Minutes
**Drug Utilization Review Board Meeting**
DATE: September 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; MassHealth and Clinical Pharmacy Services staff.

**Absent:** N/A

**Agenda Items:**
- Welcome and Introductory Remarks
- Guest Speaker
- Antidiabetic Agents Quality Assurance Analysis
- Pipeline Update
- PD-1 and PD-L1 inhibitors Assurance Analysis
- Vaccines Quality Assurance Analysis
- MHDL Update
- DUR Operational Update
- MassHealth Update
- Synagis (palivizumab) Quality Assurance Analysis

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **Guest Forum** | Pharmaceutical Representative Testimony<br>• Dr Matthew Clark | **Follow Up**<br>Informational/Advisory |
| Action | Discussion<br>• Dr Matthew Clark presented testimony on Fintepla (fenfluramine) on behalf of Zogenix, Inc. | **Conclusion**<br>Informational/Advisory |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **Antidiabetic Agents Quality Assurance Agents** | **<u>Antidiabetic Agents Quality Assurance Agents by Dr Mark Tesell</u>**<br>This overview is an evaluation of current medical literature and provides a brief overview of new guideline recommendations in this disease state. | **<u>Follow Up</u>**<br>Informational/Advisory |
| Action | Discussion<br>• Summarized the updated treatment principles for type two diabetes.<br>• Presented utilization and prior authorization trends.<br>• Provided recommendations for changes in management.<br>• Discussed topics<br>  o Novel glucagon emergency products<br>  o Continuous glucose monitoring update: Freestyle Libre 2<br>  o Progress on the artificial pancreas<br>  o Pipeline updates<br>• MassHealth Utilization (Trends from QA analysis)<br>  o Metformin and sulfonylureas were the most commonly used traditional diabetes agents.<br>  o Of the newer classes, Januvia (sitagliptin), Jardiance (empagliflozin) and Trulicity (dulaglutide) have seen significant utilization increases (PA was removed since the previous QA analysis).<br>  o Among other PA-requiring products, Ozempic (semaglutide) and Victoza (liraglutide) were the most commonly used agents.<br>• Hot Topic:<br>  o Novel Glucagon Preparations<br>  ▪ Baqsimi (glucagon)<br>  • Intranasal, 3mg<br>  • Non-inferior vs. IMG<br>  • Small usability studies suggest quicker administration vs. IMG<br>  • GI, nasal irritation/sneezing<br>  • Non-injection<br>  • No reconstruction<br>  • Recommendation: Preferred product<br>  ▪ Gvoke (glucagon)<br>  • Prefilled syringe<br>  • Hypopen auto-injector<br>  • Non-inferior vs. IMG<br>  • Small usability studies suggest quicker administration vs. IMG<br>  • GI, nasal irritation/sneezing | **<u>Conclusion</u>**<br>The board reviewed and accepted the presentation. |

- No reconstruction
- Recommendation: PA required

- Freestyle Libre 2
  - FDA approved on June 15, 2020
  - Advantages vs. Freestyle Libre 1
    - Alarms
    - Slightly better accuracy
    - Second approved “iCGM”
  - Plans to pursue future integration with systems from Insulet, Tandem and Bigfoot.
  - Competitor Dexcom G7 was delayed until 2021.
- Pipeline Updates
  - Tripeptide (Lilly)
    - Dual GIP/GLP-1 agonist
    - Phase III trials
      - Improved efficacy vs. GLP-1 agonists
      - Questions around tolerability
    - Possible launch in 2022
  - High Dose GLP-1s
    - Trulicity (dulaglutide)
      - AWARD-11: dulaglutide 3mg and 4.5mg greater reductions in HbA1c than 1.5mg (-1.71% and -1.87% vs. -1.53%: P<0.05 for both comparisons)
    - Ozempic (semaglutide): Sustain Forte results Q4 2020
  - Miscellaneous
    - Recently approved
      - Lyumjev (insulin lispro)
        - New ultra-rapid acting insulin
        - Currently under review
    - Generic pipeline
      - Byetta (exenatide): 2020
      - Limited others in near future

Questions

- Dr Greg Low inquired about the glucagon products. Both products are being prescribed in as a two-pack and he inquired about how MassHealth is reviewing this, and if DUR had any comments on glargine.
- Dr Mark Tesell responded that there are no quantity limits currently in place for the glucagon two-pack products since patients need access to these products. Dr Tesell stated as well that they will go back and look at the requests for these medications and see if there can be adjustments in the guidelines for patients needing more than one glucagon medication. Dr Tesell stated that in response to the glargine inquiry, that the medication was launched recently and is currently under review.

| | | |
|---|---|---|
| | • Dr Karen Ryle commented that glucagon had a single dose but it was decided to discontinue it. They are currently only prescribing the two-pack of glucagon. Dr Ryle suggested that this product should not be split up in favor of the single dose since the current situation (i.e., billing) is complicated.<br>• Dr Michael Thompson commented about the presentation being done well.<br>• Dr Tesell replied that there are different products in process and they are continuing to update and stay current. | |

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

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **Pipeline Update** | **Pipeline Update by Dr Collin Jerard**<br>The Pipeline Update will provide a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development. | **Follow Up**<br>Informational/Advisory |
| Action | Discussion<br>• Aducanumab<br>o New chemical entity<br>o Anti-beta amyloid antibody<br>o Manufactured by Biogen and Eisai<br>o Treatment of Alzheimer's disease<br>o BLA has been accepted by the FDA and granted priority review with a decision expected by March 7, 2021.<br>o Population: Adult patients age 50 to 85 years old with Alzheimer's disease<br>o Administered HD and LD aducanumab IV once monthly<br>• Cabotegravir<br>o New chemical entity<br>o INSTI<br>o Manufactured by ViiV Healthcare<br>o HIV PrEP in men and transgender women who have sex with men<br>o Study results were presented on July 8, 2020.<br>o Administered intramuscular every two months | **Conclusion**<br>The board reviewed and accepted the presentation. |

| | | |
|---|---|---|
| | | |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **PD-1 and PD-PL1 inhibitors Quality Assurance Analysis** | **PD-1 and PD-PL1 inhibitors Quality Assurance Analysis by Dr Stephanie Tran**<br>This overview is an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state. | **Follow Up**<br>Informational/Advisory |
| Action | Discussion<br>• Reviewed pharmacy and medical claims utilization for the PD-1 and PD-L1 requests<br>• Reviewed PA requests<br>• Proposed recommendations for management<br>• Revisited the management of Yervoy (ipilimumab)<br>• Management and QA Methods<br>  ○ Management Strategy: All PD-1 and PD-L1inhibitors require PA<br>  ○ Criteria<br>  ▪ Appropriate diagnosis<br>  ▪ Specialist involvement<br>  ▪ Appropriate dosing<br>  ▪ Previous trials, concomitant therapies and testing requirements (consistent with FDA-approved labeling and NCCN guideline recommendations)<br>  ○ Methods<br>  ▪ Pharmacy claims/PAs (July 1, 2019 to June 30, 2020<br>  ▪ Medical claims (April 1, 2019 to March 31, 2020<br>  ▪ Case by case targeted for review<br>• QA Analysis Comparison<br>• Previous QA (presented March 15, 2018)<br>  ○ Pharmacy: Five unique utilizers<br>  ○ PAs: 24<br>  ○ Medical:<br>  ▪ Keytruda (pembrolizumab): 193<br>  ▪ Opdivo (nivolumab): 112<br>  ○ Approved for 28 indications across 11 cancer types<br>• Current QA (presented August 20, 2020<br>  ○ Pharmacy: 22 unique utilizers<br>  ○ PAs: 33 | **Conclusion**<br>The board reviewed and accepted the presentation. |

| | | |
|---|---|---|
| | ○ Medical:<br>▪ Keytruda (pembrolizumab): 477<br>▪ Opdivo (nivolumab): 230<br>▪ Tecentriq (atezolizumab): 70<br>▪ Imfinzi (durvalumab): 78<br>○ Approved for 39 indications across 21 cancer types.<br>• Subanalysis: Yervoy (ipilimumab)<br>○ The FDA approved in 2011.<br>▪ Monotherapy for the treatment of melanoma<br>▪ Combination with Opdivo (nivolumab): Renal Cell Carcinoma, Colorectal Cancer, Hepatocellular Cancer, Non-Small Cell Lung Cancer<br>▪ Due to infusion, managed without PA.<br>○ Utilization, Other Insurers, and Cost<br>▪ Pharmacy: One utilizer<br>▪ Medical: 32 utilizers<br>▪ Other insurers: If PD-1/PD-L1 managed, Yervoy (ipilimumab) was managed with same manner<br>▪ Weight-based dosing<br>○ Recommendations<br>▪ It is recommended to place Yervoy (ipilimumab) on PA to ensure appropriate use.<br>▪ Criteria will follow FDA-approved labeling and NCCN guideline recommendations.<br>• QA Analysis Summary<br>○ No changes in criteria from review of PA or call center feedback.<br>○ Criteria was updated based on a review of FDA-approved indications and NCCN guidelines. New indications were added to the guideline.<br>○ Opportunities may exist for preferred product designation.<br><br>Questions<br>• Dr Greg Low inquired that if there was no inappropriate use for the medication, why is it of any use to require PA? He also understood that when there is money invested, MassHealth needs to make sure that everything is legitimate.<br>• Dr Stephanie Tran responded that there is no need to answer the question, since Dr Low already answered his own question. | |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|

| | | |
|---|---|---|
| **Vaccines Quality Assurance Analysis** | **<u>Vaccines Quality Assurance Analysis by Dr Karen Stevens</u>**<br>This overview is an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state. | **<u>Follow Up</u>**<br>Informational/Advisory |
| Action | Discussion<br>• A brief overview of the national vaccine immunization program was provided.<br>• Evaluated current MassHealth management<br>• Present utilization, cost and overview of PA requests<br>• Review Advisory Committee on Immunization Practices and updated recommendation<br>• Noteworthy News<br>• National Vaccine Immunization Program<br>  ○ Most successful example of effective preventative care in U.S.<br>  ▪ Most vaccine preventable illnesses in the U.S. declined by >90% after routine childhood immunizations.<br>• Pharmacy Utilization July 1, 2019 to June 30, 2020<br>  ○ Paid Claims<br>  ▪ Totals<br>  • 8,114 unique utilizers<br>  • 10,862 paid claims<br>  • $1,078,391 spent<br>  ▪ Highest Utilized Non-PA agents<br>  • Boostrix (780 UU)<br>  • Pneumovax (540 UU)<br>  • Prevnar 13 (338 UU)<br>• Medical Claims Summary: May 1, 2019 to April 30, 2020<br>  ○ Unique Utilizers: 64,938<br>  ○ Number of Claims: 267,436<br>  ○ Total Amount Paid: $5,212,502<br>  ○ Most Utilized Agents:<br>  ▪ Tdap with 82,760 claims<br>  ▪ Pneumovax 23 with 44,842 claims<br>  ▪ Gardasil 9 with 39,085 claims<br>• MassHealth Prior Authorizations<br>• PA Required<br>  ○ Gardasil 9: individuals <9 or ≥46 years old<br>  ○ Shingrix: individuals <50 years old<br>  ○ Zostavax: individuals <50 years old<br>• Four requests for Shingrix (recombinant herpes zoster vaccine) in individuals < 50 years old were made. | **<u>Conclusion</u>**<br>The board reviewed and accepted the presentation. |

| | | |
|---|---|---|
| | • All were approved due to some form of immunodeficiency/immunosuppression.<br>• Only two members went on to have Shingrix administered<br><br>Recommendations<br>• Add additional guidance for consultants to review requests for administration of Shingrix (recombinant herpes zoster vaccine) to individuals < 50 years of age due to immunocompromised state.<br>• Per CDC website, Zostavax (live herpes zoster vaccine) will no longer be sold in the U.S. starting July 1, 2020.<br>  ○ The Guideline and MHDL will be updated once obsolete for one year.<br><br>Questions<br>• Dr Julita Mir inquired about the change for the pharmacies where children are given the immunizations. She asked if that was similar for the immunizations for the adults where immunizations can be received from the pharmacies.<br>• Dr Karen Stevens responded that the standard immunizations that are recommended, should be able to be received on the retail side. The issue would come in where the pharmacies have access to the immunizations that are needed at the time.<br>• Dr Julita Mir inquired about the allergic reactions and side effects of the previous dose.<br>• Dr Karen Stevens responded that she hoped the pharmacy can outreach to the prescriber's offices if there was an issue with the immunization.<br>• Mr Timothy Fensky stated that a current guideline on giving immunizations has been distributed to pharmacies. The guideline can also be viewed on the Massachusetts Board of Pharmacy website.<br>• Dr James Gagnon inquired about whether the guideline has any information about the pediatric patients receiving immunization and if the pediatric offices are being informed.<br>• Mr Timothy Fensky responded that if a child does not have a pediatrician, the pharmacy is supposed to refer them to one. If the child does have a pediatrician, the immunization information should be relayed to the pediatrician's office.<br>• Dr Laurie Spring stated that there is a hesitancy to immunize a child. They do immunize adults (18 years or older). She stated they check the system that they have and make sure that the information is current and up-to-date when immunizing a patient. | |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **MassHealth Update** | **<u>MassHealth Update by Dr Paul Jeffrey</u>**<br>The MassHealth Update is a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health. | **<u>Follow Up</u>**<br>Informational/Advisory |
| Action | Discussion<br>• MassHealth has been working with managed care partners on creating a partially unified formulary, with a decision coming soon.<br>  ○ Support from DUR Team with guidelines<br>  ○ The implementation target date is January 1, 2021.<br>  ○ After January 1, 2021, we will look at how and when to keep the formulary updated<br>• A fair amount of success with direct negations was noted.<br>  ○ FY12 to FY20 rebates received escalated from 35% in FY12 to 55% in FY20.<br>  ▪ Invoiced over $1 Billion last year for pharmacy rebates<br>  ○ Direct negotiation authority received in 2019, currently has 32 medications currently under contract and a total incremental savings value of $92 million annualized.<br>• We are currently implementing a new version of POPS processing system.<br>  ○ The contract has been signed.<br>  ○ We are in the system design phase of the process.<br>• COVID-19<br>  ○ Several changes have been implemented.<br>  ○ MassHealth has paid 240,000 or more claims since implementing for 90-day supplies since the pandemic has started.<br>  ○ This represents a little over 6.2% of total claims to date.<br>  ○ A program was recently implemented for MassHealth members who were displaced due to the quarantine. | **<u>Conclusion</u>**<br>Informational |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **DUR Operational Update** | **<u>DUR Operational Update by Dr Patricia Leto</u>**<br>A DUR Operational Overview will be discussed, including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics. | **<u>Follow Up</u>**<br>Informational/Advisory |
| Action | Discussion<br>• A review COVID-19 pharmacy claim accommodations was provided.<br>• A Hydroxychloroquine request overview was also provided.<br>• Review call center metrics<br>• Claim Accommodations<br>  ○ 90-day Supply<br>  ▪ 168,465 claims from March 15, 2020 through July 19, 2020<br>  ▪ Percentage of all paid claims: 5.99%<br>  ○ Early Refill Override<br>  ▪ DUR Calls<br>  • Highest daily number of calls: 487 on July 18, 2020<br>  ▪ Pharmacy Override<br>  • Highest number of daily pharmacy override: 5,180 on March 21, 2020<br>• MassHealth Prior Authorization Requests 2017 – 2020<br>  ○ The highest number of claims was near 14,000 in 2018.<br>• Call center volume: 2017 – 2020<br>  ○ The highest number of calls received by the call center was near 11,000 in 2018.<br>• MassHealth Prior Authorization Volume: 2015 – 2020 Monthly Average<br>  ○ The highest number of prior authorizations received were 10,547 in 2018.<br>  ○ Current average number of requests per month: 7,600 (to date)<br>• Call Center Statistics<br>  ○ Abandoned Rate: 1.7%<br>  ○ Average Queue Time of Abandoned Call: 45 seconds<br>  ○ Average Wait Time of Answered Call: 18 seconds<br>  ○ Average Treatment Time: Four minutes and 16 seconds<br>• MassHealth Appeals: The monthly average of appeals is four per month.<br>• Provider Outreach Volume: Monthly average is 864 per month<br>  ○ The highest volume of calls was about 1,300 in May and June 2020.<br>• Top Ten Medications Requested for Prior Authorization: July 1, 2019 | **<u>Conclusion</u>**<br>The board reviewed and accepted the presentation. |

| | | |
|---|---|---|
| | through June 30, 2020<br><br>• Clindamycin<br>• Methylphenidate<br>• Eliquis<br>• Clonidine<br>• Pregabalin<br>• Trulicity<br>• Testosterone<br>• Tretinoin<br>• Latuda<br>• Linzess<br>• Prior Authorization Compliance Time: July 2019 through June 2020<br>o Response Time<br>▪ Total requests: 97,853<br>▪ 70% of all PAs decisions within six hours<br>▪ 99.8% of all PAs decisions within 24 hours<br>o Response Time: DUR Call Center Hours<br>▪ Total requests: 97,853<br>▪ 91% of all PAs decisions within six hours<br>▪ 99% of all PAs decisions in less than nine hours | |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **MHDL Update** | **MHDL Update by Dr Ryan Bettencourt**<br>The 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**<br>Informational/Advisory |
| Action | Discussion<br>• New Additions: Effective September 21, 2020<br>o 12 medications were added to the MassHealth Drug List.<br>▪ 11 medications will require prior authorization.<br>▪ One medication is restricted to distribution by a medical professional.<br>• Changes Made in Prior Authorization Status<br>o Thirteen medications for cardiovascular agents no longer require prior authorization.<br>o Ten medications for antidiabetic agents will no longer prior authorization.<br>o One medication for opioid dependance will no longer require prior authorization.<br>o One medication for topical corticosteroid agent will require prior authorization.<br>o Six medications will require prior authorization below newly established age limits. PBHMI criteria will apply. | **Conclusion**<br>The board reviewed and accepted the presentation. |

| | | |
|---|---|---|
| | ○ Four medications will require prior authorization for PBHMI criteria.<br>○ Three medications for modafinil agents will no longer require prior authorization with in quantity limits. Prior authorization below newly established age limits will be required. PBHMI criteria will apply.<br>• Changes Made to MassHealth Brand Name Preferred Over Generic Drug List<br>○ Eight medications will be added to the brand name preferred over generic drug list.<br>○ One medication will be removed from the brand name preferred over generic drug list<br><br>Questions<br>• Mr Timothy Fensky inquired about Humalog being preferred brand over generic, which started September 21.<br>• Dr Ryan Bettencourt responded that was correct and it was Humalog 75/25. | |

| Agenda Item | Discussion | Conclusions/Follow Up |
|---|---|---|
| **Synagis (palivizumab) Quality Assurance Analysis** | **Synagis (palivizumab) Quality Assurance Analysis by Dr Mckenzie Taylor**<br>This overview is an evaluation of current medical literature and will provide a brief overview of new guideline recommendations in this disease state. | **Follow Up**<br>Informational/Advisory |
| Action | This presentation was tabled until the next MassHealth DUR board meeting. | **Conclusion**<br>The board reviewed and accepted the presentation. |

The meeting adjourned at 8:00 p.m.

Respectfully submitted by Mylissa Price, Director of Clinical Account Maganament

Date: _____