Minutes
Drug Utilization Review Board Meeting
DATE: June 8, 2022

Meeting Purpose: Quarterly Drug Utilization Board Meeting
Meeting opened at 6:00 p.m. by Christy Stine, MD, PhD

The meeting was conducted under Massachusetts Public Meeting Law requirements.

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

Absent: James Gagnon, RPh, PharmD; Michael Thompson, MD

Agenda Items:

- Welcome and Introductory Remarks
- Guest Speaker
- Minutes
- Resident Research Project: A Pre-Post Evaluation of Health Care Utilization and Costs Among Patients with Asthma-initiating Dupilumab in a Medicaid Population
- Resident Research Project: Changes in Healthcare Resource Utilization Following Initiation of Ustekinumab in Members with Inflammatory Bowel Disease in a Medicaid Population
- Oncology Products: Indication Market Withdrawals
- MHDL Update
- DUR Operational Update
- Open Forum
- Narcolepsy Agents Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Guest Speaker	Keyla Caba, a Medicaid patient, spoke on behalf of inflammatory bowel disease and ustekinumab.	**Follow Up** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion to approve the minutes for March 2022, was made by Greg Low, RPh, PhD and seconded by Timothy Fensky, RPh.	**Follow Up** Minutes are approved.

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: A Pre-Post Evaluation of Health Care Utilization and Costs Among Patients with Asthma-initiating Dupilumab in a Medicaid Population	**Resident Research Project: A Pre-Post Evaluation of Health Care Utilization and Costs Among Patients with Asthma-initiating Dupilumab in a Medicaid Population by Dr. Eliza Anderson** This was an overview of a research project developed by pharmacy practice residents.	**Follow Up** Informational/Advisory

Action	Discussion
	• Background
	  ○ Prevalence
	  ▪ In the United States, asthma affects approximately 25 million people.
	  ○ Societal Costs
	  ▪ The estimated societal cost of asthma is $82 billion each year.
	  ▪ Approximately 50% of all asthma-related healthcare costs have been associated with severe asthma.
	  ○ Treatment Options
	  ▪ Guidelines have recommended the consideration of biologic therapies for patients with severe asthma.
	  ▪ Dupilumab currently is the most recent FDA approved biologic for add-on treatment for moderate to severe eosinophilic asthma and/or OCS-dependent asthma.
	• Study Objective
		Conclusion
		The board reviewed and accepted the presentation.

	○ Primary: To compare the incidence of asthma-related emergency department visits with hospitalizations pre- and post-dupilumab initiation. Conclusions ○ Discussion ▪ The number of ED visits or hospitalizations related to asthma and pharmacy claims for OCS and asthma rescue medications decreased; however, results were not statistically significant. ▪ Total costs for asthma related exacerbations increased; however, results were not statistically significant. ○ Limitations ▪ The study period overlapped with the start of the COVID-19 pandemic. ▪ Pharmacy claims were not a true measure of patient adherence to a medication. ▪ Pharmacy costs of dupilumab were not included. ○ Conclusions ▪ Although results were not statistically significant, there was a reduction in ED visits or hospitalizations and claims for asthma rescue medications after dupilumab was initiated. ▪ Future studies should evaluate the cost-effectiveness of dupilumab in the management of asthma. Questions • Low inquired if there was a power analysis done for the research project. ○ Anderson responded that she did not complete one for this current research project. • Low stated there were too few patients to have power and would not expect to have power at 40% significance. He also stated that this did not look like a sample but an entire population and offered feedback on the analysis. ○ Anderson thanked him for the feedback.	

Agenda Item	Discussion	Conclusions/Follow Up
Resident Research Project: Changes in Healthcare Resource Utilization	**Resident Research Project: Changes in Healthcare Resource Utilization Following Initiation of Ustekinumab in Members with Inflammatory Bowel Disease (IBD) in a Medicaid Population - by Dr. Wilson Haong** This was an overview of a research project developed by pharmacy practice residents.	**<u>Follow Up</u>** Informational/Advisory

Following Initiation of Ustekinumab in Members with Inflammatory Bowel Disease in a Medicaid Population		

Action	Discussion
	• Background
	  ○ IBD
	  ▪ Comprised of UC and CD
	  ▪ IBD was most prevalent in Western countries with the rates being highest in areas of northern latitude.
	  ▪ Progressive and relapsing IBD in nature and can lead to long-term complications.
	  ○ Treatment
	  ▪ The goal of treatment is induction and maintenance of remission.
	  ▪ DMARDs (e.g., corticosteroids, aminosalicylates, thiopurines)
	  ▪ TIMs (e.g., anti-TNFs, IL-12/23 inhibitors, integrin receptor antagonists, S1P receptor modulators, oral JAK inhibitors)
	  ○ Previous Studies
	  ▪ Cost drivers include hospitalizations, ED visits, health care services, and treatment with TIMs
	  ▪ ICER found that ustekinumab for UC had one of the highest incremental cost-effectiveness ratios among TIMs.
	• Study Objective
	  ○ The change in IBD-related health care utilization in patients initiating with ustekinumab was evaluated.
	Conclusions
	• Discussion
	  ○ Mean annual IBD-related medical costs decreased by $2,104 per member (P = 0.32).
	  ▪ This was driven by a reduction in inpatient hospitalization costs ($2,245).
	  ○ The total number of mean annual IBD-related events increased by 0.29 events per member (P=0.71).
	  ▪ This was driven by an increase in outpatient visits (0.70).
	  ▪ Inpatient hospitalizations and ED visits declined.
	  ○ An analyses of subgroups did not yield statistically significant results (P > 0.05) except for members who have received
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	ustekinumab at high doses for which IBD-related medical costs increased ($2,459, P = 0.036). ▪ This was driven by an increase in inpatient hospitalization costs ($1,935). • Limitations o Pharmacy costs were excluded. o Patients with multiple illnesses were not accounted for. o COVID-19 pandemic o Other limitations: small sample size, reliance on claims data, retrospective nature of this analysis, absence of comparator groups and indirect costs. • Conclusions o Initiation of treatment with ustekinumab was not associated with statistically significant changes in IBD-related medical costs or events in all members. o Increased medical costs were observed in patients receiving high doses. ▪ Payers may consider management strategies for patients receiving high doses of ustekinumab. o Consideration should be given to evaluate IBD-related health care utilization in pivotal clinical trials. o Future studies should: ▪ Investigate indirect medical costs and pharmacy costs associated with ustekinumab treatment; and ▪ compare IBD-related health care utilization and costs to other TIMs. Questions • Low noted this was an economic analysis of the drug but there is also a quality benefit outside the scope of this presentation. o Haong replied that there was a limitation regarding not taking into account indirect costs. • Stine referenced the guest speaker, Caba, spoke on behalf of at the beginning of the meeting to look at clinical benefits.	

Agenda Item	Discussion	Conclusions/Follow Up
Oncology Products:	**Oncology Products: Indication Market Withdrawals by Dr. Kaelyn Boss**	**<u>Follow Up</u>** Informational/Advisory

Indication Market Withdrawals	This overview described the pharmacy program response to the removal from the market of products that had received the accelerated the approval in the oncology therapeutic space.	

Action	Discussion
	• Accelerated Approval Pathway
	  ○ This allows for faster approval of drugs that treat a serious condition and fulfill an unmet need.
	  ○ Agents may be approved using surrogate endpoints.
	  ○ This requires additional data to support efficacy following approval.
	  ○ Drugs unable to establish efficacy are expected to be withdrawn.
	• Oncologic Drug Advisory Committee (ODAC)
	  ○ The committee met from April 27, 2021 to April 29, 2021.
	  ○ Concern was shown over ongoing marketing of drugs that have failed to show benefit.
	  ○ Focused on checkpoint inhibitors
	  ▪ 35 of the 76 total indications for anti-PD-(L)1 antibodies are accelerated approvals
	  ○ 10 of 35 accelerated approvals still on the market despite a lack of confirmatory benefit
	  ▪ Four have been subsequently withdrawn.
	  ▪ Six have been brought to ODAC for evaluation.
	• Recent Oncology Withdrawals
	  ○ Copiktra (duvelisib)
	  ○ Farydak (panobinostat)
	  ○ Pepaxto (melphalan flufenamide)
	  ○ Ukoniq(umbralisib)
	  ○ Zydelig (idelalisib)
	• MassHealth Management Updates
	  ○ Updated Management
	  ▪ Copiktra (duvelisib) and Zydelig (idelalisib)
	  • Non-withdrawn indications will remain on MHDL.
	  • Withdrawn indications will be removed from MHDL.
	  • Requests for withdrawn indications will be reviewed on a case-by-case basis.
	  ▪ Farydak (panobinostat)/ Pepaxto (melphalan flufenamide) and Ukoniq (umbralisib)
	  • These drugs will be removed from the MHDL.
	  • Related criteria will be removed from the guideline.
	  • One member currently approved for Farydak (panobinostat), outreach to prescriber to address withdrawal will occur.
		<u>Conclusion</u>
		N/A

	Questions
	• Low stated that there are currently too few withdrawals of medications related to the Accelerated Approval pathway. He stated the FDA should continue to follow up with the drug companies to complete the studies after the approvals.
	• Ryle inquired if the Accelerated Approval pathway is related to the orphan drug status.
	  ○ Boss replied that it was to fulfill an unmet need. She stated that she was unclear if the two pathways were linked.
	• McGee inquired about the time for the Accelerated Approval pathway and if any of the drugs are automatically withdrawn.
	  ○ Boss stated it is intended for trials to happen within five years. However, there has been a drug that is currently on the market longer without the trials. A drug is not automatically removed from the market. She stated that there was a committee meeting in April of 2021.
	• McGee inquired if there was another meeting regarding this issue.
	  ○ Boss stated that this meeting was for oncology drugs. She did not see another meeting coming up regarding withdrawals.
	• Stine inquired about ramifications about not doing the confirmatory trials.
	  ○ Boss replied that manufacturers will state that they are unable to do the trials for various reasons.	

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	**MHDL Update by Dr. Meghan Serell** MHDL Overview included new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with a recent publication rollout.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• There were 12 additions to the MHDL Drug list effective as of June 27, 2022.
	• Of the 12 additions, ten will require PA and two will not.
	• Changes in PA status
	  ○ One hematologic agent will require prior authorization.
	  ○ One constipation agent will no longer require prior authorization.
	  ○ One butalbital-containing agent will require prior authorization.
		<u>Conclusion</u>
		The board reviewed and accepted the presentation.

	○ One agent will no longer be restricted to the health care professional who administers the drug as well as no longer requiring prior authorization. ○ One opioid reversal agent will no longer 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. ○ Six agents will be removed from the MassHealth Brand Name Preferred Over Generic Drug List. • Changes to the New FDA "A"-rated Generics ○ Four updates and PA will be required for the brand name medication. • Changes to the Miscellaneous Documents on the MassHealth Drug List ○ The MassHealth COVID-19 Pharmacy Program Emergency Response document has been updated to include FDA approval for Olumiant for members ≥ 18 years of age. ○ The MassHealth Quick Reference Guide has been updated to reflect recent changes to the MassHealth Drug List. ○ Two initiatives have been updated on the pharmacy initiatives list. ○ One medication will be added to the non-drug product list while two products will no longer require PA. ○ The MassHealth ACPP/MCO Unified Pharmacy Product List has been updated to reflect recent changes to the MassHealth Drug List. ○ One drug will be added to the MassHealth Supplemental Rebate/Preferred Drug List. ○ The MassHealth Acute Hospital Carve-Out Drugs list has been updated.	

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	**DUR Operational Update by Dr. Kristen Danis** The DUR Operational Overview included statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics.	**Follow Up** Informational/Advisory
Action	Discussion • MassHealth PA requests from 2019 to April 2022 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then some removed in August 2020.	**Conclusion** The board reviewed and accepted the presentation.

- MassHealth call center volume from 2019 to April 2022 (calendar year to date) showing with COVID leniencies initiated in March 2020 and then removed in August 2020.
- The monthly average for PAs from 2017 to 2022 (to date) were reviewed. The peak average was 10,547 per month in 2018 while currently (2022: to date) the average per month is 9,050.
- The call abandonment rate generally less than 2% (the overall average is 1.2%).
- The average wait time of answered call generally under the 30-second range (overall average is 14 seconds).
- Average treatment time consistently around four minutes.
- MassHealth Appeals: Current monthly average is four.
- Provider Outreach Volume: Current monthly average is 621 calls.
- Top Ten Medications Requested for Prior Authorization – April 1, 2021, to March 31, 2022.

1. Clindamycin Age Restriction	6. Clonidine Pediatric Behavioral Health Initiative
2. FreeStyle Libre Prior Authorization	7. Testosterone Prior Authorization
3. Dexcom Prior Authorization	8. Pregabalin Prior Authorization
4. Tretinoin Age Restriction	9. Botulinum Prior Authorization
5. Methylphenidate Pediatric Behavioral Health Initiative	10. Ozempic Prior Authorization

- Prior Authorization Compliance Response Time – April 2021 to March 2022
  - Total requests:107,843 requests
  - 74% of all Pas decisions within six hours.
  - 99.9% of all Pas decisions in less than 24 hours.
  - Over 50% of all Pas decisions in less than three hours
- Prior Authorization Compliance Response Time during Call Center hours – April 2021 to March 2022
  - Total requests: 107,843 requests
  - 94% of all Pas decisions within six hours.
  - 99 % of all Pas decisions in less than nine hours.

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	**MassHealth Update by Dr. Kimberly Lenz** The MassHealth Update is a summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health.	**Follow Up** Informational/Advisory

Action	Discussion
	• Federal Health Emergency
	  ○ This is scheduled to expire in July 2022.
	  ○ CMS will supply states with 60-day advanced notice.
	  ▪ Notification has not yet been received.
	  ▪ Possible extension up to 90-day
	• Claims Processing
	  ○ Covid-19 Antigen Testing Kits
	  ▪ As of June 8, 2022, over 98,000 individual tests were paid for.
	  ▪ Currently seeing an increase in tests due to an increase of COVID numbers.
	  ○ Specialized Pediatric Formulas through the Pharmacy Benefit
	  ▪ This was started due to the shortages nationally.
	  ▪ Meeting with partners
	  ▪ Processing claims through pharmacy
	  • Roughly 200 to 300 claims
	  ○ Permanent 90-day Supply Program
	  ▪ This is planned to be rolled out July 18, 2022.
	  ▪ It consists of generic, low-cost medications.
	  ▪ Three months after starting, there will be a mandatory component.
	  • Will be exceptions to mandatory
	  ○ Remove Copay on expanded list of drugs
	  ▪ Many were on the previous list for a $1 copay.
	  ▪ The roll out is scheduled for January 2023.
	• Direct Negations
	  ○ Currently have contracts with 18 manufactures for 51 drugs.
	  ○ Seven value-based contracts with manufacturers
	  ○ ~$230 million (annualized) including non-drug products
	• Re-procuring ACO and Managed Care Programs
	  ○ This is going into effect in early spring.
	  ○ A fully unified formulary will be tied to this new contract start date.
	
	Questions
		Conclusion
		The board reviewed and accepted the presentation.

	• Ryle inquired about the change in the $1 copay to no copay.
	  ○ Lenz responded that there are plans with broader lists as well as currently trying to address other issues (ex: health care disparities). She gave examples as to what types of drugs they would affect.
	• Labelle inquired about the 90-day exception and exception for housing status.
	  ○ Vangel and Lenz responded that there is no marker for housing status but the prescription would have to be written for 90 days.
	• Fensky inquired about how MassHealth would identify individuals using special packaging and compliance packaging.
	  ○ Vangel responded that there would be a submission clarification code to account for it.	

Agenda Item	**Discussion**	**Conclusions/Follow Up**
Open Forum	**Open Forum**	**<u>Follow Up</u>** Informational/Advisory
Action	Discussion • This presentation was tabled until the next DUR Board meeting.	**<u>Conclusion</u>** N/A

Agenda Item	**Discussion**	**Conclusions/Follow Up**
Narcolepsy Agents Quality Assurance Analysis	**Narcolepsy Agents Quality Assurance Analysis by Dr. Andrew Coelho** This overview was an evaluation of current medical literature and had provided a brief overview of new guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	Discussion
	• Prior Authorization Criteria
	  ○ General PA Criteria
	  ▪ Diagnosis
	  ▪ Age restrictions (excluding oxybates)
	  ▪ Specialist Prescriber
	  ▪ Quantity limits
	  ▪ Sleep study
	  ▪ Less costly trials
		<u>Conclusion</u>
		N/A

	○ Specific PA Criteria ▪ Sunosi (all indications) • Monotherapy or clinical rationale for combination ▪ Xywav • Medical necessity for use over Xyrem ▪ Idiopathic Hypersomnia • Member does not have hypersomnia due to another medical, behavioral, or psychiatric disorder. • Member is not currently utilizing a drug that can cause EDS. ▪ OSA (all applicable agents) • CPAP/BiPAP/appliance use, surgery, or clinical rationale for why it is not appropriate • Evidence-based Medicine Review ○ Updates to FDA-approved labels ▪ None require a criteria update. ○ Clinical Guidelines ▪ No updates in clinical guidelines since the last evidence-based medicine review. ○ Anticipated generics ▪ Xyrem (sodium oxybate): 2022 to 2023 • Pre-emptively placed on Brand Name Preferred Over Generic List ○ Pipeline ▪ FT218 (once-nightly oral sodium oxybate) • May be preferred due to administration; FDA decision delayed (was due October of 2021). • This is currently under patent litigation. • Recommendations ○ Require PA for concomitant use of modafinil and armodafinil ▪ Agents previously required PA; now only restricted for QL ▪ Concomitant use in member identified via PA appeal (for exceeding QL) ▪ There is no clinical literature to support the combination. ○ Update PA criteria to specifically restrict Sunosi (solriamfetol) in combinations with safety concerns. ▪ There are significant cardiovascular safety concerns when Sunosi used in combination with stimulants or stimulant-like agents (modafinil/armodafinil). ▪ There are less concerns with combinations of other agents utilized for narcolepsy (e.g., oxybate, pitolisant). • Conclusions ○ Low utilization class	

	▪ Utilization of modafinil agents has increased over the past three years. ▪ There was a jump in utilization after the PA restriction was loosened. ▪ Utilization of costly brand-name agents remains limited. o High costs, mostly attributed to costly brand agents o Limited prior authorization requests ▪ There were no notable cases to suggest changes in management strategy. o Management adjusted based on available clinical literature ▪ Modafinil/armodafinil: restrict concomitant use ▪ Sunosi: restrict only unsafe/concerning combinations ▪ Address PA requests for off-label indications to provide guidance on reviewing PAs for these indications Questions • McGee inquired about current PAs as well as concurrent use of the medication. She also inquired if there was a clinical rational about the use of the medication for narcolepsy. o Coelho responded that it would go live September 2022 and there are no current PAs submitted. • Low inquired about any current sleep studies for support of this and if there are any issues in request of getting medication. o Coelho stated he has not seen any issues regarding getting support of medication for this diagnosis. o McGee stated that most sleep studies are being done at home. o Stine responded that a certain sleep study must be done by a specialist and cannot be done at home such as for narcolepsy. She also stated that some sleep studies can rule out other sleep issues and may narrow down the diagnosis field to find out what is it or is not.	

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price

Date: _____