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| MinutesDrug Utilization Review Board MeetingDATE: December 9, 2020 |  |

**Meeting Purpose:** Quarterly Drug Utilization Board Meeting

Meeting opened at 6:00 p.m. by Sarah M McGee, MD

**Attendance:** Melissa Coyle, PharmD; Timothy Fensky, RPh; James Gagnon, RPh, PharmD; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, RPh; Greg Low, RPh, PhD; Sarah M McGee, MD; Julita Mir, MD; Karen Ryle, MS, RPh; Laura Spring, MD; Christy Stine, MD, PhD; Michael Thompson, MD

**Absent:** N/A

**Agenda Items:**

* Welcome and Introductory Remarks
* COVID-19 Update
* Clinical Team Update
* Neuromuscular Blockers Quality Assurance Analysis
* DUR Operational Update
* MHDL Update
* MassHealth Update
* Butalbital Containing Agents Quality Assurance Analysis

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **Minutes** | Motion to approve the minutes for September 2020 was made by Greg Low, RPh, PhD and seconded by Timothy Fensky, RPh. | **Follow Up**Minutes are approved. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **Covid-19 Update** | Covid-19 Update by Dr Karen StevensThis overview will provide a clinical update on novel vaccines and therapeutics recently in use as well as anticipated from the drug pipeline. | **Follow Up**Informational/Advisory |
| Action | Discussion * WHO declares global pandemic of the coronavirus disease (COVID-19) on March 11, 2020.
* As of December 8, 2020, > 68 million cases in > 200 countries and territories
	+ > 1.5 million deaths worldwide
	+ In the U.S., COVID-19 is 3rd leading cause of death behind heart disease and cancer
	+ Since beginning of 2020:
* > 560 treatments have been explored (investigational vs repurposing of currently available therapies)
* > 230 vaccines in development
* Covid-19 Interventions
	+ Therapeutics
		- Veklury (remdesivir)
		- Dexamethasone
		- Olumiant (baricitinib)
		- Bamlanivimab
		- Casirivimab/ Imdevimab
	+ Vaccines
		- Pfizer
		- Moderna
		- AstraZeneca
		- Pipeline
	+ Convalescent Plasma
* Who will be first to receive?
	+ Phase 1a
		- Healthcare Personal
		- Residents of long-term care facilities
	+ Phase 1b
		- Workers in essential and critical industries
	+ Phase 1c
		- People at high risk for severe COVID-19 illness due to underlying conditions
		- People ≥ 65 years old

Questions* Dr Greg Low stated that he heard different numbers about what was going to be distributed for the antibodies. He also mentioned he stresses to people skeptic of the vaccine that the trial sizes were very large.
* Dr Karen Stevens mentioned that with the Pfizer vaccine, even after receiving only the first dose, efficacy was also promising.
* Dr Greg Low inquired about a recent call with Pfizer and the minimum count of 975 that would be placed in a custom made cooler.
* Dr Karen Stevens clarified that there were five doses per vial and 975 vials per cooler.
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **Clinical Team Update** | Clinical Team Update by Dr Mark TesellOverview of projects and accomplishments of the clinical pharmacist team of the MassHealth Drug Utilization Review Program. | **Follow Up**Informational/Advisory |
| Action | Discussion * Formulary Management
	+ Drug Utilization Review
	+ Quality Assurance
	+ Call Center Support
	+ Unified Preferred Product List
* Market Intelligence
	+ Pipeline Monitoring Budget Impact Forecasting
	+ Negotiation Clinical Support
* Education/Dissemination
	+ CAR-T
	+ Compounding
	+ Hepatitis C
	+ Opioid/benzodiazepine Management
	+ PBHMI
	+ Synagis
	+ Care Referrals
	+ Special Populations
* Clinical Initiatives
	+ Staff Development
	+ Residency
	+ Student Precepting
	+ Publication
	+ National/Regional Conference Presentation
* Formulary Management: Unified Preferred Product List-Preparing for Deploy on January 1, 2021
	+ Identification of Agents included
		- Preferred products exist
		- Cost saving opportunities
		- Class unification to promote uniform care
	+ Unified Guideline Development
		- 32 unified guidelines
		- Stability/grandfathering
	+ Support
		- Guideline discussion sessions
		- MCO FAQ development
		- Drug list materials (Drug List Summary Document)
		- Provider communications
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **Neuromuscular Blockers Quality Assurance Analysis** | Neuromuscular Blockers Quality Assurance Analysis by Karen StevensThis 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 * Two serotypes most often used clinically:
* Botulinum toxin type A (Dysport[abobotulinumtoxinA],Xeomin [incobotulinumtoxinA], Botox[onabotulinumtoxinA])
	+ Formation of neutralizing antibodies may lead to resistance after repeated use leads to nonresponsiveness.
	+ ~ 6.5% of patients treated for cervical dystonia will develop resistance to type A toxin.
* Botulinum toxin type B (Myobloc [rimabotulinumtoxinB])
* Botulinum toxins are not interchangeable either in formulation or dose
* MassHealth Policies
	+ Due to large number of off-label requests and high cost of agents, MassHealth requires PA for all NMBs.
	+ The MassHealth Pharmacy Program does not pay for legend or non-legend preparations for cosmetic purposes [CMR 406.413 (B)(1)].

Questions* Dr Sarah McGee inquired that the prescriber could be a urogynecologist as opposed to a urologist for overactive bladder indication.
* Dr Karen Stevens responded that is correct.
* Dr Mylissa Coyle inquired about the billing, asking if there is any requirement that MassHealth has that it must be billed through the office or through the pharmacy.
* Dr Karen Stevens responded, on the request it would state if it was to be billed through the office and MassHealth does not have any requirements one way or the other.
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **DUR Operational Update**  | DUR Operational Update by Dr Patricia LetoA DUR Operational Overview will be discussed, including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics. | **Follow Up**Informational/Advisory |
| Action | Discussion * MassHealth prior authorization requests from 2017 to 2020 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then removed in August 2020.
* MassHealth call center volume from 2017 to 2020 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then removed in August 2020.
* The monthly average from prior authorizations from 2015 to 2020 (to date) were reviewed. Peak average of 10,547 per month in 2018 while currently 2020 (to date) average per month is 7,931.
* Abandoned rate generally in the 2% range
* Average wait time of answered call generally in the 20 second range
* Average treatment time consistently around four minutes
* MassHealth Appeals: Current monthly average is four
* Provider Outreach Volume: Current monthly average is 861 calls
* Top Ten Medications Requested for Prior Authorization – October 1, 2019 to September 30, 2020

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| 1. Clindamycin
 | 6. Tretinoin |
| 1. Pregabalin
 | 7. Clonazepam |
| 1. Methylphenidate
 | 8. Eliquis |
| 1. Clonidine
 | 9. Latuda |
| 1. Testosterone
 | 10. Linzess |

* Prior Authorization Compliance Response Time– October 2019 to September 2020
	+ Total requests: 95,691 requests
	+ 63% of all PAs decisions with in six hours.
	+ 99.8% of all PAs decisions in less than 24 hours.
* Prior Authorization Compliance Response Time during Call Center hours – October 2019 to September 2020
	+ Total requests: 95,691 requests
	+ 84% of all PAs decisions with in six hours.
	+ 98% of all PAs decisions in less than nine hours.
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **MHDL Update** | MHDL Update by Dr Christopher NelsonThe MHDL overview includes new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with a recent publication rollout. | **Follow Up**Informational/Advisory |
| Action | Discussion * Thirteen new drugs added to the list that went into effect as of December 21, 2020, and need prior authorization.
* Two new drugs will be restricted to a healthcare professional and not available at a retail pharmacy.
* One antiemetic agent no longer requires prior authorization, while one will no longer require prior authorization within newly established quantity limits.
* One antiemetic agent will require prior authorization and one will require prior authorization when exceeding newly established quantity limits.
* One glaucoma agent will no longer require prior authorization.
* One Alzheimer’s agent will no longer require prior authorization within quantity limit.
* Two Alzheimer’s agents will no longer require prior authorization below age limits.
* Three Alzheimer’s agents will no longer require prior authorization within quantity limits. Pediatric Behavioral Health Medication Initiative criteria will still apply.
* Four agents will be added to the MassHealth Brand name Preferred Over Generic Drug List while one agent will be removed.
* COVID-19 Pharmacy Program Emergency Response added information regarding Veklury (remdesivir),which recently gained FDA approval.
* MassHealth ACCPP/MCO Unified Pharmacy Product list which added a new table of preferred products that significantly expands the previous list to over 200 products. This list will be effective on January 1, 2021.
* Chimeric Antigen Receptor (CAR-T) Immunotherapies Monitoring Program added one medication that requires prior authorization.
* Luxturna Monitoring Program has added one medication that requires prior authorization as well as a new prior authorization form.
* MassHealth Supplemental Rebate/Preferred Drug List as added one medication that requires prior authorization.
* MassHealth Acute Hospital Carve-Out Drugs List added two medications that require prior authorization.

Questions* Dr Michael Thompson inquired if prior authorization was based on cost for Lyumjev (insulin lispro).
* Dr Christopher Nelson responded that was correct, it was cost based.
* Dr Mark Tesell also responded that it was correct, the cost to MassHealth was greater than some of the other insulins.
* Dr Greg Low inquired about Luxturna and if it was prior authorization based on indication or step therapy or were there other clinical criteria.
* Dr Christopher Nelson responded that Luxturna, Tecartus and Vyondys 53 (goloditsen) did have other clinical criteria requirements and some with monitoring programs.
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **MassHealth Update** | **MassHealth Update by Dr Paul Jeffrey**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 | Discussion * Currently no signed state budget and operating the past six months under the emergency of the pandemic with a potential finalized budget at the end of the first week of December.
* Partial Uniform Formulary will be implementing a January 1, 2021 start date.
	+ Acknowledged hard work of MCO partners and MH clinical pharmacy team
	+ Currently working on finalizing the Formulary work of MCO.
* Potential for new additions to the MHDL in the next few business days related to direct contracting activity.
* Currently have many contracts in process due to be signed by the end of the month, Agreements in principle on two or more alternative payments contracts with announcements coming soon. These were obtained under the authority to enter under value-based agreement. MassHealth received the authority from CMS.
* COVID-19 vaccine
	+ There are two task force currently operating within MassHealth alone.
	+ Currently working hard to make sure MassHealth is prepared to support the process.
 | **Conclusion**The board reviewed and accepted the presentation. |

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| **Agenda Item** |  **Discussion** | **Conclusions/Follow Up** |
| **Butalbital Containing Agents Quality Assurance Analysis** | Butalbital Containing Agents Quality Assurance Analysis by Dr Michael JonesThis 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 * Headache Classification
	+ Migraine
		- Moderate to severe pain
		- Unilateral
		- Pulsating quality
	+ Cluster headache
		- Severe pain
		- Unilateral
		- Sharp, stabbing quality
	+ Tension-type headache (TTH)
		- Mild to moderate pain
		- Bilateral
		- Non-pulsating (pressing/tightening) quality
* Discussion
	+ Decrease in quantity limit to 20 units/month has contributed to a reduction in unique utilizers and units per claim.
	+ Majority of requests for migraine headaches (87%)
		- Indication lacks FDA approval
		- Limited data demonstrating efficacy
		- Substantive risks associated with use
* Recommendations
	+ CGRP inhibitors enter marketplace; add as a required trial prior to approval (migraine indication)
* Next steps
	+ Continue to monitor consensus guidelines
	+ Will butalbital products continue to fall out of favor?
	+ Would tighter management be advised?
 | **Conclusion**The board reviewed and accepted the presentation. |

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_