



Meeting Purpose: Quarterly Drug Utilization Board Meeting
 Meeting opened at 6:00 p.m. by Timothy Fensky RPh

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
- DUR Operational Update
- Resident Research Project: Cost-Benefit Analysis of Sacubitril/Valsartan Among Patients with Heart Failure with Reduced Ejection Fraction in a Medicaid Population
- Resident Research Project: Evaluating the Effect of Proactive Interventions for Prior Authorization Recertifications on Continuity of Care in a Specialized Medicaid Population
- Opioid Therapeutic Case Management Workgroup Quality Assurance Analysis
- MHDL Update
- MassHealth Update
- Asthma/Allergy monoclonal antibodies Agents Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	<u>Quarterly Operational Statistics presentation given by Dr Patricia Leto</u> DUR Operational Overview including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics. This will include operational impacts due to COVID-19.	<u>Follow Up</u> Informational/Advisory
Action	Discussion <ul style="list-style-type: none"> • COVID-19 Overview <ul style="list-style-type: none"> ○ Pharmacies may dispense up to a 90-day supply within reason <ul style="list-style-type: none"> ▪ Effective 3/15/20; with a peak of 2,295 around 3/22/20 ▪ Processed 96,670 claims for 90-day supply through 5/31/20 ▪ Percentage of all paid claims was 5.53%. ○ Early Refills <ul style="list-style-type: none"> ▪ Allowed with at least one refill remaining on prescription 	<u>Conclusion</u> The board reviewed and accepted the presentation.

	<ul style="list-style-type: none"> ▪ Override at the pharmacy level available. ▪ Emergency Prescription Refill: Supports Public Health Council guidance allowing pharmacists to add a refill to chronic medication if the prescriber is unavailable. ▪ Effective 3/15/20 with a peak of 1,191 around 3/22/20 ▪ Processed 24,142 claims with override through 5/31/20 ▪ Percentage of all paid claims was 1.38%. ▪ Prescription Delivery - Payment adjustment to professional dispensing fee when medications are delivered to members residence <ul style="list-style-type: none"> ▪ Lower of the provider's usual and customary charge for prescription delivery or \$8.00 ▪ Only when MassHealth is the primary payer ▪ Once per provider per member per day ▪ Not payable for claims for members living in any type of institution or residential facility (except for homeless shelters). ▪ Peak prescription delivery claims per day 5/4/20 of 339 ▪ Distribution by location: 5,862 total claims through 5/31/20; 1,354 claims for Worcester, MA • DME coverage changes <ul style="list-style-type: none"> ○ Allow payment through pharmacy benefit in addition to DME <ul style="list-style-type: none"> ▪ Paid claims for non-insulin syringes, peak flow meters, vaporizers, and home blood pressure monitors ▪ Prior Authorization (PA) Requests averaged 9,000 per month in FY19, with a peak in March FY18 of 13,552 PA requests. • Call Abandonment Rate was generally below 2%. • The Average Answered Call Wait Time was nine seconds. • The overall call Time for Answered Calls was four minutes and three seconds, noting the standard is under four minutes. • Appeals averaged six per month, noting a current decrease in appeals. • Provider outreach averaged 13% of call volume and averaged 787 calls per month (4/2019-4/2020). • The Top 10 PA medications noted: <ul style="list-style-type: none"> • Eliquis • Methylphenidate • Trulicity • Clindamycin • Clonidine • Testosterone • Tretinoin • Latuda • Oxycodone • Botox • Discussed the PA turn-around time during business hours. It was noted that the statutory mandate is 24 hours. In the time frame between 4/2019 and 3/2020, 108,903 requests were reviewed with 73% completed in six hours and 99.9% completed within 24 hours. • Also noted that the PA turn-around time for the same time frame was 92% 	
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	<p>reviewed in six hours and 99% reviewed in less than nine hours when adjustments are made for Call Center open hours.</p> <p>Questions</p> <ul style="list-style-type: none"> • Dr Lewicki inquired about 100,000 refills for 90 days. • Dr Leto clarified that was the total 90-day claims that were received. • Dr Lewicki then followed up with an inquiry if the claims were due to COVID-19 requests or were just regular prior authorizations. • Dr Leto answered they were just total claims that were received. • Dr Lewicki inquired if there was an analysis about the increase in numbers due to COVID-19 to see the difference in claims that have been received. • Dr Leto responded that the 90-day supply was an addition that was made for COVID-19. We may previously have only seen claims where MassHealth was the second insurance. • Dr Low inquired about the percentage of claims that had the opportunity to be 90-day versus the percent of total of claims? • Dr Leto responded that currently we do not have that data. 	
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Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion to approve the minutes for December was made by Christy Stine, MD, and seconded by Karen Ryle, MS, RPh.	<u>Follow Up</u> Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: Cost-Benefit Analysis of Sacubitril/Valsartan Among Patients with Heart Failure with Reduced Ejection Fraction in a Medicaid Population	<p><u>Resident Research Project: Cost-Benefit Analysis of Sacubitril/Valsartan Among Patients with Heart Failure with Reduced Ejection Fraction in a Medicaid Population by Dr Alan Gabot</u></p> <p>This an overview of a research project developed by current pharmacy practice residents.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
<p>Action</p>	<p>Discussion</p> <ul style="list-style-type: none"> • Provided an overview of signs and symptoms. • Evaluated the current guidelines and methodologies. • Discussed MassHealth limitations. • Reviewed real-world clinical data to support utilization. <p>Findings</p> <ul style="list-style-type: none"> • The cost benefit did not outweigh the additional costs of sacubitril/valsartan in all members. • Sacubitril/valsartan may offer better value in adherent members. • Additional studies needed evaluating larger populations for a longer period of time. <p>Questions</p> <ul style="list-style-type: none"> • Dr Jeffrey inquired if consideration was given to using in the net cost of the drug in the calculations. • Dr Gabot responded that consideration was given to reporting the net cost, but ultimately the decision was made to calculate pharmacy costs based on total amount paid. This may be a possible limitation of the study. • Dr Jeffrey stated that may not be the correct information since it may have some deductions. He has concerns about the research data since the information may not be complete. • Dr Thompson inquired about the exclusion of 340B claims and the numbers that decreased due to the cost of the drug as well as the data. • Dr Gabot stated that there were different ways the calculation could have been done, but the reason 340B pharmacy claims were excluded was because the cost of 340B claims is lower than non-340B claims which would have skewed the study results. 	<p><u>Conclusion</u> The board reviewed and accepted the recommendation.</p>

	<ul style="list-style-type: none">• Dr Low noted the variability being high but was concerned about the data that was given and the conclusion of the data.• Dr Gabot replied that we did not have the comparative groups that would have been a good comparator.• Dr Low inquired about the massive negative cost of the medication ranges in Medical Claims.• Dr Gabot responded this number included members that did not have a medical claim.• Dr Low followed up with a question if Dr Gabot was checking zero as a sensitivity range.• Dr Gabot responded that was correct.	
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Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: Evaluating the Effect of Proactive Interventions for Prior Authorization Recertifications on Continuity of Care in a Specialized Medicaid Population.	<p><u>Resident Research Project: Evaluating the Effect of Proactive Interventions for Prior Authorization Recertifications on Continuity of Care in a Specialized Medicaid Population. by Dr Soumya Vishwanath</u></p> <p>This an overview of a research project developed by current pharmacy practice residents.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
<p>Action</p>	<p>Discussion</p> <ul style="list-style-type: none"> • Provided an overview of signs and symptoms. • Evaluated the current guidelines and methodologies. • Discussed MassHealth limitations. • Reviewed real-world clinical data to support utilization. <p>Findings</p> <ul style="list-style-type: none"> • Intervention resulted in 3.6-fold increase in new PA submissions and/or provider response. • The majority of PAs (75%) resulted in successful outreach and a new PA submission. • Multiple forms of outreach may be necessary. • Future considerations include <ul style="list-style-type: none"> ○ studies examining proactive PA interventions for additional at-risk populations; and ○ studies comparing forms and frequency of outreach. • ROI of this intervention will be conducted. <p>Questions</p> <ul style="list-style-type: none"> • Dr Jeffrey was surprised about the comparison between the positive and negative outcomes since the information includes prior authorizations of those in groups that are getting more attention per se. • Dr Vishwanath responded that she was surprised as well. She stated it would have been a positive outcome if the PA was submitted in 30 days. She also researched what the data would 	<p>Conclusion The board reviewed and accepted the recommendation.</p>

	<p>show if it was submitted on day 31 or day 50. On average most PA's were submitted 13 days after the PA expiration date. If one was to expand the population in searching, there were a number of the PA requests that were submitted between 31 and 40 days after the expiration date, as well as those submitted six months later.</p> <ul style="list-style-type: none">• Dr Thompson inquired what the risk or timeframe might be for the PA to be re-submitted or the person not be on the medication.• Dr Vishwanath responded that if a prior authorization ends today (i.e., June) one would have gone to the pharmacy and wait for the prescriber to submit it. It depends on one's prescriber's office in submitting the request. DUR has a 24-hour turnaround time for PA's.• Dr Tesell stated that there is an emergency override for prior authorization that has expired but has not been re-summitted in time. Dr Tesell commented that the data of the presentation also included data of members with TPL.• Dr Vishwanath responded that was correct, that the presentation did include that data.	
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Opioid Therapeutic Case Management Workgroup Quality Assurance Analysis	<p><u>Opioid Therapeutic Case Management Workgroup Quality Assurance Analysis by Dr Alan Gabot</u></p> <p>This overview is an evaluation of member cases reviewed by the opioid therapeutic case management workgroup.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
<p>Action</p>	<p>Discussion</p> <ul style="list-style-type: none"> • Provided an overview of background and objective. • Evaluated the current methodology and results. • Discussed results and recommendations. <p>Findings</p> <ul style="list-style-type: none"> • Purpose of TCM Workgroup <ul style="list-style-type: none"> ○ Manage fraud, abuse, and misuse of opioids. ○ Facilitate the implementation of opioid guideline criteria. ○ Review for specific therapy issues (e.g., high dose opioids and duplicate therapies). ○ Enhance communication with MassHealth prescribers regarding pain management. ○ Facilitate care coordination for complex medical cases. • Reasons for Outreach <ul style="list-style-type: none"> ○ Clarification for PA requirements (e.g., pain consults) ○ Additional information for treatment plans ○ Trials with less costly alternatives ○ Concerning medication combinations (e.g., COBI) • TCM workgroup served as an effective tool to evaluate concerning opioid regimens and conduct appropriate interventions <p>Questions</p> <ul style="list-style-type: none"> • Dr McGee inquired if it was correct that there was no subsequent intervention because the case was referred to MassHealth legal. • Dr Gabot responded that was correct. • Dr McGee inquired about looking back at the comparison between 2012 and now, and if that is a relatively stable phenomenon or if there was a change over time. • Dr Gabot responded he is not sure. • Dr Stevens responded that the cases are referred to the Provider Integrity Unit, and sometimes are escalated to the MassHealth Fraud Unit. Once referred, DUR no longer has access to the outcomes. • Dr McGee inquired about the attention into detail of this area that has 	<p>Conclusion The board reviewed and accepted the recommendation.</p>

	<p>increased.</p> <ul style="list-style-type: none"> • Dr. Stevens responded that the TCM Workgroup does not make that kind of recommendation lightly, and it occurs after documenting a pattern from a prescriber. 	
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Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	<p><u>MassHealth Drug List (MHDL) Update given by Dr Arthur Lam</u></p> <p>An MHDL overview was presented and included new additions, changes in Prior Authorization (PA) status, and related attachment updates implemented with the October publication rollout.</p>	<p><u>Follow Up</u></p> <p>Informational/Advisory</p>
Action	<p>Discussed new drug additions and changes that have gone into effect on June 29, 2020.</p> <ul style="list-style-type: none"> • 17 new drugs will be added to the drug list. • Two Antiviral agents will no longer require PA. • One Triptan will no longer require PA within QL. • Three Ophthalmic Anti-inflammatory agent will no longer require PA. • One Antiretroviral agent will no longer require PA. • Two calcitonin gene-related peptide inhibitors will be added to the MassHealth Supplemental Rebate/Preferred Drug List. • Three antiretroviral agents will be added to the MassHealth Supplemental Rebate/Preferred Drug List. • One long-acting paliperidone agent will be added to the MassHealth Supplemental Rebate/Preferred Drug List. 	<p><u>Conclusion</u></p> <p>The board reviewed and accepted the recommendation.</p>

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	<p><u>The MassHealth Update presented by Dr Paul Jeffrey.</u></p> <p>The MassHealth Update was a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, and public health.</p>	<p><u>Follow Up</u></p> <p>Informational/Advisory</p>
Action	<p>MassHealth Update</p> <ul style="list-style-type: none"> • MassHealth made a plan in response to COVID-19 and is now in a position to rollback the allowances made during the crisis. MassHealth is currently waiting for word to proceed. <ul style="list-style-type: none"> ▪ Allowances for items that were granted under Executive Order and State of Emergency – will not be rolled back until the State of Emergency ends. ▪ If a bulletin was issued, MassHealth would issue a bulletin that rolls back the allowances. ▪ There is a current list (i.e., 90-day supplies, early refills, etc.) – currently monitored and will be submitted as part of the pharmacy roll-back plan. • FY20/21 Budget Uncertainty <ul style="list-style-type: none"> ▪ Current revenues for the state are down ▪ Some of our spending is down due to the under utilization of some of the routine services across the United States due to COVID-19. ▪ MassHealth is expecting a surge in enrollment for FY21. • Mass General Law <ul style="list-style-type: none"> ▪ The regulations allowing direct negotiation and target value thresholds became effective as of March 2020. ▪ The Team has signed agreements with manufacturers on 31 different drugs and keeping us on track to meet our budget target. ▪ FY21 budget target has doubled versus FY20 budget target. ▪ Of the 31 drugs, a group of those were involved in alternative payment methodologies. ▪ Using the authority from CMS, MassHealth was able to enter into three value-based supplemental rebate contracts. • Rebating Strategy <ul style="list-style-type: none"> ▪ The Pharmacy program generates revenue for the Commonwealth. ▪ Discovered opportunities to grow the rebate program. ▪ FY20 invoiced an additional \$127 million in historical rebates going back to 2010. • Preferred Drugs <ul style="list-style-type: none"> ▪ Extend the preferred status of the drug to the managed care programs. 	<p><u>Conclusion</u></p> <p>The board reviewed and accepted the recommendation.</p>

	<ul style="list-style-type: none"> ▪ Socializing with the MCOs and the Mass Association of Health Plans about building towards a more uniform formulary. ▪ For the end of this year MassHealth will be moving to add an additional group of drugs to the partial unified formulary starting January 1, 2021. ▪ Going forward the process will be more evenly paced with a regular communication schedule with the MCOs. <ul style="list-style-type: none"> • Workgroup <ul style="list-style-type: none"> ▪ Digital Therapeutics adoption <ul style="list-style-type: none"> ▪ Reset/Reset-O moving forward ▪ Numerous other products to be considered • Co-Pays <ul style="list-style-type: none"> ▪ Modifying co-pays – sharing ▪ As of July 1, 2020, co-pays will change significantly. ▪ Substance abuse will be available without co-pay. ▪ Grade A/B by the US preventative services task force will be available for no co-pay. ▪ Several medications will be added to those lists such as prep for HIV. ▪ Vaccines will be available without co-pay. ▪ As of July 1, 2020, MassHealth members with an income level that is less than 50% of the federal poverty level will be exempt from co-pays. <p>Questions</p> <ul style="list-style-type: none"> • Ms Labelle inquired if MassHealth is going to pay the contingency management award for Reset and Rest-O. • Dr Jeffrey responded that MassHealth is still evaluating the product. • Dr Lenz responded that there is a contingency management that is built into the plan. The contingency management award is built into the behavior modification/education modules and adherence/persistence. • MassHealth wouldn't be paying for the contingency management rather for the education module and adherence management. • Dr Lewicki inquired about the test strips and when the new contract (s) will be awarded. • Dr Jeffrey replied that the target date is January 1, 2021, and it depends on the preferred product line and will keep people informed. 	
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Asthma/Allergy monoclonal antibodies Agents Quality Assurance Analysis	<p><u>Asthma/Allergy monoclonal antibodies Agents Quality Assurance Analysis</u> <u>by Dr Karen Stevens</u></p> <p>This overview is an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state.</p>	<p><u>Follow Up</u> Informational/Advisory</p>
<p>Action</p>	<p>Discussion</p> <ul style="list-style-type: none"> • Review various indications for monoclonal antibodies. • Evaluate current MassHealth management. • Discuss recent off-label dosing requests for omalizumab. <p>Findings</p> <ul style="list-style-type: none"> • Xolair <ul style="list-style-type: none"> • Update appendix section for CIU to allow CIIIs to review: <ul style="list-style-type: none"> • Titration of Xolair above FDA-approved dose (step-wise approach to 450 mg and potentially 600 mg Q4W if only partial response to 300 mg Q4W) or reduced frequency Q2W • Review requests for children ≥ four years of age using standard approval criteria. • Dupixent <ul style="list-style-type: none"> • Update MHDL and guideline with expanded age indication for AD. 	<p><u>Conclusion</u> The board reviewed and accepted the presentation.</p>

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____