Minutes
Drug Utilization Review Board Meeting
DATE: 3/13/19

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

Attendance: Timothy Fensky, R. Ph; Joel Goldstein, M.D.; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, R.Ph.; Greg Low, R.Ph.; Karen Ryle, M.S., R. Ph.; Christy Stine, M.D.; Michael Thompson, M.D.;

Absent: Audra R. Meadows, PhD; M.D.; Therese Mulvey, M.D.; Arthur Yu-shin Kim, M.D.

Agenda Items:
I. Welcome and Introductory Remarks
II. Guest Forum
III. Minutes
IV. Annual Pipeline Continuing Education Program
V. Vitrakvi (larotrectinib) New Drug Review
VI. MHDL Update
VII. DUR Operational Update
VIII. MassHealth Update
IX. Antiparkinsonian Agents Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Pharmaceutical Representative Testimony • Dr. David Freilich spoke from Amneal Pharmaceuticals about Rytary.	**Follow Up** Informational/Advisory
Action	Discussion: • Dr. David Freilich gave information regarding Rytary for the treatment of Parkinson's disease.	**Conclusion** Informational/Advisory

Minutes	A motion was made by Karen Ryle, M.S., R. Ph to accept the September 12, 2018, minutes as written. A motion was made by Michael Thompson, M.D. to accept the December 12, 2018, minutes as written.	**Follow Up** N/A
Action	The minutes for September 12, 2018, were seconded by Karen Ryle, M.S., R. Ph. The minutes for December 12, 2018, were seconded by Michael Thompson, M.D. All were approved.	

Agenda Item	Discussion	Conclusions/Follow Up
Annual Pipeline Continuing Education Program	Presentation given by Pavel Lavitas & Mckenzie Taylor This overview is an evaluation of current medical literature and will provide a brief overview of the place in therapy of this agent.	**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:** ➢ Referring to the results of the phase III REGENERATE study of obeticholic acid in patients with non-alcoholic steatohepatitis (NASH) and F2-F3 fibrosis, a Board member asked whether the results were available for the individual components of the co-primary endpoints (i.e., decrease in fibrosis ≥ 1 stage, no NASH progression). It was noted that the results of the study are currently available only as part of a manufacturer press release which did not provide such specific detail. ➢ A Board member inquired about the mechanism of action of AR101 and Viaskin Peanut in the treatment of peanut allergy and whether patients may be able to take peanuts as the result of treatment. It was explained that both agents work by exposing patients to small, escalating doses of peanut protein derivatives, leading to desensitization of patients to peanut protein. This lowers patient's risk of life-threatening reactions in case of accidental exposure to peanuts; however, the therapies are not intended to allow for safe consumption of peanuts daily. ➢ A Board member commented on the long duration (60 hours) of infusion for Zulresso (brexanolone.)	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Vitrakvi (larotrectinib) New Drug Review	Vitrakvi (larotrectinib) New Drug Review was given by Stephanie Tran. This overview is an evaluation of current medical literature and will provide a brief overview of the place in therapy of this agent.	**Follow Up** Informational/Advisory
Action	**Discussion** • Reviewed tropomyosin receptor kinase (TRK) fusion cancer. • Reviewed Vitrakvi (larotrectinib) and its place in therapy. • Noted no head-to-head comparators and no long-term durability of response and overall survival unknown. • Noted availability as an oral capsule and oral solution at an annual cost almost $400K. • Reviewed the known details of the Vitrakvi Commitment Program.™ **Recommendations** • This agent provides a promising treatment for neurotrophic receptor tyrosine kinase (NTRK) gene fusion tumors with an overall response rate of 75% in a clinical trial (N=55) and is FDA-approved for adult and pediatric patients. • Vitrakvi (larotrectinib) is under review and publication on the MassHealth Drug List and is anticipated for April 2019. • Vitrakvi Commitment Program™ provides a unique value payment system.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	
MHDL Update	MassHealth Drug List (MHDL) Update given by Amy Jasinski. MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates implemented with the December publication rollout.	**Follow Up** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on March 11, 2019 • Fourteen new drugs were added to the drug list and seven will require PA. • Baclofen Injection (Gablofen#) was added to the FDA "A" Rated MH Drug List. • Four drugs were added to the Anti-anxiety Drug List. • Five drugs were added to the Brand Name to the Preferred Over Generic Drug List. • One drug was removed from Brand Name over Generic Drug List. • Two Prior Authorization Forms were also added from the MassHealth Drug List for Calcitonin Gene-Related Peptide (CGRP) Inhibitors and Chimeric Antigen Receptor (CAR)-T Immunotherapies.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	Quarterly Operational Statistics presentation given by Patricia Leto. DUR Operational Overview statistics associated with Prior Authorization (PA) review, PA response, and Call Center metrics.	**Follow Up** Informational/Advisory
Action	• Prior Authorization (PA) Requests averaged 7,000 per month in FY17, with a peak in March FY18 of 13,552 PA requests. • Call Volume averaged 7,000 calls per month FY17, with a peak in March FY18 of 11,101 calls. • Prior Authorizations that averaged 7,000 monthly since 2014, increased to 10,000 in 2018. • Call Abandonment Rate was approximately 1.3%. • The Average Answered Call Wait Time was 14 seconds. • The overall call Time for Answered Calls was three minutes 37 seconds, noting the standard is under four minutes. • Appeals averaged 10 to 11 per month, noting a current decrease in appeals. • Provider outreach averaged 8 to 10% of call volume. • The Top 10 PA medications noted: ➢ Methylphenidate ➢ Oxycodone ➢ Lyrica ➢ Trulicity ➢ Clindamycin ➢ Xarelto ➢ Clonidine ➢ Testosterone ➢ Eliquis ➢ Botox • Discussed the PA turn-around time during business hours. It was noted that the statutory mandate is 24 hours, and 53% of PAs are completed in six hours, with 99.9% completed within 24 hours. Also noted that the PA turn-around time including non-business hours	**Conclusion** Informational/Advisory

	was 70% in six hours with 96% in less than nine hours.	

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MassHealth Update	MassHealth Update was presented by Paul Jeffery. 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** • We are in Year Two of ACO implementation, with approximately 26,000 members shifting plans. • The Massachusetts FY20 budget was submitted by the Governor to the General Court in late January/early February. • The proposed language in FY20 will include broader ability for MassHealth to directly negotiate with manufacturers as an alternative to current state procurement rules • Value-based Purchasing Proposal Background was presented. o The MassHealth Pharmacy Spend doubled from $1B to $2B over the prior five years. ▪ This trend is expected to continue. ▪ 19 drugs in pipeline projected @ >$80Mm annually. ▪ Top 30 drugs account for ~30% of spending (>$600Mm per year). ▪ Many new drugs are first in class – i.e., no competition. o MassHealth has used competitive procurements historically under state procurement rules. Value Based Purchasing will allow: ♦ Direct negotiation with manufacturers ♦ MassHealth to establish a cost-effective target price via third party independent analysis and cost of existing therapies. ♦ Outcome-based arrangements ♦ Transparency and public hearing ▪ If no agreement between manufacturer and MassHealth– require disclosures. ▪ May require manufacturers to testify at public hearings. ▪ May impose sanctions/reasonable penalties. **-** MassHealth received a lot of feedback on the proposal is taking that into consideration for planning purposes. • Safe Harbor Proposed Rule - federal o MassHealth will likely be commenting. o Removes Anti-kickback Safe Harbor from Medicaid MCO & Medicaid Part D rebates	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Antiparkinsonian Agents Quality Assurance Analysis	Presentation was deferred until next meeting.	**Follow Up** Informational/Advisory

Meeting adjourned at 7:00 p.m.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____