Minutes
Drug Utilization Review Board Meeting
DATE: September 8, 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; James Gagnon, RPh, PharmD; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, RPh; Greg Low, RPh, PhD; Sarah M McGee, MD; Laura Spring, MD; Christy Stine, MD, PhD.

Absent: Timothy Fensky, RPh; Karen Ryle, MS, RPh; Michael Thompson, MD

Agenda Items:
- Welcome and Introductory Remarks
- Minutes
- Pipeline Update
- Synagis (palivizumab) Modulators Quality Assurance Analysis
- Obesity Treatment Update: A Clinical Overview of Wegovy (semaglutide)
- Over-the-Counter Agents Quality Assurance Analysis
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Targeted Immunomodulators Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion to approve the minutes for June 2021, was made by Sarah M McGee, MD and seconded by James Gagnon, RPh, PharmD.	**Follow Up** Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	**<u>Pipeline Update by Dr. Wilson Haong</u>** The Pipeline Update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussion • Palovarotene ○ Proposed Indication: Treatment of fibrodysplasia ossificans of progressiva (FOP) ○ Type of Agent: New chemical entity ○ MOA: Selective RARγ agonist ○ Manufacturer: Ipsen Pharma ○ FDA Designations ▪ Breakthrough Therapy ▪ Priority Review ▪ Orphan Drug ○ Ipsen Pharma announced withdrawal of NDA with intention to resubmit (original PDUFA date of November 20, 2021). ○ Population: Patients of ≥ four years old with FOP who have no flare-up symptoms within the past four weeks. ○ Administration: Chronic (5 mg QD) and episodic (20 mg QD x four weeks, followed by 10 mg QD for ≥ eight weeks) regimen for 24 months. ○ Potential Impact ▪ Epidemiology: FOP affects 1.36 million individuals; cases vary by country. ▪ Treatment Options: There are no treatment options to prevent or reverse the ossification associated with FOP. ▪ Place in Therapy: Palovarotene may be the first agent approved for the treatment of FOP. • Donanemab ○ Proposed Indication: Treatment of Alzheimer's disease ○ Type of Agent: New chemical entity ○ MOA: Anti-amyloid monoclonal antibody ○ Manufacturer: Eli Lilly and Company ○ FDA Designations ▪ Breakthrough Therapy ○ Eli Lilly plans to submit a BLA under the accelerated approval pathway later this year	**<u>Conclusion</u>** The board reviewed and accepted the presentation.

	○ Population: Patients aged 60 to 85 years who had prodromal Alzheimer's disease or mild Alzheimer's disease with dementia and who had a MMSE score of 20 to 28. ○ Administration: Intravenous donanemab (700 mg for the first three doses and 1,400 mg thereafter) every four weeks for up to 72 weeks. ○ Potential Impact ▪ Epidemiology: There are approximately 130,000 patients ≥ 65 years old with Alzheimer's dementia in Massachusetts. • Projected to be 150,000 in 2025 ▪ Treatment Options: While treatments are available that can ameliorate some symptoms of the illness, there is no cure currently available, and the disease inevitably progresses in all patients. ▪ Place in Therapy: Donanemab may be the second anti-amyloid monoclonal antibody to be approved for the treatment of Alzheimer's disease; however, there are multiple anti-amyloid antibodies undergoing phase III studies. Questions • Low inquired about speculations whether the approval of aducanumab opened or closed the door for Donanemab comparing to what is on the market. • Hoang responded that it opened the approval process because it set the precedent.	

Agenda Item	**Discussion**	**Conclusions/Follow Up**
Synagis (palivizumab) Modulators Quality Assurance Analysis	**<u>Synagis (palivizumab) Modulators Quality Assurance Analysis by Dr. Warren Smith</u>** 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 • Guidelines and Criteria ○ Indication: Prevention of Serious LRTI caused by RSV in high-risk children ○ Dosing: 15 mg/kg IM once monthly for a maximum of five doses per season	**<u>Conclusion</u>** The board reviewed and accepted the presentation.

	○ American Academy of Pediatrics Guidelines (2014) ▪ High-risk Infants • CLD • CHD • Compromised Immune Systems • Prematurity ○ MassHealth Criteria ▪ Aligns with AAP guidelines ▪ Following the QA analysis from 2019-2020 season, there were no proposed changes to the criteria. • National Respiratory and Enteric Virus Surveillance System activity is monitored weekly. ○ RSV Outbreak Definition: first of two consecutive weeks when > 50% of participating laboratories report a weekly mean percentage of positive RSV antigen-based test is > 10%. ○ PCR Diagnostic Assay ▪ Molecular testing such as the PCR diagnostic assay has become more widely use in the past decade. ▪ RSV season onset defined as the first of two consecutive weeks when the weekly mean percentage of positive tests is > 3%. • In the 2020-2021 season for Unique Utilizers, there were 132 out of 719 claims. Total paid were $1,372,143. • Outreach Calls from 2020-2021 season: ○ Prescriber Outreach Attempts 216 Successful 152 (70.4%) ▪ Most calls made to prescriber offices were to confirm member weight and administration date of most recent injection. ▪ Percentage of successful calls continued to trend up (67.9% in 2019-2020). ○ Pharmacy Outreach Attempts 12 Successful 11 (91.7%) ▪ Seven calls clarified rationale for higher-than-expected dose (pharmacies were running test claims that were later reversed). ▪ Other calls were one-off situations (i.e., office stating they didn't receive full amount of medication). Conclusions • Total number of utilizers and paid claims has continued to decrease over last 10 years. • Nirsevimab could be the first longer-acting prophylactic RSV agent for all infants if approved. • No recommended changes based on clinical guidelines and PA review. • Impact of the ongoing unprecedented RSV season will be monitored.	

	Questions • Jeffrey inquired if the Synagis season would continue through April of 2022. • Smith responded that based on the current trend of RSV as well as how COVID is currently showing, it may continue to increase. • Low inquired if there was anything surprising about the current utilization trends. • Smith responded that there was nothing surprising about the current utilization trends. As the season continues, it is the infants who are high risk and need Synagis. It would be interesting as to where the numbers lead as the season continues.	

Agenda Item	Discussion	Conclusions/Follow Up
Obesity Treatment Update: A Clinical Overview of Wegovy (semaglutide)	**<u>Obesity Treatment Update: A Clinical Overview of Wegovy (semaglutide) by Stephanie Tran</u>** This presentation provided a brief overview of the current state of obesity treatments and provide a review of the newest FDA-approved drug for chronic weight management.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Insurance Coverage
	  ○ General
	  ▪ Obesity drugs not covered by Medicare
	  ▪ 2021 Reduce and Treat Obesity Act
	  ○ Medicaid
	  ▪ Seven state Medicaid states covered obesity treatments.
	  ○ Regulations
	  ▪ The MassHealth agency does not pay for any drug used for the treatment of obesity (130 CMR 406.413[B][4]).
	• Prevalence (Adults, Children, Adolescents)
	  ○ Age-adjusted prevalence of obesity among adults in the US is 42.4%.
	  ▪ Obesity Class 1 30.0 – 34.9
	  ▪ Obesity Class 2 35.0 – 39.9
	  ▪ Obesity Class 3 > 40.0
	  ○ Children and Adolescents Prevalence: 18%, affecting 13.7 million
	• Consequences (Adults)
	  ○ Direct medical costs: Preventive, diagnostic, and treatment
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

services
    - Indirect costs: morbidity and mortality, lost productivity
    - Obesity-related medical care costs in the United States: ~$147 billion (2008)
- Clinical Alternatives
    - FDA-approved for chronic weight management
        - Xenical (orlistat)
        - Alli (orlistat)
        - Qsymia (phentermine/topiramate)
        - Saxenda (liraglutide)
        - Belviq (lorcaserin) withdrawn February 2020
        - Phentermine, benzphetamine, diethylpropion, phendimetrazine
        - Wegovy (semaglutide)
- Wegovy (semaglutide)
    - First drug approved for chronic weight management since 2014
    - Limitation of Use
        - Contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist.
        - Safety and effectiveness in combination with other products intended for weight loss, including prescription drugs, OTC drugs, and herbal preparations, have not been established.
        - Has not been studied in patients with a history of pancreatitis.
    - Dosage and Administration
        - Self-administered injectable medication
        - Initial, 0.25 mg SC once weekly
        - Maintenance & maximum, 2.4 mg SC once weekly
    - Key Points
        - Once-weekly administration may improve adherence & treatment perception
        - STEP clinical trial program demonstrated that patients taking Wegovy with a reduced-calorie meal plan & increased physical activity achieved a significant reduction in body weight compared with placebo (reduced calorie meal plan & increased physical activity only).
        - The STEP 5 clinical trial investigated the benefits of Wegovy over a 2-year time frame (104 weeks).
            - Sustained weight loss with an average percent change in body weight of negative 16.7% in the Wegovy arm.
            - 40% of patients lost > 20% of their body weight.
        - No alarm bells raised with the FDA or obesity doctors about

	serious side effects of previous treatments for obesity. ▪ Appears to be the most efficacious of the agents approved for chronic weight management in adults. ▪ Adverse effects, contraindications, warnings, and precautions ▪ May lower blood glucose and can cause hypoglycemia; thus, the risk for hypoglycemia is higher when used concomitantly with insulin secretagogue or insulin. ▪ Stigma surrounding obesity as a disease • Patients may be hesitant to seek treatment. ▪ Lingering safety doubts may persist after several high-profile withdrawals. Conclusions • Massachusetts regulations do not permit the coverage of agents for the treatment of obesity. • The MassHealth Pharmacy Program is currently evaluating coverage implications and engaging stakeholders on the role of drug products in obesity management. • Coverage of agents for the treatment of obesity in the United States is sparse and is guided by Medicare. • Obesity affects a large portion of the US population and it has health and financial consequences. • Wegovy (semaglutide) clinical efficacy data is promising compared to other FDA-approved weight management medications. Questions • Jeffrey commented that as a health care system, we acknowledge that weight is a problem but not one that we are adequately addressing. He also commented that we have been struggling with this issue as a stigma as well as other health issues. Jeffrey mentioned that if we are to go forward there will need to be regulations and guideline changes that will need to be implemented. • Gagnon stated that the stigma point was valid, and that it could make an impact on analysis of the budget as his experience diagnosis in under-documented. • Low inquired about the comparison for medical coverage (i.e., procedures for obesity) between MassHealth and pharmacy. • Jeffrey responded that MassHealth covers gastric bypass as well as various surgeries and medication for genetic causes of obesity. • Lenz stated that they discuss this subject with MassHealth Medical directors to make sure both pharmacy and medical side are updated. • Low suggested that we need a clearer understanding of the treatment for obesity.	

Agenda Item	Discussion	Conclusions/Follow Up
Over the Counter Agents Quality Assurance Analysis	**<u>Over-the-Counter Agents Quality Assurance Analysis by Dr. Andrew Coelho</u>** This overview was an evaluation of current over-the-counter product coverage and discuss any adjustments to MassHealth Pharmacy Program policy.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Over the Counter (OTC) - Designation used to describe a medical product that can be purchased by the end-user without a prescription.
	• Several different types of products may be classified as OTC.
	  ○ Definitions and requirements vary.
	  ○ Ability to purchase without a prescription is consistent.
	• State Medicaid Programs are not required to cover most OTC products but may elect to cover these products based on the needs of their patients.
	  ○ Utilization management can be implemented as indicated (e.g., trials with less costly alternatives).
	• MassHealth has elected to cover certain OTC products through the pharmacy benefit when a valid prescription has been issued.
	• Covered Products
	  ○ OTC Drugs
	  ○ Vitamins, supplements
	  ○ Medical supplies, devices
	• Product Listings
	  ○ MassHealth OTC Drug List
	  ○ MassHealth Drug List (MHDL)
	  ○ MassHealth Non-Drug Product List
	  ○ ACPP/MCO Unified Pharmacy Product List
	• Utilization Management
	  ○ Many OTC agents covered without prior authorization (PA).
	  ○ PA is required for some agents/classes.
	  ▪ Established criteria listed on the MHDL.
	  ▪ Others evaluated case by case.
	• Prior Authorizations – OTC Agents
	  ○ OTC Agents, Unclassified
	  ▪ Evaluated case by case.
	  ▪ Requests typically denied for:
	  • Generic available;
	  • Formulation not covered;
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	• Rx agent covered. ○ Medical Foods ▪ Not typically covered by MassHealth Pharmacy • Previous approvals for levomethylfolate are grandfathered; new starts are denied. • Other agents are faxed back, not reviewed by MHDUR (case-by-case evaluation may apply). ○ Coenzyme Q10 (age limit)/Probiotics (age limit)/Pseudoephedrine (dose limit)/Vitamins, Brand Name/Combination ▪ Have established PA criteria. ▪ No notable PAs identified that may require adjustment of current management strategy. Conclusion • OTC Products are associated with a significant cost. ○ High volume, low average cost per claim ○ Several high-cost products with low or limited utilization • Few PA requests, approvals were appropriate, and no adjustments to criteria required. ○ Certain classes have higher denial rates (e.g., vitamins). • All MassHealth MCOs provide OTC coverage; however, evaluating differences is challenging. • Full evidence-based reviews will be completed for OTC classes (probiotics, coenzyme Q10, etc.). ○ Cost data, literature review, criteria updates if applicable, etc.	

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	**<u>MHDL Update by Dr. Ryan Bettencourt</u>** MHDL Overview including new additions, changes in PA status, and related attachment updates to be implemented with a recent publication rollout.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussion • There were 10 additions to the MHDL Drug list effective as of September 20, 2021. • Of the 10 additions, seven will require PA and three will not. • One medication will be restricted to be administered by a health care professional. • Changes in PA status	**<u>Conclusion</u>** The board reviewed and accepted the presentation.

	○ One gout agent will no longer require PA. ○ Four ophthalmic anti-allergy and anti-inflammatory agents will no longer require PA. ○ One topical dermatologic agent will no longer require PA. ○ One serotonin–norepinephrine reuptake inhibitor will no longer require PA. ○ One antiretroviral agent will no longer require PA. • Changes to the MassHealth Brand Name Preferred Over Generic Drug List ○ Twelve agents will no longer require PA. ○ Three agents will be removed from the MassHealth Brand name Preferred Over Generic Drug List. • New FDA "A"-rated Generics ○ One medication is added to the drug list and will need PA for patient that is < 60 years will apply to brand and generic products. • Changes to Miscellaneous Documents on the MassHealth Drug List ○ One document has been updated to reflect recent changes for the MassHealth COVID-19 Pharmacy Program Emergency Response. ○ The MassHealth Quick Reference Guide has been updated to reflect recent changes to the MassHealth Drug List. ○ One document has been updated and the new Pharmacy Initiatives. ○ The MassHealth Pharmacy Covered Professional Services List has been updated to reflect recent changes to the MassHealth Drug List. Questions • McGee inquired about Prevnar 13 being replaced with Prevnar 20. • Bettencourt replied that the information about Prevnar 13 is still currently active on the drug list as of the September board meeting, but the drug company will have more information in October 2021. • Low stated that he had issues with Glumetza about the brand over generic. • Bettencourt responded that medication would continue to stay on the brand-over-generic list. • Lenz replied that both brand and generic requires PA and medical necessity documentation is required.	

Agenda Item	**Discussion**	**Conclusions/Follow Up**

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<tr>
<td>DUR Operational Update</td>
<td><u>DUR Operational Update by Dr. Jeannine Beauregard</u>
DUR Operational Overview including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics</td>
<td><u>Follow Up</u>
Informational/Advisory</td>
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<tr>
<td>Action</td>
<td>Discussion

MassHealth PA 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 for PAs 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.
Call abandonment rate 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 five.
Provider Outreach Volume: Current monthly average is 746 calls.
Top Ten Medications Requested for Prior Authorization – July 1, 2020 to June 31, 2021.
<table>
<tr><td>1. Clindamycin</td><td>6. Clonidine</td></tr>
<tr><td>2. Tretinoin</td><td>7. Testosterone</td></tr>
<tr><td>3. Pregabalin</td><td>8. FreeStyle Test Strips</td></tr>
<tr><td>4. Methylphenidate</td><td>9. Botulinum</td></tr>
<tr><td>5. Clonazepam</td><td>10. Linzess</td></tr>
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Prior Authorization Compliance Response Time – July 2020 to June 2021

Total requests:105,633 requests
62% of all PAs decisions with in six hours.
99.5% of all PAs decisions in less than 24 hours.

Prior Authorization Compliance Response Time during Call Center hours – July 2020 to June 2021

Total requests: 105,633 requests
84% of all PAs decisions within six hours.
99.7 % of all PAs decisions in less than nine hours.

Questions

Labelle inquired about lessons learned during COVID and the PA process and the cost savings.
Beauregard responded that the staff schedules were adjusted accordingly to accommodate the volume of work.

</td>
<td><u>Conclusion</u>
The board reviewed and accepted the presentation.</td>
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	• Labelle inquired about the patients' medication utilization trends. • Beauregard responded that the numbers of PA volumes would reflect that. • Lenz commented that there are programs (e.g., delivery programs) that will continue. • Labelle inquired about the co-pays being withdrawn. • Lenz commented that the co-pays came off for certain criteria and will be evaluated in future.	

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	**<u>MassHealth Update by Dr. Paul Jeffrey</u>** 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
	• Formulary Management
	  ○ Unified Formulary-To be implemented January 2023 with all Managed Care Partners.
	  ○ Thank you to Managed Care Partners and the DUR and OCA team for work to implement.
	• Direct Negotiations with Legislation
	  ○ Over $160 Million (adding non-drug products pushing $200 million supplemental rebate revenue).
	  ○ Thank you to the pharmaceutical industry especially for their continued collaboration.
	• New Project
	  ○ Address the New Medicaid Inmate Exclusion Policy—not permissible for inmates to receive benefits from Medicaid.
	  ○ Jails currently have issues controlling medication costs.
	  ○ Large numbers of inmates going into/leaving jail on Medicaid.
	• News article on women being able to access birth control
	  ○ Family-planning medication can be accessible for a 12-month supply.
	  ○ Listed under COVID regulations for MassHealth.
	  ○ Regulations are being updated to be explicit on rules and to continue access.
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

Agenda Item	Discussion	Conclusions/Follow Up
Targeted Immunomodulators Quality Assurance Analysis	**Targeted Immunomodulators Quality Assurance Analysis by Dr. Diala Nicolas** This overview was 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 • This presentation was tabled until the next DUR Board meeting.	**Conclusion** The board reviewed and accepted the presentation.

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: _____