**Minutes**
**Drug Utilization Review Board Meeting**
**DATE:** 12/12/2018

**Meeting Purpose:** Quarterly Open Board Meeting
Meeting opened at 6:00 p.m. by Standing in for Chair, Sara McGee.

**Attendance:** Timothy Fensky, R.Ph; Joel Goldstein, M.D.; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, R.Ph.; Greg Low, R.Ph., Therese Mulvey, M.D.; Karen Ryle, M.S., R.Ph; Christy Stine, M.D.; and Michael Thompson, M.D.

**Absent:** Audra R. Meadows, PhD; M.D.; Sophie McIntyre, Pharm.D; and Arthur Yu-shin Kim, M.D.

**Agenda Items:**
I. Welcome and Introductory Remarks
II. Guest Forum
III. Pipeline
IV. Clinical Team Update
V. Epidiolex (cannabidiol) New Drug Review
VI. hATTR Amyloidosis Overview
VII. Seasonal Respiratory Illness Updates: Influenza/Respiratory syncytial virus
VIII. MHDL Update
IX. DUR Operational Update
X. MassHealth Update
XI. Calcitonin Gene Related Peptide Inhibitor Update

| Agenda Item | Discussion | Conclusions/Follow Up |
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| **Guest Forum** | Pharmaceutical Representative Testimony<br>• Dr. Elizabeth Lubelczyck –Evidence and Outcomes Liaison with Eli Lilly and Company.<br>• Dr. Steven Miller –Medical Science Liaison for Greenwich Biosciences | **Follow Up**<br>Informational/Advisory |
| **Action** | Discussion:<br>• Dr. Elizabeth Lubelczyck gave information regarding Emagality for the prevention and treatment of migraine in adults.<br>• Dr. Steven Miller gave information on Epidiolex. It is the first and only FDA-approved medication to be approved for seizures associated with Dravet Syndrome or Lennox-Gastaut Syndrome in patients two years of age or older. | **Conclusion**<br>Informational/Advisory |

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| **Pipeline Update Summary** | Presentation given by Pavel Lavitas | **Follow Up**<br>Informational/Advisory |
| **Action** | Discussion:<br>The Pipeline Update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development.<br><br>*Eligible for one hour of Pharmacist CE credit. | **Conclusion**<br>Informational/Advisory |

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| Clinical Team Update | Presentation given by Mark Tesell<br>Overview of projects and accomplishments of the clinical pharmacist team of the MassHealth Drug Utilization Review Program.<br><br>**Discussion:**<br>• Clinical projects and accomplishments for fiscal year 2018 were reviewed.<br>• New drug reviews, guidelines, and proposals were summarized and quantified.<br>• Progress related to MassHealth clinical initiatives was discussed.<br>• An overview of contributions of pharmacy practice residents and students on the DUR rotation was provided.<br>• An overview of disseminated work related to the MassHealth pharmacy program was presented.<br>• Described trends in clinical projects. | **Follow Up**<br>Informational/Advisory |
| **Action** | **Conclusions:**<br>**Looking Forward**<br>• Expansion of management and research:<br>– Opioid management<br>• Focus on polypharmacy<br>– PBHMI<br>• Outcomes analysis<br>Literature reevaluation<br>• Development of clinical initiatives/programs<br>– Pharmaceutical compounding<br>– Oncology<br>• Evaluate role of clinical pathways in pharmacy program<br>– Expand budget impact modeling<br>• Development of other management strategies<br>– Site of care optimization<br>– Increased supplemental rebating<br>• Continued focus on dissemination | **Conclusion**<br>Proceed with recommendations as stated. |

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| **Epidiolex (cannabidiol) New Drug Review** | Epidiolex (cannabidiol) New Drug Review was given by Andrew Coelho.<br>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**<br>Informational/Advisory |
| **Action** | **Discussion**<br>• Epidiolex (cannabidiol) and its Food and Drug Administration-approved indications were reviewed.<br>• Clinical trials for Epidiolex (cannabidiol) were summarized.<br>• The recommended management strategy for Epidiolex (cannabidiol) FDA-Approved: June 25, 2018, was discussed.<br>• Approved indications for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age and older, were discussed.<br>• Recommended dosing: 2.5 to 10 mg/kg twice daily and is available as a 100 mg/mL oral solution.<br>• Dosage adjustment is required for patients with hepatic impairment.<br><br>**Recommendations**<br>• Epidiolex (cannabidiol) is the first substance derived from marijuana, which was approved by the FDA. A prior authorization requirement was recommended.<br>• Prescriber provides documentation of **ALL** of the following:<br>  • Diagnosis of DS or LGS<br>  • Prescriber is a neurologist or consult notes from a neurology office are provided<br>  • Member is ≥ two years of age<br>  • IR or ADR to **TWO** or CI to all anticonvulsants noted below (based on diagnosis):<br>  • **For LGS**: clobazam, topiramate, lamotrigine, valproic acid or felbamate<br>  • **For DS**: clobazam, valproic acid, stiripentol, topiramate, clonazepam, levetiracetam, zonisamide, ethosuximide or phenobarbital<br>• Member will be using the requested agent as adjunctive therapy<br><br>**Questions:**<br>➢ A member inquired about a Risk Evaluation and Mitigation Strategy (REMS) or limited distribution. It was noted that there is no REMS program to date. The product may have limited distribution among specialty pharmacies. | **Conclusion**<br>Informational/Advisory |

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| hATTR Amyloidosis Overview | <u>hATTR Amyloidosis Overview given by Tasmina Hydery</u><br>This overview is an evaluation of current medical literature and provides a brief overview of select newly approved and pharmaceutical pipeline agents in late-stage development. | **<u>Follow Up</u>**<br>Informational/Advisory |
| **Action** | **Discussion**:<br>• The pathophysiology, the incidence, and staging of hATTR amyloidosis was reviewed.<br>• The current treatment guidelines and recommendations for polyneuropathy of hATTR was outlined.<br>• Phase III clinical trial data for Onpattro (patisiran) and Tegsedi (inotersen), was evaluated.<br>• The cost for Onpattro (patisiran) and Tegsedi (inotersen) with the Institute for Clinical and Economic Revew's (ICER) value-based price benchmarks was compared.<br>• Pipeline treatment options for hATTR amyloidosis was identified.<br><br>**Recommendations:**<br>• hATTR amyloidosis is a rare, progressive, multi-system illness where many patients are misdiagnosed or underdiagnosed, and historically, treatment options for the polyneuropathy-predominant disease have been limited.<br>• In clinical trials, Onpattro (patisiran) and Tegsedi (inotersen) demonstrated improvements in neuropathy impairment and quality of life compared to placebo.<br>• Onpattro (patisiran) and Tegsedi are currently under review and pending addition to the MassHealth Drug List.<br><br>**Questions:**<br>➢ A member of the Board inquired if there is a known number of people who have this disorder. There is no known number at this time since there is no current ICD-10 code. The current prediction made by the pipeline team was one-three members.<br>➢ A member or the Board stated there is a code for Amyloidosis. It was agreed to further research this.<br>➢ A Board member inquired about the Neuropathy improvements score that was primarily of pain relief. It was noted that the neuropathy impairment score looks at motor sensory and autopneumatic neuropathies as it specifically measures impairment on the nerves.<br>➢ A Board member noted that the important point is that 50% of the patients in both trials of these drugs experienced improvement in the quality of life score. It was noted that the analysis was focused on the primary end point, which changed from base line to mNIS+7.<br>➢ A Board member inquired if there may be a clinical trial to study the progression of stages. It was noted that there was an extension study that is being conducted for patisiran, and also studies being conducted for other endpoints, such as cardiac endpoints. | **<u>Conclusion</u>**<br>Informational/Advisory |

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| Seasonal Respiratory Illness Updates: Influenza/Respiratory syncytial virus | Seasonal Respiratory Illness Updates: Influenza/Respiratory Syncytial Virus given by Mark Tesell<br>This overview is an evaluation of current medical literature and provides a brief overview of new guideline recommendations in this disease state. | **Follow Up**<br>Informational/Advisory |
| **Action** | **Discussion**:<br>• AAP guidelines for prophylaxis with Synagis (palivizumab) were reviewed.<br>• Utilization trends for Synagis (palivizumab) were analyzed.<br>• Relevant updates to the monitoring program were proposed.<br>• The potential place in therapy of Xofluza (baloxavir) was discussed.<br>• Current ACIP recommendations for Flumist (influenza virus vaccine) were discussed.<br><br>**Recommendations:**<br>• Synagis (palivizumab) utilization has slightly increased from the 2016-2017 season. However, no changes to the current approval criteria are recommended at this time.<br>• Continuing the monitoring program is appropriate to ensure adherence and proper billing.<br>• Flumist will be added back to the MassHealth Drug List following its removal due to ACIP recommendations.<br>• Xofluza (baloxavir) is currently under review and is pending addition to the MassHealth Drug List.<br><br>**Questions:**<br>➢ A member of the Board inquired about the cost Xofluza. It was noted that the cost of Tamiflu would be less for MassHealth. | **Conclusion**<br>Informational/Advisory |

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| **MHDL Update** | MassHealth Drug List (MHDL) Update given by Arthur Lam<br>The MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with a recent publication rollout. | **Follow Up**<br>Informational/Advisory |
| **Action** | New drug additions and changes that will go into effect on December 10, 2018, were discussed.<br>• There will be thirteen new drugs added to the drug list and seven will require PA.<br>• BICNU (Carmustine) has been added to the FDA “A” Rated MH Drug List.<br>• Ten drugs will be added to the Brand Name to the Preferred Over Generic Drug List.<br>• Two drugs were removed from Brand Name over Generic Drug List.<br>• Two Prior Authorization forms were also removed from the MassHealth Drug List, the | **Conclusion**<br>Informational/Advisory |

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| | Topical Immune Suppressant form, and the Osteoporosis Initiative form.<br><br>**Questions:**<br>➢ A member inquired about why Zarxio is requiring PA and forcing people to use alternatives. Kim Lenz responded that the net cost of the drug is more expensive than alternatives. | |

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| **DUR Operational Update** | Quarterly Operational Statistics presentation given by Patricia Leto<br>The DUR Operational Overview including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics, was discussed. | **Follow Up**<br>Informational/Advisory |
| **Action** | • Prior Authorization (PA) requests averaged 7,000 per month FY17, peak March FY18 with 13, 552 PA requests.<br>• Call Volume averaged 7,000 calls per month FY17, with a peak in March FY18 of11,101 calls.<br>• The Call Abandonment Rate was approximately 1.5%<br>• The Average Answered Call Wait Time was 37 seconds.<br>• The overall call time for answered calls was 14 seconds, noting the standard is under four minutes.<br>• Appeals averaged 10 to 11 per month. A current decrease in appeals was noted.<br>• Provider outreach averaged 8 to 10% of call volume<br>• The Top 10 PA medications noted:<br>➢ Methylphenidate ➢ Xarelto<br>➢ Lyrica ➢ Eliquis<br>➢ Clindamycin ➢ Lantus<br>➢ Clonidine ➢ Trulicity<br>➢ Oxycodone ➢ Botox<br>• The PA turn-around time during business hours, was discussed. It was noted that the statutory mandate is 24 hours.<br>➢ 50% of PAs are completed in six hours, with 99.9% completed within 24 hours.<br>• It was noted that the PA turn-around time including non-business hours was 69% in six hours with 96% in less than nine hours. | **Conclusion**<br>Informational/Advisory |

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| MassHealth Update | Kim Lenz, Pharm. D., MassHealth gave MassHealth Update.<br>The MassHealth Update is a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health. | **Follow Up**<br>Informational/Advisory |

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| **Action** | **MassHealth Update**<br>• We are in year two of ACO implementation, with approximately 26,000 members shifting plans.<br>• Submission of the FY20 budget is expected by the end of January or first part of February.<br>• The proposed language in FY20 will include broader ability for MassHealth to negotiate with manufacturers.<br>• A value-based purchasing proposal background was presented.<br>  ○ MassHealth Pharmacy spending doubled from $1B to $2B over prior five years<br>  ▪ This trend is expected to continue.<br>  ▪ 19 drugs in the pipeline are projected @ >$80Mm annually.<br>  ▪ The top 30 drugs account for ~30% of spending (>$600Mm per year).<br>  ▪ Many new drugs are first in class – i.e., no competition.<br>  ○ MassHealth has used competitive procurements historically.<br>  ▪ State procurement rules<br>  ○ Direct negotiation with manufacturers<br>  ▪ MassHealth establishes a cost-effective target price.<br>  • 3rd party independent analysis<br>  • Cost of existing therapies<br>  ▪ This may include an outcome-based arrangement.<br>  ○ Transparency and public hearing<br>  ▪ If no agreement – require disclosures<br>  ▪ It may require manufacturer to testify at public hearing.<br>  ▪ It may impose sanctions/reasonable penalties.<br>**We received a lot of feedback. MassHealth is taking that into consideration for relevant language in the outside section of the budget.**<br>• New RFA Announcement<br>  ○ RFAs for seven drugs without competition<br>  ▪ Posted tomorrow | **<u>Conclusion</u>**<br>Informational/Advisory |

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| **Calcitonin Gene Related Peptide Inhibitor Update** | Presentation was deferred until next meeting. | **<u>Follow Up</u>**<br>Informational/Advisory |

Meeting adjourned at 7:00 PM.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____