Minutes
Drug Utilization Review Board Meeting
DATE: 9/11/19

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 pm by Timothy Fensky

Attendance: Timothy Fensky, RPh; Joel Goldstein, MD; Lori Lewicki, RPh; Greg Low, RPh, PhD; Sarah M McGee, MD; Christy Stine, MD

Absent: Colleen Labelle, MSN, RN-BC, CARN; Therese Mulvey, MD; Karen Ryle, MS, RPh; Michael Thompson, MD

Agenda Items:
I. Welcome and Introductory Remarks
II. Guest Forum
III. Guest Forum
IV. Minutes
V. Pipeline Update Summary
VI. Annual Special Populations Update
VII. Palivizumab Quality Assurance Analysis
VIII. Cystic Fibrosis Transmembrane Conductance Regulators Quality Assurance Analysis
IX. MHDL Update
X. DUR Operational Update
XI. MassHealth Update

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Pharmaceutical Representative Testimony • Dr Elizabeth Lubelcczyk	**Follow Up** Informational/Advisory
Action	Discussion • A Lilly Pharmaceuticals representative presented testimony on galcanezumab for treating episodic cluster headaches.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Guest Forum	Medical Representative Testimony • Dr Peter Chang	**Follow Up** Informational/Advisory
Action	**Discussion** • A Massachusetts Eye Research & Surgery Representative presented testimony on fluocinolone acetonide intravitreal implant for treatment of retinopathy. **Questions** • Dr Jeffrey inquired about the cost of the implant or the cost of the services. • Dr Chang replied that the cost of the product is about $8800. He compared to the cost of other medications such as Eylea, where the injection is about $2,000 and administered every six to eight weeks. The implant lasts from two to three years. The cost analysis of shots is about $42,000 where the cost of the implant only is about $8,800. • Dr Low asked for clarification if the agent is covered by MassHealth insurance. • Dr Chang noted that both agents are covered by the insurance.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Approval of the June DUR Board Minutes was deferred until the December meeting.	**Follow Up** N/A

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	Pipeline Update Summary by Dr Alan Gabot The Pipeline Update provided a brief overview of clinical and/or regulatory updates regarding select pharmaceutical pipeline agents in late-stage development.	**Follow Up** Informational/Advisory

Action	**Discussion**
	• Reviewed Triheptanoin – New Chemical Entity
	  ○ Treatment of metabolic disorders (i.e. Adult Polyglucosan body disease, Rhett Syndrome and Glucose one Transporter deficiency)
	• Reviewed Ceftobiprole – New Chemical Agent
	  ○ Treatment of MRSA
	
	Findings
	• Triheptanoin
	  ○ Summary of update
	  ○ NDA submitted to the FDA
	  ○ OL, SA, MC, phase II study (N=29)
	  ○ Population**:** Patients ≥6 months old with severe LC-FAOD
	  ○ Administration
	  ▪ Triheptanoin PO four times daily
	  ▪ Dosing based on caloric intake
	  ○ Potential impact
	  ▪ FAOD affects ~2,000 to 3,500 people in the US
	  ▪ Treatment includes avoiding prolonged fasting, maintenance of constant energy, fat-restricted diet, and MCT oil
	  ▪ May be the first FDA-approved treatment for LC-FAOD
	  ○ Projected market entry: An FDA decision is expected by Q2 2020
	
	• Ceftobiprole
	  ○ Primary endpoint/Results
	  ▪ Percentage of patients with early clinical response at 48 to 72 hours
	  ▪ Ceftobiprole: 91.3%
	  ▪ VAN plus ATM: 88.1%
	  ▪ Difference: 3.3% (95% CI, -1.2 to 7.8)
	  ○ Secondary endpoint/Results
	  ▪ Percentage of patients with clinical success at the TOC visit
	  ▪ Ceftobiprole: 90.1%
	  ▪ VAN plus ATM: 89.0%
	  ▪ Difference: 1.0% (95% CI, -3.5 to 5.6)
	  ○ Potential impact
		Conclusion
		Informational/Advisory

	○ ABSSSIs account for 2.6% of ED visits with 13.9% of cases resulting in hospitalizations ○ Treatment depends on the type of skin infection and whether the infection is recurrent ○ May provide an additional treatment option for ABSSSI ○ Projected market entry ▪ An NDA submission is expected by 2H 2021	

Agenda Item	Discussion	Conclusions/Follow Up
Annual Special Populations Update	Annual Special Populations Update by Dr Stephanie Tran and Dr Kaelyn Boss This overview is a summary of the current structure of the Drug Utilization Review Special Populations Program and will summarize clinical outcomes of the program over the past year.	**Follow Up** Informational/Advisory
Action	**Discussion** • Promotes collaboration between MassHealth and resources within Commonwealth Medicine to enhance quality of care • Pharmacy services provided to: • Community Case Management (CCM) o Enhanced Coordination of Benefits (ECOB) o Department of Children and Families (DCF) o Boston Children's Hospital (BCH) o Collaboration with MassHealth Drug Utilization Review (DUR) team • Clinical Pharmacist o Manage interactions with other departments o Communicate significant changes in the MHDL to CCM staff to help ensure continuity of care for members o Provide information to treating clinicians to help them streamline drug regimens to obtain the most clinically effective, cost efficient drug therapies available o Participate in multidisciplinary team reviews o Complete medication reviews as needed to aid in an appeal o Provide educational trainings to multidisciplinary team on relevant pharmacy topics • Operational Pharmacist o Provide member-specific information o Assist in medication procurement o Identify pharmacies that offer special formulations of drugs • Workflow Changes o Triage responsibility from clinical to operational pharmacist o Improved efficiencies in providing service to MassHealth members o Greater shared responsibilities • Residency Core Rotation o Primary goal of the three-month rotation is to learn how to properly intervene and adequately respond to/facilitate consultations to ensure that members gain access to medically necessary medications	**Conclusion** Informational/Advisory

	▪ Involvement in at least 30 consults and track members to determine resolution ○ Quality improvement project ○ Contribute to weekly CCM meetings & medication reviews ○ Present a 30-minute presentation to the CCM multidisciplinary team on a relevant pharmacy topic • General Updates ○ The Special Populations program remains active in providing services for CCM and ECOB. ○ In addition to providing operational and clinical consults, the team presented an in-service to CCM entitled *Cannabidiol: Medicinal Uses and Future Implications* (April 2019) **Findings** • Trends in Consultations • Operational cases: ○ Medication procurement ▪ Billing issues (MassHealth and TPL) ▪ MassHealth coverage questions ▪ Identifying compounding pharmacies ○ PA assistance • Clinical cases: ○ Medication reviews to address current concerns ○ Medication reviews to aid in appeal consideration ○ General drug information • Received 251 consults for 175 unique CCM members • Clinical cases (n=41) ○ Medication reviews for appeal ○ Drug information requests • Operational cases (n=194): ○ Issues related to dual eligibility ○ Medication procurement assistance ○ Coverage questions (MassHealth vs Medicare) • Clinical and operational cases (n=16) ○ Medication procurement assistance with recommendations about therapeutic alternatives • Received 22 ECOB cases • Operational cases (n=21) ○ Medication procurement assistance ○ Coverage questions ○ Requests for pharmacy claims information • Operational and clinical cases (n=1) • Received two cases from DCF ○ Question regarding pick-up of medications for DCF members	

	○ Question about current status of a PA • Received four cases from other sources (e.g. member, family, etc.) ○ Operational cases (n=2) ▪ Questions about pharmacy benefit coverage	

Agenda Item	Discussion	Conclusions/Follow Up
Palivizumab Quality Assurance Analysis	Palivizumab Quality Assurance Analysis by Dr Mckenzie Taylor This overview is an evaluation of current medical literature and will provide a brief overview of guideline recommendations in this disease state.	**Follow Up** Informational/Advisory

Action	**Discussion**
	• Provide background information on respiratory syncytial virus and the American Academy of Pediatrics clinical guidelines for prophylaxis with Synagis® (palivizumab)
	• Assess current MassHealth criteria
	• Analyze utilization trends for Synagis® (palivizumab)
	• Present methodology and outcomes from the monitoring program
	• Impact of RSV in the US
	  ○ RSV has been associated with 2.1 million outpatient visits and over 57,000 hospitalizations in children <five years old
	  ○ 90% of RSV related deaths occur in children <five-year-old
	• Humanized monoclonal antibody
	• MOA: Binds to the surface of RSV to inhibit membrane fusion
	• Indication: *Prevention* of serious LRTI caused by RSV in high risk children
	• Dosing: 15 mg/kg IM once a month throughout RSV season
	• Maximum five doses per season
	• Primary benefit of prophylaxis is ↓ in hospitalization
	• Cost-effectiveness in all at-risk children has not been demonstrated
	
	Findings
	• Utilization trends were lower than what was observed in 2017-2018 RSV season
	  ○ Approximately 450 requests in the 2017-2018 season compared to 285 in the 2018-2019 season
	  ○ Absolute denial rate ~35%
	• Review relevant literature evaluating impact of guideline changes on RSV hospitalization as it becomes available
	• Changes to monitoring program include:
	  ○ End-date PA for members with a confirmed hospitalization for RSV after consultation with the prescriber
	  ○ Monitor pharmacy billing for increased/decreased doses as compared to previously billed dose
	  ○ Perform outreach calls for fills that are seven days past the expected fill date
		Conclusion
		Informational/Advisory

	Questions • Dr Kim Lenz inquired what data was used. • Dr Taylor stated the data that was used was from members that had a diagnosis of RSV, not necessarily hospitalization, and of the Pas there were five approvals and one denial. • Dr Lenz inquired if it was the five out of the seventeen that was reviewed. • Dr Taylor responded that it was just in general, out of all the approvals that were issued. • Dr Lenz inquired that out of the one hundred and sixty-four approvals that were issued, five members went on to have RSV? • Dr Taylor confirmed that yes, five did have RSV. • Dr Lenz inquired if they used all three doses. • Dr Taylor stated that she does not know. They could have had a hospitalization, she only knows that they have a claim for RSV.	

Agenda Item	Discussion	Conclusions/Follow Up
Cystic Fibrosis Transmembrane Conductance Regulators Quality Assurance Analysis	<u>Cystic Fibrosis Transmembrane Conductance Regulators Quality Assurance Analysis Dr Karen Stevens</u> This overview is an evaluation of current medical literature and will provide a brief overview of guideline recommendations in this disease state.	**<u>Follow Up</u>** Informational/Advisory

Action	**Discussion**
	• Brief review of key background information for cystic fibrosis (CF)
	• Overview of currently available CFTR modulators and MassHealth PA criteria
	• Evaluate recent utilization and cost data for these agents in the MassHealth population
	• Present an overview of current PA requests, MPR and outcomes data for MassHealth members
	• Review Pipeline for CF therapy
	• Most common life-shortening autosomal recessive disorder among Caucasians
	• Estimated that 30,000 individuals in the U.S. have CF
	• Caused by mutations in CFTR gene
	  ○ Disruption in normal CFTR protein production
	  ○ Dysregulation of salt and water movements
	  ○ Thick, sticky mucus buildup in lungs, pancreas liver and reproductive tract
	• PA Requests
	  ○ Kalydeco®
	  ▪ Two unique utilizers
	  ▪ Paid claims for both in POPS
	  ○ Orkambi®
	  ▪ 19 unique utilizers
	  ▪ 15 members with paid claims in POPS
	  ▪ Seven members with TPL
	  Two members subsequently switched to Symdeko®
	  ○ Symdeko®
	  ▪ 20 unique utilizers
	  • 19 homozygous for F508del
	  • 16 had previous documentation of prior Orkambi® utilization
	  ▪ 17 members with paid claims in POPS
		Conclusion
		Informational/Advisory

	▪ 10 with TPL **Recommendations** • Remove requirement for baseline ppFEV1 for individuals < 6 yo • Update MHDL and guideline for expanded FDA-approval of Symdeko® for those ≥ 6 yo • Add new Symdeko® formulation (50/75 mg-75 mg tablet) to MHDL requiring prior authorization • **Pipeline (Targeting CFTR Function)** o Triple therapy: VX-445 (elexacaftor), tezacaftor, ivacaftor ▪ FDA accepted NDA 8/20/19, granted Priority Review (PDUFA date 3/19/2020) ▪ 24-week Phase III study: one F508del mutation and one minimal function mutation • Primary endpoint: mean absolute improvement in ppFEV1 from baseline of 14.3 (P<0.0001) • 63% reduction in annualized rate of pulmonary exacerbations ▪ Four-week Phase III study: two F508del mutations ▪ absolute change in ppFEV1 from baseline of 10.0 (P<0.0001) ▪ Could target > 90% of CF population • **Things to watch for:** o Possible collaboration for gene editing technology o Potential development of mRNA therapies	

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	MassHealth Update was presented by Dr Paul Jeffrey 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**
	• Acknowledge Chief Provider and Pharmacy Programs
	• Renegotiation with the POPs Program (currently ongoing)
	• Rebate Program
	  ○ Accumulated rebate claims
	  ○ Invoices went out
	• MassHealth Prescription Drug Pricing FY Budget Reforms (September 2019)
	  ○ MassHealth Budget signed
	  ○ Information will be posted on the website
	  ○ Allows for direct Supplemental Rebates negotiations with manufacturers and establishing value target prices for drugs
	Questions
	• Dr Stine inquired if there is a start date?
	• Dr Jeffrey replied that it is going on now and there is a budget obligation.
	• John Campbell, Bristol- Myers Squibb inquired about the target of 200 and also inquired if this information will be made public.
	• Dr Jeffrey stated that information is currently public.
	• Another question was asked was of Dr Jeffrey if this is price set.
	• Dr Jeffrey stated the reforms are somewhat equivalent to rate setting.
		Conclusion
		Informational/Advisory

Agenda Item	Discussion	
MHDL Update	<u>MassHealth Drug List (MHDL) Update given by Dr Amy Jasinski</u> MHDL Overview including new additions, changes in Prior Authorization (PA) status, and related attachment updates implemented with the October publication rollout.	**<u>Follow Up</u>** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on October 7, 2019 • Nine new drugs will be added to the drug list and eight will require PA • Five urinary disfunction drugs will no longer require PA, one will require PA exceeding QL • Three antihistamine agents will no longer require PA, on will require PA for use above QL • One drug is being removed from the MassHealth-Over-the-Counter Drug List • One agent is being added to the MassHealth Brand Name Preferred Over Generic Drug List • Seven agents will be removed from the MassHealth Brand Name Preferred Over Generic Drug List	**<u>Conclusion</u>** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	<u>Quarterly Operational Statistics presentation given by Dr Patricia Leto</u> DUR Operational Overview statistics associated with Prior Authorization (PA) review, PA response, and Call Center metrics.	**<u>Follow Up</u>** Informational/Advisory
Action	• Prior Authorization (PA) Requests averaged 9,000 per month in FY19, 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. • Call Abandonment Rate was approximately 1.3%. • The Average Answered Call Wait Time was one minute and 29 seconds. • The overall call Time for Answered Calls was 17 seconds, noting the standard is under four minutes. • Appeals averaged 14 per month, noting a current slight increase in appeals • Provider outreach averaged 8% to 10% of call volume which is about 675 calls • The Top 10 PA medications noted: ➢ Methylphenidate ➢ Clonidine ➢ Eliquis ➢ Testosterone ➢ Trulicity ➢ Tretinoin	**<u>Conclusion</u>** Informational/Advisory

	➢ Lyrica ➢ Latuda ➢ Clindamycin ➢ Xarelto • Discussed the PA turn-around time during business hours. It was noted that the statutory mandate is 24 hours, and 70% of PAs are completed in six hours, with 99.9% completed within 24 hours. This is 118,374 requests. • Also noted that the PA turn-around time including non-business hours was 86% in six hours with 98% in less than nine hours. This of 118,374 requests. **Questions** • Dr Lewicki asked about Rentin A, which is on the preferred list; and a way to put it in the system so that we do not get the rejection the call center does not receive a call? • Dr Leto responded keep any eye on availability, we are in contact with MassHealth about availability. We do receive phone calls to provide overrides in cases such.	

Meeting adjourned at 8:00 pm.

Respectfully submitted by Vincent Palumbo, Director of DUR

Date: _____