Minutes
Drug Utilization Review Board Meeting
DATE: June 9, 2021

Meeting Purpose: Quarterly Drug Utilization Board Meeting
Meeting opened at 6:00 p.m. by Greg Low, RPh, PhD

The meeting was conducted under Massachusetts Public Meeting Law requirements.

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

Absent: Sarah M McGee, MD

Agenda Items:
- Welcome and Introductory Remarks
- Minutes
- Resident Research Project: Does Outreach to Providers Improve Treatment Rates Among Medicaid Members with Hepatitis C Virus (HCV) Confirmed by Genotype Testing?
- Resident Research Project: Analysis of Pre-Exposure Prophylaxis Utilization in a Medicaid Population
- PA Recertification Clinical Program
- CFTR Modulators Quality Assurance Analysis
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Hereditary Angioedema Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion to approve the minutes for December 2020 was made by Christy Stine, MD, PhD and seconded by Melissa Coyle, PharmD. Motion to approve the minutes for March 2021 was made by Colleen Labelle, MSN, RN-BC, CARN and seconded by Christy Stine, MD, PhD.	**Follow Up** Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: Does Outreach to Providers Improve Treatment Rates Among Medicaid Members with Hepatitis C Virus (HCV) Confirmed by Genotype Testing?	**Resident Research Project: Does Outreach to Providers Improve Treatment Rates Among Medicaid Members with Hepatitis C Virus (HCV) Confirmed by Genotype Testing? by Dr Collin Jerard** This was an overview of a research project developed by current pharmacy practice residents.	**Follow Up** Informational/Advisory

Action	Discussion
	• HCV
	  ○ Acute HCV is generally asymptomatic and often remains undetected.
	  ○ Though 75 to 85% of patients with acute HCV eventually develop chronic infection.
	• Incidence & Prevalence
	  ○ Incidence increased from 11,800 in 2010 to 50,300 in 2018.
	  ○ Based on CDC estimates, chronic HCV prevalence is close to three million persons in the US living with active HCV infection.
	  ○ Approximately 45% of persons with HCV infection are unaware of their HCV status.
	• Identified Gaps in Care
	  ○ The number of patients who receive HCV RNA testing after a reactive anti-HCV antibody result.
	  ○ The number of patients with chronic HCV infection that are engaged in care.
	  ○ The number of patients engaged in care that are prescribed treatment.
	• Study Objectives
	  ○ Primary: Compare the percent of patients with a paid pharmacy claim for an HCV treatment following provider outreach compared to patients without provider outreach.
	  ○ Secondary: Evaluate the reasons why HCV therapy was not initiated in the provider outreach group after the completion of HCV genotype testing.
	Conclusions
		Conclusion
		The board reviewed and accepted the presentation.

	• Discussion
	  ○ HCV genotype testing claims did not confirm HCV diagnosis.
	  ○ No correlation between the provider who submitted for HCV genotype testing versus the treating provider.
	  ○ Future studies?
	• Limitations
	  ○ Provider outreach could not be completed for all patients due to a lack of prescriber data included in medical and pharmacy claims.
	  ○ The lack of HCV therapy could not be determined based on claims alone for the control group.
	  ○ The unknown effects of COVID-19 on access to care.
	  ○ Sample size limited the power to detect differences between groups.
	• Conclusions
	  ○ Provider outreach did not lead to a statistically significant increase in treatment rates between the outreach group and the control group (P=1.0).
	  ○ There were five categories of reasons identified as to why HCV therapy was not initiated in the outreach group.
	
	Questions
	• Dr Low inquired if there are any future plans for this research considering this subject is valuable information and could be used to help others learn from the results and take the next steps in researching the topic. Dr Low also inquired if this could be presented as a poster.
	• Dr Jerard stated that he did present this as a poster at the AMCP annual virtual event. He also stated that he did intend to create a manuscript for this research project and submit it to a journal. Dr Jerard commented that this research project could inform future research and listed what could be completed in future studies to further improve the outcomes.	

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: Analysis of Pre-Exposure Prophylaxis Utilization in a Medicaid Population	**Resident Research Project: Analysis of Pre-Exposure Prophylaxis Utilization in a Medicaid Population by Dr Warren Smith** This was an overview of a research project developed by current pharmacy practice residents.	**Follow Up** Informational/Advisory

Action	Discussion
	• Approximately two million new cases of HIV infection occur annually worldwide.
	• Behavioral and pharmacological prevention strategies are standard practices to reduce the spread of HIV. For certain patient populations at risk of infection, PrEP therapy was recommended.
	• Data on geographic differences in utilization of PrEP in a Medicaid population is limited.
	• Objective
	  ○ To evaluate geographic differences in the utilization of two PrEP therapies, emtricitabine/tenofovir disoproxil fumarate (Truvada) and emtricitabine/tenofovir alafenamide (Descovy) among MassHealth plans.
	• The average claim count per member was highest for the PCC/FFS population in the fourth quarter of 2019 (2.09, range 1.89 to 2.09) and was highest for the MCO population in the first quarter of 2020 (2.11, range 1.98 to 2.11)
	• Suffolk County had the highest percentage of unique members utilizing PrEP therapy in both the PCC/FFS and MCO populations, despite being the third most populous county. Conversely, Middlesex County had the second highest percentage of unique members utilizing PrEP therapy in both the PCC/FFS and MCO populations, despite being the most populous county.
	• Prescribers were largely located in Suffolk County, which includes Boston and has a large concentration of academic hospitals and health centers.
	• Limitations
	  ○ Retrospective-claims analyses inherently have limitations and carry the risk of inaccurate or incomplete data and/or billing inaccuracies.
	  ○ The analysis included members with ≥ one pharmacy claim for PrEP therapy which does not account for variations in the duration of use for PrEP therapy.
	  ○ Prescribers could have practice sites in more than one county, potentially causing them to be duplicated in the total number of unique prescribers.
	
	Conclusions
	• Similar geographic distribution in the utilization of PrEP between PCC/FFS and MCO populations
	  ○ Highest number of PrEP claims were focused within the same counties (Suffolk, Middlesex, Essex, and Hampden)
	• Educational materials to expand MassHealth member awareness of PrEP and to promote appropriate prescribing among providers may optimize
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	PrEP utilization. • Ongoing county analyses of PrEP utilization are necessary to address any potential needs for those targeted educational materials and prescriber outreach. Questions • Colleen Labelle inquired if there was an increase in PrEP utilization noticed in his research. • Smith stated that this was worth looking into in the future. The data that was available only went to the second quarter of 2020 and was limited. Dr Smith mention that COVID-19 could have impacted the numbers. Dr Smith also mentioned that since the therapies have been approved longer, as well as COVID-19 passing, will hopefully increase the numbers. • Colleen Labelle commented that the educational materials that were mentioned for patients are also important for the providers. Colleen Labelle also commented the provider outreach is a bigger issue and impacted by the providers comfort with PrEP. • Smith replied that when he researched his project, he came across articles stating variety of reasons some prescribers were uncomfortable prescribing PrEP. Dr Smith also mentioned that he believed if these were removed it may increase use.	

Agenda Item	Discussion	Conclusions/Follow Up
PA Recertification Clinical Program	**PA Recertification Clinical Program by Dr Kaelyn Boss** This overview provided a brief update of a program implemented to support the recertification of prior authorization for MassHealth members.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• **Prior Authorization**
	  ○ Formulary management strategy used to assess medical necessity and encourage use of effective and less costly therapies.
	  ○ Providers advised to track patients' PAs and assess need for recertifications.
	• **Population**
	  ○ CCM is a care coordination program for medically complex Massachusetts Medicaid (MassHealth) members
	  ○ High medication volume and frequent PA requirement
	• **Literature Evaluation**
	  ○ Therapy delays and limited access to medications are some
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	systemic barriers to medication adherence. ○ Not taking medications as prescribed is associated with an additional estimated $2,550.34 per year per patient in medical costs. • Research Results ○ PAs were submitted 2.7 days prior to expiration (intervention group) versus 13 days after expiration (comparison group). ○ Estimated that the cost avoided due to increased compliance was $2,550.34 per PA submission prior to the PA expiration date. ○ Program resulted in an estimated return on investment of $14 per $1 spent on outreach. • Expansion to Other Populations ○ Possible Populations ▪ Anticonvulsants (2,680 PAs annually) ▪ HIV (28 PAs annually) ▪ PBHMI (3,344 PAs annually) Questions • Dr Low inquired about prior authorizations that were not extended as well as any lessons learned about ones that went to review for extension or would stop for any reason. Dr Low also inquired if they were all extended. • Dr Boss replied that in some cases members were switched to a different prescriber or new medication therapy and PA was not needed to be extended. Dr Boss also explained that to verify what prior authorizations needed to be extended, they use filters. For example, PAs for antibiotics are usually short-term and do not need to be extended. • Dr Coyle stated that pharmacist reviews would be appropriate for outreach and inquired about the filtering process for the provider outreach and the extension process. • Dr Boss replied that the information that they looked at was if the member had current coverage as well as filtering out any medications not appropriate for continued use. Dr Boss continued that they also looked at if the request was already submitted for the medication but for a different dosage. • Dr Jeffrey suggested updating the process for extending medication prior authorizations. • Timothy Fensky inquired about pharmacies helping by sending in requests for patients. Dr Fensky gave an example as to when he is at a long-term care facility, he can submit a request for a patient by being able to see the complete record and help fill out the form. • Dr Boss stated that she had seen requests come in with pharmacy information, but the prescriber is required sign the request. Dr Boss also stated she will need to check with regulations about if other signatories are acceptable besides the prescriber. Dr Boss said it is something that could	

	be investigated. • Dr Jeffrey stated that there was a regulatory issue with other signatures.	

Agenda Item	Discussion	Conclusions/Follow Up
CFTR Modulators Quality Assurance Analysis	**CFTR Modulators Quality Assurance Analysis by Dr Karen Stevens** This overview was an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• CF is the most common life-shortening autosomal recessive disorder among Caucasians.
	• Estimated that > 30,000 individuals in the U.S. have CF.
	• Caused by mutations in CFTR gene.
	  ○ Disruption in normal CFTR protein production
	  ○ Dysregulation of salt and water movements
	  ○ Thick, sticky mucus buildup in lungs, pancreas liver and reproductive tract
	• Types of CFTR Modulators
	  ○ Potentiators: “gating”: Hold the gate open so chloride can flow through cell membrane.
	  ○ Correctors: “trafficking”: Help CFTR protein maintain correct shape and move to cell surface
	  ○ Amplifiers: Increase amount of CFTR protein produced – none are available yet (ataluren development program discontinued)
	
	Recommendations
	• Several expanded indications for the agents since last review
	  ○ ~ 8% of U.S. CF population remain ineligible.
	• Majority of MH members have switched to newest agent, Trikafta, where applicable
	  ○ noted increase in tolerance, positive response to therapy.
	  ○ 6/9/21: FDA approved expanded use of Trikafta in children six to 11 years of age.
	  ▪ Guideline was updated to reflect new indication.
	• Reminder was given to consultants not to deny recertification if missing documentation of response to therapy.
	  ○ Issue one-month provisional approval and outreach to office
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	**MHDL Update by Dr Meghan Serell** 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** Informational/Advisory

Action	Discussion
	• There were 23 additions to the MHDL Drug list effective as of June 28, 2021.
	• Of the 23 additions, 21 will require prior authorization and two will not require prior authorization.
	  ○ One medication is a carve-out drug.
	  ○ Twp medications will be restricted to administration by a health care professional.
	• Changes in prior authorization status
	  ○ One anticonvulsant agent will require prior authorization when exceeding newly established dosing limits.
	  ○ One antipsychotic agent will require prior authorization when exceeding newly established quantity limits.
	  ○ Four antipsychotic agents will no longer require prior authorization within updated quantity limits. Pediatric Behavioral Health Medication Initiative criteria will apply.
	  ○ Two injectable antibiotic agents will no longer require prior authorization.
	  ○ One glaucoma agent will no longer require prior authorization.
	  ○ Three dermatologic agents will no longer require prior authorization.
	  ○ One hereditary angioedema agent will require prior authorization.
	  ○ One oncology agent will require prior authorization.
	• Changes to the MassHealth Brand Name Preferred Over Generic Drug List
	  ○ Seven agents will be added to the MassHealth Brand Name Preferred Over Generic Drug List.
	  ○ Four agents will be removed from the MassHealth Brand name Preferred Over Generic Drug List.
	• Changes to Miscellaneous Documents on the MassHealth Drug List
	  ○ Four agents were added to the MassHealth Non-Drug Product List
	  ○ The MassHealth ACPP/MCO Unified Pharmacy Product List has been updated and has been effective as of July 1, 2021.
		Conclusion
		The board reviewed and accepted the presentation.

	○ Three Pharmacy Initiatives documents have been updated. ○ One agent has been added to the MassHealth Acute Hospital Carve-Out List Questions • Dr Low inquired about Thyquidity not needing a prior authorization. • Dr Serell replied that Thyquidity does not need a prior authorization based on drug cost and other similar medications that were currently available without prior authorization. • Dr Tesell also explained the cost of the medication was low, with further discussion the decision was not to require prior authorization.	

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	**DUR Operational Update by Dr Kristen Danis** DUR Operational Overview 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 2021 (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 2021 (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 2021 (to date) were reviewed. Peak average of 10,547 per month in 2018 while currently 2021 (to date) average per month is 9,231. • Abandonment rate is generally in the 2% range. • Average wait time of answered call generally in the 30 second range. • Average treatment time consistently around four minutes. • MassHealth Appeals: Current monthly average is four. • Provider Outreach Volume: Current monthly average is 857 calls. • Top Ten Medications Requested for Prior Authorization – April 1, 2020, to March 31, 2021. 1. Clindamycin 2. Pregabalin 3. Methylphenidate 4. Clonidine 5. Tretinoin 6. Clonazepam 7. Testosterone 8. Botulinum Toxin 9. Linzess 10. Famotidine	**Conclusion** The board reviewed and accepted the presentation.

	• Prior Authorization Compliance Response Time – April 2020 to March 2021
	  ○ Total requests: 96,838 requests
	  ○ 62% of all PAs decisions with in six hours.
	  ○ 99.4% of all PAs decisions in less than 24 hours.
	• Prior Authorization Compliance Response Time during Call Center hours – April 2020 to March 2021
	  ○ Total requests: 96,838 requests
	  ○ 83% of all PAs decisions with in six hours.
	  ○ 99.6% of all PAs decisions in less than nine hours.
	Questions
	• Dr Coyle stated that she thinks that MassHealth is great when it comes to the prior authorization turn around time process as well as the calls to address an issue when Dr Coyle submits a request. Too many other payers are not as smooth or quick to deal with, so Dr Coyle prefers to submit a request to MassHealth over other payers knowing it will be a smooth process. She also commented that MassHealth is doing a good job.
	• Dr Jeffrey commented that the Drug Utilization Review team always does an exceptional job, and it is always great to see the statistics and hear the feedback.	

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

Action	Discussion
	• COVID-19 still has leniencies in place.
	  ○ 90-day supplies (9.5%)
	  ▪ To be converted from COVID-19 to regulatory 90-day supply
	  ○ Pay for deliveries.
	  ▪ Average 4,500 per month in 2021
	  ▪ Will be part of regulatory update to continue to pay for deliveries
	  ○ Vaccines
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	▪ Past week (May – June) – 977 per day average ▪ Previous week (May) – 1,277 per day average ○ New Rates to consider ▪ Medicare paying administrative vaccination fees. ▪ Medicare paying in home infusions. ○ Contemplating reimbursing test kits through pharmacy (currently no date for this) ○ MA State of Emergency ended as of June 15, 2021. ○ Federal Emergency to end as of December 31, 2021. • Continued Negotiations ○ Thank you to Pharmaceutical Industry and their continued discussions. ○ Have met budget target ($150 million) this fiscal year. ○ 44 contracts – seven are value based. • Digital Therapies (DT) – Due Diligence Notice posted ○ Negotiations are currently in process for FDA approved DT used in substance/opioid use disorder. ○ As of the DUR Board meeting it was publicly posted one week, needs to be posted two weeks for negotiations to proceed. • Unified Product List – July 1, 2021 ○ Thank you for the cooperation and support from our managed care partners. • Back to Work ○ EOHHS is scheduled to go back to working on site two days and from home three days. ○ Commonwealth Medicine has a different policy. ○ The DUR Board was in discussion about how the meetings will be held and will be making their decision prior to the next meeting. • Waivers ○ CMS Waiver to be submitted by July 1, 2021. ○ It was decided not to pursue MCO pharmacy carve-out. Strategy changed to modify managed care plans to ▪ create pass-through PBM payment model ▪ accommodate a Unified formulary for 1/1/2023 ○ Different methodology for paying 340b drugs. ○ Medicaid inmate exclusion policy – Needs to be investigated. ▪ Department of Correction members (90%?) come in with Medicaid	

Agenda Item	Discussion	Conclusions/Follow Up

Hereditary Angioedema Quality Assurance Analysis	**Hereditary Angioedema Quality Assurance Analysis by Dr Stephen Alvarez** This overview was an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Hereditary angioedema is a rare, autosomal-dominant genetic disorder.
	• Characterized by swelling attacks that can affect the limbs, face, GI tract, and airway.
	• Prior to available effective treatment, HAE was associated with a mortality rate of ~ 30% due to asphyxiation from laryngeal swelling.
	• Prevalence of HAE is estimated at ~ 1 per 60,000 people.
	• ~ 40% of patients experience the first HAE attack by age five, and 75% by age 15.
	• Types of Treatment
	  • On-Demand - Terminate current attack
	  • Short-Term Prophylaxis (STP) - Prevent an attack following an invasive procedure.
	  • Long-Term Prophylaxis (LTP) - Minimize the frequency and severity of attacks.
	• Current Approval Criteria
	  • All agents
	  • Diagnosis of hereditary angioedema
	  • Prescriber is an allergist or immunologist or provides consultation notes from an allergist or immunologist regarding the diagnosis.
	  • Long-Term Prophylaxis
	  • ONE of the following:
	  • More than one HAE event per month
	  • History of recurrent laryngeal attacks
	
	Recommendations
	• In a one-year period, there were 30 PA requests for HAE agents.
	• 16 of the 30 PA requests were randomly selected for QA review and all were reviewed appropriately.
	• All members for whom a PA request was submitted were ultimately approved for treatment.
	• Given the high cost of Kalbitor (ecallantide), it is recommended to manage with prior authorization.
	
	Questions
	• Dr Jeffrey inquired about other plans having preferred products.
	• Dr Alvarez answered that there was a review done in the past and it was
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	not common. • Dr Low stated that it looked like there was a lot of variation in the dose that was given making it hard to distinguish between the costs. • Dr Alvarez agreed there were variations, including dosage and a lot of them were weight based.	

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: _____