss</u> This is an overview of a research project by a current pharmacy practice resident.	**<u>Follow Up</u>** Informational/Advisory

Action	**Discussion**
	• Concurrent use of benzodiazepines and opioids is associated with 31 to 61% of fatal overdoses.
	• In Massachusetts, benzodiazepines were present in approximately 42% of opioid overdose deaths in the first six months of 2018.
	• MassHealth evaluates high risk members on opioid therapy through the HD Opioid TCM Workgroup.
	  ○ HD opioid regimens
	  ○ SA opioid monotherapy
	  ○ Frequent denials or provisional approvals
	• MassHealth will be initiating a new program regarding chronic concomitant use of benzodiazepines and opioids.
	  ○ PA requirement
	  ○ Case discussion through HD Opioid TCM workgroup
	  ○ Outreach to prescribers
	• The objective of this analysis was to compare characteristics of adults within the MassHealth population who were prescribed concurrent benzodiazepine and opioid therapy and experienced an overdose to a random sampling of members who did not experience overdose.
	• **Study outcome:** Proportion of patients in each population with prespecified risk factors
	  ○ Risk factors identified through primary literature review
	  ▪ Demographics → POPS data
	  ▪ Pharmacy related risk factors → MassHealth pharmacy claims data
	  ▪ Comorbid disease states → MassHealth medical claims data
	
	Recommendations
	• This analysis identified several key risk factors as being associated with a higher incidence of overdose. These include:
	  ○ oxycodone immediate-release use
	  ○ concomitant gabapentin or pregabalin use
	  ○ alcoholism and SUD
	  ○ history of overdose
		Conclusion
		Informational/Advisory

	○ PTSD • Next step: ○ Apply the findings in the development of criteria for referral to HD Opioid TCM workgroup **Questions** • A Board member asked about the increase of stimulants. • Dr Boss responded that if a member obtains a stimulant from another source or by another means, the numbers are not going to be reflected through MassHealth claims data. One example is the member paying out of pocket. • Board member asked if Dr Boss has access to the prescription monitoring program. • Dr Boss responded that she does not have access to the program.	

Agenda Item	Discussion	Conclusions/Follow Up
Spravato (esketamine) New Drug Review	Spravato (esketamine) New Drug Review by Dr. Ashley Chiara This overview is an evaluation of current medical literature and will provide a brief overview of the place in therapy of this agent.	**Follow Up** Informational/Advisory

Action	**Discussion**
	• Reviewed Spravato (esketamine) and its Food and Drug Administration-approved indication
	• Described current clinical trial data for Spravato® (esketamine).
	• Summarize the pertinent warnings, precautions, and administration-related concerns for Spravato (esketamine)
	• Discussed the recommended management strategy for Spravato (esketamine)
	• FDA-Approved: March 5, 2019
	• Approved Indications:
	  ○ Treatment of adults with treatment-resistant depression (TRD) in conjunction with an oral antidepressant
	  ○ **Not** approved as an anesthetic agent
	• S-enantiomer of racemic ketamine, a non-selective, noncompetitive antagonist of the N-methyl-D-aspartate (NMDA) receptor
	• Esketamine must be administered under the direct supervision of a healthcare provider at a REMS certified treatment center.
	• A treatment session consists of nasal administration of esketamine and post-administration observation (minimum two hours).
	  ○ Observed for dissociation and sedation
	  ○ Blood pressure monitoring
	  ○ Patients should not drive home or until a full night of sleep.
	
	Recommendations
	• Advantages
	  ○ New mechanism of action
	• Disadvantages/Unanswered Questions
	  ○ Black Box Warnings and REMS program
	  ○ High cost compared to antidepressant class
	  ○ Started with new oral antidepressant in clinical trials
	• Key Facts
	  ○ Requires administration in a certified REMS center
	  ○ Being studied for rapid reduction of symptoms in patients at imminent risk for suicide (adults and children 12 to 18 years of age)
	• ICER Evaluation
		Conclusion
		Informational/Advisory

	○ Evidence is insufficient to assess the net health benefit of esketamine versus ketamine, ECT, TMS, oral antidepressants, or augmentation with antipsychotics (e.g., olanzapine). ○ Price of $295 per 28 mg intranasal device • Incremental cost-effectiveness ratio of approximately $198,000 per QALY compared to no additional treatment • Falls above the cost-effectiveness threshold of $150,000 per QALY • It was recommended to add Spravato (esketamine) the MHDL requiring PA **Questions** • Board Member asked if the patient has to go to the prescriber's office and remain for two hours for the prescribed inhalation. • Dr. Chiara confirmed noting the necessity to monitor symptoms or side effects. • A Board member inquired about medication being dispensed prescriber or pharmacy. • Dr. Chiara will be exclusively administered in the prescriber's office	

Agenda Item	**Discussion**	
MHDL Update	<u>MassHealth Drug List (MHDL) Update given by Dr Amy Jasinski</u> MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates implemented with the December publication rollout.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on July 15, 2019. • Nine new drugs will be added to the drug list and eight will require PA. • One new drug will not require PA. • One drug will be added to the Brand Name to the Preferred Over Generic Drug List • Four drugs will be removed from Brand Name Preferred Over Generic Drug List.	**<u>Conclusion</u>** Informational/Advisory

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	• Prior Authorization (PA) Requests averaged 7,000 per month in FY17, with a peak in March FY18 of 13,552 PA requests. • Call Volume averaged 7,000 calls per month FY17, with a peak in March FY18 of 11,101 calls. • Call Abandonment Rate was approximately 0.8%. • The Average Answered Call Wait Time was 12 seconds. • The overall call Time for Answered Calls was 3 minutes and 52 seconds, noting the standard is under four minutes. • Appeals averaged 14 per month, noting a current decrease in appeals. • Provider outreach averaged 8% to 10% of call volume which is about 675 calls. • The Top 10 PA medications noted: ➢ Methylphenidate ➢ Clonidine ➢ Lyrica ➢ Xarelto ➢ Clindamycin ➢ Testosterone ➢ Eliquis ➢ Tretinoin ➢ Trulicity ➢ Oxycodone • Discussed the PA turn-around time during business hours. It was noted that the statutory mandate is 24 hours, and 59% of PAs are completed in six hours, with 99.9% completed within 24 hours. This represents 123,037 requests. • Also noted that the PA turn-around time including non-business hours was 76% in six hours with 96% in less than nine hours. This represents 123,037 requests.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	MassHealth Update was presented by Dr Kimberly Lenz The MassHealth Update is a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health.	**Follow Up** Informational/Advisory

Action	**MassHealth Update**
	• The Massachusetts FY20 budget was submitted by the Governor to the General Court and all are still waiting patiently on a signed budget.
	  ○ Asked for direct negotiation authority in the State legislation and cautiously optimistic on positive response
	• Member Experience Program has been created
	  ○ Coordination between physical health and behavioral health work on the same level for person
	• Big Focus on Data Analytics - Coordinate all systems
	• CMS Value Based Templates – State plan amendment (SPA) for MA submitted to CMS
	  ○ Implemented – approved in several states to-date
		Conclusion
		Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Immunoglobulin Quality Assurance Analysis	Immunoglobulin Quality Assurance Analysis presentation given by Dr Karen Stevens This overview is an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state.	**Follow Up** Informational/Advisory

Action	**Discussion**
	• Discussed background information on immune globulins and their various uses in clinical practice
	• Evaluated recent utilization and cost data for MassHealth members
	• Presented a summary of current prior authorization (PA) requests for these agents
	• Reviewed historical comparison of utilization from last evaluation
	• Introduced several newly approved immune globulins
	  ○ Panzyga (immune globulin IV [human-IFAS])
	  ▪ FDA-approved 8/2/18
	  • PID in adult and pediatric patients ≥ 2 yo
	  • Chronic ITP in adults	

	▪ Dosing for PID: 300 to 600 mg/kg q three to four weeks ▪ Dosing for ITP: 1 g/kg (on two consecutive days) ○ Cutaquig (immune globulin SC [human-HIPP]) ▪ FDA-approved 12/12/18 • PID in adults ▪ Weekly dosing ▪ Both products from OctaPharma USA, Inc • Continued increase in utilization for wide variety of indications. • Preparations have undergone significant changes that have increased their tolerability, safety and efficacy. ○ Availability of SC agents for PID ○ Alternative route of administration for those with venous access issues or intolerability of infusion-related adverse events ○ Flexibility to administer at home • Slower absorption may lead to less fluctuations in IgG levels. • Immune globulin agents considered equally effective in clinical setting, though some differences among products might limit interchangeability for patients. **Recommendations** • Add Panzyga and Cutaquig to MHDL requiring PA similar to other agents for PID and ITP. • Updated guideline for expanded FDA-approved indication of CIDP for Privigen and Hizentra. • Appendix section for non-FDA approved indications updated to reflect current treatment recommendations where appropriate. **Questions** • Board Member asked if Dr. Stevens knew of any related literature or any other agents she has seen. • Dr Stevens replied that she has personally had not known of any related literature. There are many autoimmune disorder requests that DUR reviews and it makes decisions based on the trials that the patients have had. • A Board member has stated that they were not sure all the requests that were surveyed were approvals and inquired if there were any denials. • Dr Stevens responded that there were some denials. These are cases where the denial is not re-submitted, the member has another insurance that covers the medication, or a medication previously suggested had been successfully used. • The same Board Member inquired if this was a class that we discussed in another meeting and if it was worthwhile to continue	

	• Dr Stevens responded yes, and noted that cost considerations are a factor in requiring PA. • Board Member inquired about increases, such as volume by patient, and if DUR has an analysis by dose vs. agent. • Dr Stevens responded that such an analysis does not currently exist. She noted the cost for the various agents has remained consistent.	

Meeting adjourned at 7:00 pm

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____