Minutes

Drug Utilization Review Board Meeting

DATE: 6/13/2018

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 p.m. by Chair, Audra Meadows.

Attendance: Joel Goldstein, M.D.; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, R.Ph.; Greg Low, R.Ph., PhD; Audra R. Meadows, M.D.; Christy Stine, M.D.;

Absent: Timothy Fensky, R.Ph; Sarah M. McGee, M.D.; Sophie McIntyre, Pharm.D.; Therese Mulvey, M.D.; Karen Ryle, M.S., R.Ph; Michael Thompson, M.D.; Arthur Yu-shin Kim, M.D.

Agenda Items:

I. Welcome and Introductory Remarks
II. Guest Forum
III. Minutes
IV. Pipeline
V. HIV Clinical Update
VI. ADHD Medications Quality Assurance Analysis
VII. Calcitonin Gene Related Peptide Inhibitor Overview
VIII. MassHealth Update
IX. DUR Operational Update
X. Clostridium Difficile Guideline Update

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Pharmaceutical Representative Testimony Dr. William Sidel -Tris Pharmaceutical Dr. Karen Phillips- Amgen Pharmaceutical	**Follow Up** Informational/Advisory
Action	**Discussion**: A Tris pharmaceutical representative presented testimony on Dyanavel XR. • Treatment for ADHD and recommendation for MassHealth Drug List • www.DyanavelXR.com informational page for more information on medication • An Amgen pharmaceutical representative presented testimony on Aimovig. • May 17th approval date • Migraine treatment • Once monthly self-administered dose	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	A motion was made by Greg Low, R. Ph. Ph.D. to accept the March 14, 2018, minutes as written.	**Follow Up** N/A
Action	The minutes were seconded by Colleen Labelle, MSN RN-BC CARN. All minutes were approved.	

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update Summary	Presentation given by Sage Bagwell	**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.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
HIV Clinical Update	Presentation given by Pavel Lavitas This presentation was an evaluation of the current medical literature and provided a brief overview of select newly approved and pharmaceutical pipeline agents in late-stage development. **Discussion:** • Identified recently FDA-approved HIV antiretroviral combination products. • Discussed potential advantages, disadvantages, and the place in therapy of new HIV antiretroviral products. • Propose drug management recommendations.	**Follow Up** Informational/Advisory
Action	**Conclusions:** • There are currently five new HIV Antiretrovirals that have been FDA approved over the last several months. – Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) • Approved on February 7, 2018. • The cost is slightly higher compared to alternatives. • Covered without prior authorization – Juluca (dolutegravir/rilpivirine)	**Conclusion** Proceed with recommendations as stated.

Agenda Item	Discussion	Conclusions/Follow Up
	• Approved on November 21, 2017. – Trogarzo (ibalizumab-uiyk) • Approved on March 6,2018. • It must be administered by a trained professional. • It may increase the cost of therapy. – Symfi Lo and Symfi (efavirenz/lamivudine/ tenofovir disoproxil fumarate) • Approved on February 5, 2018, and on March 22, 2018. – Cimduo (lamivudine/tenofovir disoproxil fumarate) • Approved on February 28, 2018. **Recommendations:** • Several HIV antiretroviral products were recently FDA-approved and are being reviewed to determine appropriate drug management. **Questions:** ➢ A member of the audience inquired about differences in the adherence of HIV medications. Pavel Lavitas responded that there are no indications of misuse of HIV antiretroviral medications. DUR has been tracking medication adherence such as medication possession ratios, and in the past has found the adherence overall was very reasonable. ➢ Dr. Meadows asked about adherence to PrEP (pre-exposure prophylaxis). ➢ Pavel Lavitas noted a large uptake, and adherence with PrEP (but no recent numbers), and data is about one year old. Data included patients with Truvada use without HIV. ➢ Dr. Jeffrey noted that we will be conducting a more comprehensive analysis. ➢ Audra Meadows inquired if people are becoming more aware about spikes in HIV cases relative to IV drug abuse, and Dr. Jeffrey responded, yes.	

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ADHD Medications Quality Assurance Analysis	<u>ADHD Medications Quality Assurance Analysis was given by Mark Tesell</u> Quality Assurance Analysis is an evaluation of drug utilization and/or prior authorization requests to ensure evidence-based and cost-effective drug use.	**<u>Follow Up</u>** Informational/Advisory
Action	**Discussion** • Identified the agents used to treat ADHD. • Described the long-acting cerebral stimulant class and the selection of preferred products. • Analyzed historical pharmacy claims data to determine the impact of preferred product implementation. • Reviewed Prior Authorization (PA) criteria and sample PA cases.	**Conclusion** Informational/Advisory

	• Pharmacologic Treatments for ADHD ○ Stimulants (amphetamines, methylphenidate) ○ Clonidine, Guanfacine ○ Atomoxetine ○ Non-FDA Approved Agents: ▪ Bupropion, TCAs, modafinil, memantine **Recommendations** • Utilization and PA requests suggest that implementation of long-acting preferred stimulants was successful. • Proportion of paid claims for preferred products and Concerta changed from 50% to 96% in the three months post-implementation • Low absolute denial rate for PA agents (72%) • Increase in upfront cost to reduce net cost after rebate • PA requests reviewed appropriately →no criteria changes recommended.	

Agenda Item	Discussion	Conclusions/Follow Up
Calcitonin Gene Related Peptide Inhibitor Overview	CGRPI Overview given by Karen Stevens The Overview was an evaluation of current medical literature and provided a brief overview of select newly approved and pharmaceutical pipeline agents in late stage development.	**Follow Up** Informational/Advisory
Action	**Discussion**: • Reviewed background information on migraine prevalence, pathophysiology and common triggers. • Presented overview of current acute and preventive therapy options for migraines. • Defined the role of CGRP in migraine pathology. • Evaluated clinical trial data for recently approved erenumab as well as other CGRP-inhibitors in development. • Examined key findings from the Institute for Clinical and Economic Review (ICER) Report. **Recommendations:** • Study endpoints met – Suggests MoAb CGRP-inhibitors provide some clinical benefit as preventative therapy for episodic and chronic migraines – Potential benefit of oral CGRP-inhibitors for acute treatment (no agents approved yet) • Studies showed large placebo effect – Similar to previous migraine studies • Short-term data has shown agents are well-tolerated. • Unanswered questions: • Lack of long-term safety/efficacy data • Safety/efficacy in patients with certain comorbidities unknown (e.g.,	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
	cardiovascular disease, liver disease with oral CGRP-inhibitors) • Consensus guidelines not yet updated for this class **Questions:** ➢ Dr. Goldstein inquired about combination therapies. ➢ Karen Stevens noted that the trials allowed the one preventative medication in addition to the trial medication. We may see additional data coming out later that may be different.	

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	<u>MassHealth Drug List (MHDL) Updates given by Amy Jasinski</u> MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates to be implemented with an upcoming publication rollout.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on June 18, 2018. • There will be seventeen new drugs added to the drug list and eleven will require PA. Two will only require PA when used outside of an established Quantity Limit and four will not require PA. • Akynzeo and palonosetron 0.25 mg/2 mL injection will require PA > 2 vials/28 Days • One drug will be added to MassHealth Supplemental Rebate/Preferred Drug List. • Two antibiotics will no longer require PA. • Four drugs will be added to the Brand Name Preferred Over Generic list. • Table 72 will be updated from Immunotherapy – Oral to Agents Not Otherwise Classified. • Verbiage describing non-preferred brand-name and generic drugs will be updated.	**<u>Conclusion</u>** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	Quarterly Operational Statistics presentation given by Patricia Leto DUR Operational Overview including statistics associated with Prior Authorization (PA) review and PA response, and Call Center metrics.	**Follow Up** Informational/Advisory

Action	• Prior Authorization (PA) Requests – average 7,000 per month (FY17), peak March FY18 with 13,552 PAs requested
	• Call Volume – 7,000 calls per month (FY17), peak March FY18 with 11,101 calls
	• Abandonment rate about 4.4%
	• Average answered call wait time – .42 seconds
	• Overall call time for answered calls – one minute and 49 seconds
	  ➢ Goal under four minutes
	• Pharmacy Edits
	  • Refill was too soon (40%)
	  • Prior authorization required (41%)
	  • DUR Reject Error (18%)
	  • CSMP Lock In (1%)
	• Appeals average 10 to 11 per month. Currently an increase in appeals
	• Provider outreach
	  ➢ Average eight to 10%
	• Top 10 PA medications
	  ➢ Methylphenidate
	  ➢ Aripiprazole
	  ➢ Clonidine
	  ➢ Lyrica
	  ➢ Oxycodone
	  ➢ Clindamycin
	  ➢ Lantus
	  ➢ Xarelto
	  ➢ Botox
	  ➢ Eliquis
	• PA turn-around time during business hours
	  ➢ Statutory mandate is 24 hours
	  ➢ 55% done in six hours
	  ➢ 99.9 within 24 hours
	• PA turn-around time during non-business hours
	  ➢ 78% done in six hours
	  ➢ 99% within less than nine hours
	
	Comments:
	
	Tricia stated that the DUR team has done a phenomenal job trying to keep up with the extra volume and are proud of the extra effort and the extra hours that have been put in to maintain compliance to maintain the same level of quality to the members and to the providers as best that we can.
		Conclusion
		Informational/Advisory

	Questions: ➢ Kim Lenz inquired about the rise in March statistics volume. ➢ Tricia Leto responded that it was related to the opioid dose reduction. Additionally, we generally see a seasonal PBHMI PA spike in March.	

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MassHealth Update	Paul Jeffrey, Pharm. D., MassHealth gave a 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** MassHealth launched the Payment & Care Delivery Innovation project creating 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 Central ➢ 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 – will be continuously monitored. ➢ Initiated some work with the Model B ACOs – Data exchange issues, more timely pharmacy data ➢ CMS – No answer on 1115 waiver request for pharmacy regulatory relief. o Pricing Language – made it onto the Governor's budget to give MassHealth Program authority to negotiate pricing with pharmaceutical industry on pricing related matters. ➢ Monitoring current bills in legislature. **Comments:** Dr. Jeffrey made two acknowledgements. One was to Sage Bagwell, whom the Board has had a chance to see throughout the year, and has completed her Residency. It really is a pleasure to have a Pharmacy Residency Program. Unlike Medical Residencies, not every pharmacist has to complete a Residency. A Pharmacy Residency selection process allows us to get the best and the brightest, and Sage is definitely an example of that. It has been a pleasure to have her work with us and we wish her the best in the future. Sage's research project this year was selected by the Academy of Managed Care Pharmacy at their annual meeting in April as the best poster	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
	presentation by a Pharmacy Resident out of a large number of submissions,. Dr. Jeffrey also mentioned Colleen Labelle. She has been selected by NEHI (Network for Excellence in Health Innovation.) He noted that she shares that platform with Scott Gotlieb,(Commissioner of the FDA), Senator Hatchman and Congressman Waxman. For those in the industry, you know that Senator Hatchman and Congressman Waxman modernized the drug laws that we currently have in existence today. Dr. Jeffrey noted that Colleen is in great company, and she is exceptional. Congratulations!	

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

Meeting adjourned at 8:00 p.m.

Respectfully submitted by: Vincent Palumbo, Director of DUR

Date: _____