Minutes
Drug Utilization Review Board Meeting
DATE: 9/12/2018

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 p.m. by Standing in for Chair, Sara McGee.

Attendance: Joel Goldstein, M.D.; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, R.Ph.; Greg Low, R.Ph., PhD; M.D.; Sarah M. McGee, M.D.; Christy Stine, M.D.; and Michael Thompson, M.D.

Absent: Timothy Fensky, R.Ph; Audra R. Meadows, Sophie McIntyre, Pharm.D; Therese Mulvey, M.D.; Karen Ryle, M.S., R.Ph; and Arthur Yu-shin Kim, M.D.

Agenda Items:
I. Welcome and Introductory Remarks
II. Guest Forum
III. Pipeline
IV. Hepatitis C Clinical Update
V. Minutes
VI. Preferred Products Agents Overview
VII. Librax (chlordiazepoxide/clidinium) Quality Assurance Analysis
VIII. MassHealth Update
IX. DUR Operational Update
X. Hereditary Angioedema Agents Quality Assurance

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Pharmaceutical Representative Testimony Dr. William Baker – Senior Medical Science Liaison II, Genetic Diseases, Shire Pharmaceuticals, LLC.	**Follow Up** Informational/Advisory
Action	Discussion: Information regarding Takhzyro (lanadelumab-flyo) injection for Hereditary Angioedema,	**Conclusion** Informational/Advisory

	which is currently being reviewed by the FDA.	

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update Summary	Presentation given by Kaelyn Boss	**Follow Up** Informational/Advisory
Action	Discussion: The Pipeline Update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development. *Eligible for one hour of Pharmacist CE credit. Questions: ➢ A Board member asked the route of administration for an Alzheimer's drug. (An injection) ➢ A Board member asked how Xolair is being used in those patients who have allergies. (An EpiPen would still be required, as Xolair does not cure food allergies.)	Conclusion Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Hepatitis C Clinical Update	Presentation given by Mark Tesell This overview is an evaluation of the utilization of hepatitis C agents by the MassHealth pharmacy program, and provides a brief overview of current medical literature. **Discussion:** • Reviewed changes to the preferred products effective January 8, 2018. • Summarized prior authorization criteria principles for preferred agents and reviewed the Hepatitis C Monitoring Program. • Reviewed pharmacy utilization and PA requests for Hepatitis C Agents. • Presented analysis of percentage of members with HCV diagnosis and a PA request. • Provided recommendations for the Hepatitis C Medication Monitoring program.	**Follow Up** Informational/Advisory

Action	**Conclusions:** • The preferred product adoption has remained high prior to and post new product designation on January 8, 2018. • Demographics continued moving towards treatment naïve members and members with early stage liver disease as compared from 2013 to 2015. • Significant increases in utilization associated with the ACO transition in March 2018, were noted. • A review of sample PA's indicated appropriate review using MassHealth guidelines. • The Hepatitis C Monitoring Program continues to ensure appropriate regimen use, adherence, and documentation of clinical cure. • Some members continue to be lost to follow-up and require outreach to prescribers' offices within two weeks of a denial if a resubmission is not received (but warranted). • While many eligible MassHealth members have been treated, a significant number remain (~80% of those with an appropriate diagnosis). **Questions:** ➢ A Board member inquired about the futility rule. It was noted that futility rules are a general guidance. A detectable viral load after four weeks of treatment indicates that the treatment is unlikely to work.	**Conclusion** Proceed with recommendations as stated.

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion made by Greg Low, R.Ph., PhD., to accept the June 13, 2018, minutes as written.	**Follow Up** N/A
Action	Minutes were seconded by Colleen Labelle, MSN RN-BC CARN. All approved.	

Agenda Item	Discussion	Conclusions/Follow Up
Preferred Products	Presentation was given by Mark Tesell This overview is an evaluation of the utilization of preferred products, which is designed to show adoption of preferred products post implementation.	**Follow Up** Informational/Advisory
Action	**Discussion** • Defined supplemental rebate and its application to the MassHealth pharmacy program. • Listed agents impacted by the MassHealth Supplemental Rebate/Preferred drug list initiative. • Described trends in the utilization of these products before and after the implementation date. • Proposed a brief "lessons learned" for designation of preferred products and recommend strategy moving forward. **Findings** • Following designation of preferred products, a transition in market share occurred across multiple therapeutic classes. • PA criteria was developed to facilitate review of non-preferred products. – Consideration given to specific scenarios where a non-preferred product may be medically necessary. – A determination was made for each class of non-preferred products, to allow members that are stable on a non-preferred product(s) to continue use of the product(s). – Feedback from stakeholders (e.g., DMH) was considered. • Continued efforts to pursue supplemental rebates in select classes where multiple therapeutics alternatives exist that are generally deemed to be similarly safe and effective, was recommended.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Librax Quality Assurance Analysis	Librax (chlordiazepoxide/clidinium) Quality Assurance Analysis given by Andrew Coelho The Overview was an evaluation of current medical literature and will provide a brief overview of a new guideline recommendations in this disease state.	**Follow Up** Informational/Advisory

Action	Discussion: • Presented the Federal law regarding drug marketing and the Drug Efficacy Study Implementation (DESI) program • Reviewed Librax (chlordiazepoxide/clidinium) and clinical literature supporting its use. • Discussed recommended updates to the management strategy for Librax (chlordiazepoxide/clidinium). Recommendations: • Members would have to meet all the criteria as well as the diagnosis. Questions: ➢ A Board member inquired about the current utilization, and it was noted that MassHealth has one utilizing member that had transitioned while on this medication from an MCO.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	MassHealth Drug List (MHDL) Updates given by Amy Jasinski MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with an upcoming publication rollout.	**Follow Up** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on September 10, 2018. • There will be eight new drugs added to the drug list and seven will require PA. One will not require PA. • The FDA "A"' Rated Generic Drug ertapenem is the generic of Invanz #. • Two Multiple Sclerosis agents will now require PA.	**Conclusion** Informational/Advisory

	• Three otic antibiotic agents will no longer require PA. • Five glaucoma agents will no longer require PA. • Eleven anticonvulsant agents will no longer require PA for age < six years. PBHMI polypharmacy criteria still apply. • One nutrient product was added to the MassHealth Over-the-Counter Drug List. • Three drugs were added to the MassHealth Brand Preferred Generic Drug List. • One drug was removed from the MassHealth Brand Preferred Generic Drug List.	

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	Quarterly Operational Statistics presentation given by Patricia Leto A DUR Operational Overview including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics, was presented.	**Follow Up** Informational/Advisory
Action	• Prior Authorization (PA) Requests averaged 7,000 per month FY17, with a peak March FY18 of 13,552 PA requests. • Call volume averaged 7,000 calls per month FY17, with a peak March FY18 of 11,101 calls. • The call abandonment rate was approximately 2.7%. • The average answered call wait time was 1.15 seconds. • The overall call time for answered calls was 37 seconds, noting the industry standard of under four minutes. • Appeals averaged 10 per month. • Provider outreach calls averaged 8-10% of call volume. • Top 10 PA medications ➢ Methylphenidate ➢ Aripiprazole ➢ Clonidine ➢ Xarelto ➢ Lyrica ➢ Lantus ➢ Oxycodone ➢ Eliquis ➢ Clindamycin ➢ Trulicity • PA turn-around time during business hours ➢ Statutory mandate is 24 hours ➢ 50% done in six hours ➢ 99.9 within 24 hours • PA turn-around time during non-business hours ➢ 90% done in six hours ➢ 98% within less than nine hours **Comments:** Patricia stated that the DUR team has done an exemplary job maintaining service level agreements considering the extra volume, noting that extra hours were asked of the call center staff. **Questions:** ➢ A Board member inquired about numbers for PA volume and call volume being	**Conclusion** Informational/Advisory

	so close, and if the calls are about the PA form. It was noted that calls are from prescriber offices and pharmacies and are of multiple issues. ➢ A Board member asked if the call center receives calls from patients. It was noted that patients contact the call center and are redirected to MassHealth Customer Service or an appropriate party. ➢ A Board member inquired if staffing levels had been increased given the increased number of calls and PAs. It was noted that staffing levels have remained constant, and existing staff has been working after hours to maintain service levels. ➢ A Board member asked if membership had grown. It was noted that MassHealth membership has increased by 100,000 members.	

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	Paul Jeffrey, Pharm. D., MassHealth gave MassHealth Update. The MassHealth Update is a brief summary of recent developments in MassHealth in the context of pharmacy, managed care, or public health.	**Follow Up** Informational/Advisory
Action	**MassHealth Update** • Accountable-care organizations (ACO) (22 plans total for MassHealth) ➢ Transitioned 80,000 more members ➢ Two partnership ACO/MCO and one Primary Care/ACO models o ACO + MCO (17 types of partnership plans) ▪ Care delivery system and payment partners ▪ Extended continuity plan for low risk medications (30 days) ▪ Extended continuity plan for high risk medications (60 days) o Primary Care/ACO (aka Model B) ▪ Three ACOs contract directly with MassHealth. ➢ Currently in a 30-day Continuity of Care transition period o Created to facilitate the transition of PAs and prescriptions between and among plans to minimize disruptions. Transition period could be extended if warranted. ➢ Noted data exchange issues, initiated some work with the Model B ACOs ➢ CMS o Ruling was denied on 1115 waiver request for pharmacy regulatory relief.	**Conclusion** Informational/Advisory

	○ The Federal Government presented an offer to MassHealth of exemption to participate in a demonstration project Medicaid Part B Program, which we turned down. ○ Noted that a drug approved by an accelerated process by the FDA is subject to regulations for approved drugs. ○ The Medicaid managed rule that was approved several years ago mandated state Medicaid programs provide oversight of drug utilization to our Medicaid partners. ▪ This is the first year that we are required to acquire and submit data to CMS for review. ○ Drug Rebate Program – On September 30th, the agreements that have been in existence since 1991, unless renewed by the manufactures, will be denied. **Questions:** • A Board member inquired about CMS attention to the MCOs and if a problem precipitated this action. It was noted that there was an absence of attention in the past.	

Agenda Item	Discussion	Conclusions/Follow Up
Hereditary Angioedema Agents Quality Assurance	Presentation given by Mark Tesell This overview is an evaluation of current medical literature and will provide a brief overview of a new guideline recommendations in this disease state.	**Follow Up** Informational/Advisory
Action	**Discussion**: • Background on hereditary angioedema was provided. • The FDA-approved agents and indications for hereditary angioedema agents was listed. • Current prior authorization (PA) criteria for hereditary angioedema agents was presented. • Recent utilization and cost data for MassHealth members was evaluated. • An overview of PA requests for hereditary angioedema agents was provided. • Recommendations to current MassHealth clinical criteria and approval quantities was discussed. **Recommendation**:	**Conclusion** Informational/Advisory

	• For all agents – Diagnosis of hereditary angioedema – Prescriber is an allergist or immunologist or consult notes provided • For agents used for prophylaxis against angioedema attacks only – More than one attack per month or history of recurrent laryngeal attacks – Inadequate response, adverse reaction, or contraindication to androgen therapy • Ruconest (C-1 esterase inhibitor, recombinant) is currently approved for the treatment of acute attacks and is under review for long-term prophylaxis – Expected decision by September 21, 2018 • California Technology Assessment Forum (CTAF) will convene to review ICER's assessment of therapies for hereditary angioedema on October 25, 2018. **Questions:** • A Board member inquired if the condition improved regarding the frequency and severity of the episodes. It was noted that the exact prognosis of the patients is not known, but as a chronic condition, many patients deal with symptoms on a daily basis and there can be variability in the condition. • A Board member inquired about the patients having two doses on hand, and the timing of the second dose. It was noted that this is a quantity sufficient that if an attack occurs and the symptoms do not subside, a second dose is indicated as well as evaluation by the Emergency Room.	

Meeting adjourned at 8:00 p.m.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____