Minutes
Drug Utilization Review Board Meeting
DATE: 12/13/2017

Meeting Purpose: Quarterly Open Board Meeting
Meeting opened at 6:00 PM by Chair, Timothy Fensky.

Attendance: Timothy Fensky, R.Ph.; Colleen Labelle, MSN, RN-BC, CARN; Lori Lewicki, R.Ph.; Greg Low, R.Ph., PhD; Sarah M. McGee, M.D.; Sophie McIntyre, Pharm.D.; Therese Mulvey, M.D.; Michael Thompson, M.D.;

Absent: Leslie Fish, Pharm.D.; Joel Goldstein, M.D.; Audra R. Meadows, M.D.; Karen Ryle, M.S., R.Ph.; Christy Stine, M.D.; Arthur Yu-shin Kim, M.D.

Agenda Items:
I. Welcome and Introductory Remarks
II. Minutes
III. Clinical Items Update
IV. Clinical Team Annual Update
V. CAR-T Therapies in Oncology
VI. Pipeline Update
VII. Hemophilia Clinical Update
VIII. MassHealth Update
IX. MHDL Update
X. DUR Operational Update
XI. Alzheimer's Agents Quality Assurance Analysis

Agenda Item	Discussion	Conclusions/Follow Up
Minutes	Motion made by Greg Low, R. Ph.to accept the September 13, 2107, 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
Clinical Items Update	Pharmacy News	**Follow Up** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up

Action	Discussion:
	• New Hypertension Guideline – An Update to JNC7
	  • On November 13, the ACC/AHA released updated guidelines on the prevention, detection, evaluation and management of hypertension in adults.
	  • One in three Americans had previously been diagnosed with the condition, but now 14% more Americans will be diagnosed with high blood pressure. The new guidelines will classify 103.3 million people as having high blood pressure, while the previous guidelines placed only 72.2 million Americans in this category, according to the authors of the report.
	  • The prevalence of HTN in the U.S. increased from 32% to 46%.
	  • Out-of-office monitoring of BP is recommended to confirm HTN and to make adjustments to medication.
	  • Nonpharmacological interventions
	  • Weight loss, diet, exercise, avoidance of alcohol
	  • First-line medications: thiazide diuretics, CCB, ACE inhibitors/ARBs
	  • Most adults will require ≥ 2 antihypertensives
	
	• **Non-opioid Analgesics vs Opioids - No Difference in ED Patients with Acute Pain**
	  • DB, RCT (N=411) of ED patients with moderate to severe extremity pain (mean score, 8.7/10)
	  • Ages 21 to 64 (mean, 37)
	  • Sprain/strain (~60%), extremity fracture (~20%)
	  • Mean pain score decreases at two hours:
	  • 4.3 with ibuprofen 400 mg and acetaminophen 1,000 mg
	  • 4.4 with oxycodone 5 mg/acetaminophen 325 mg
	  • 3.5 with hydrocodone 5 mg/acetaminophen 300 mg
	  • 3.9 with codeine 30 mg/acetaminophen 300 mg
	  • No significant difference in pain reduction at two hours after a single-dose.
	  • Study limitations:
	  • A short follow-up period
	  • 18% received rescue analgesia
	  • Additional analyses did not reveal clinically important/significant difference.
	  • Data on adverse events not collected.
	  • Ibuprofen/acetaminophen combination is not commercially available which may be a barrier to adoption
	  • From 2006 to 2010, opioids were prescribed for 18.7% of ED discharges. Prescribing of non-opioid analgesics in ED could mitigate opioid epidemic by reducing initial exposure.
		Conclusion
		Informational/Advisory
		No recommendations were made by the Board.

Agenda Item	Discussion	Conclusions/Follow Up

Clinical Team Annual Update	**Discussion:**
	• Outline
	  • Review clinical projects and accomplishments for fiscal year 2017.
	  • Summarize and quantify new drug reviews, guidelines and proposals.
	  • 48 New Drug Reviews (NDRs)
	  • Clinical Guidelines
	  • 99 evidence-based medicine (EBM) updates
	  • 65 Quality assurance analyses resulting in guideline clarification and change in PA status
	  • 17 Clinical proposals
	  • Discuss progress related to MassHealth clinical initiatives.
	  • Pipeline monitoring and forecasting
	  • Opioid, Hepatitis C, Pediatric Behavioral Health Medication Initiative (PBHMI), Cystic Fibrosis and Synagis initiatives are ongoing
	  • Provide an overview of contributions of pharmacy practice residents and students on the DUR rotation.
	  • Resident poster at AMCP annual meeting
	  • Affiliated with nine schools of pharmacy
	  • Present an overview of disseminated work related to the MassHealth pharmacy program.
	  • Describe trends in clinical projects.
	  • 1,225 escalated clinical review cases
		<u>Follow Up</u>
		Informational

Action	**Conclusions:**
	• New for FY17 - July 1, 2016 to June 30, 2017
	  • Increased review of pharmacoeconomic information (e.g., ICER discussions/inclusion in project drafts)
	  • Budget impact modeling
	  • Long-range class impact project (e.g., NASH, gene therapy)
	  • Increased use of supplemental rebate
	  • New focused workgroups
	  • Compounding
	  • Oncology
	• Looking Forward
	  • Expansion of management and research:
	  • Opioid management
	  • PBHMI
	  • Hepatitis C
	  • Continued focus on dissemination
		<u>Conclusion</u>
		Informational

Agenda Item	Discussion	Conclusions/Follow Up
CAR-T Therapies in Oncology	**Discussion:** • Describe the mechanism of action of CAR-T therapies • Review Kymriah (tisagenlecleucel) and clinical data supporting its use for the treatment of acute lymphoblastic leukemia • Review Yescarta (axicabtagene ciloleucel) and clinical data supporting its use for the treatment of select non-Hodgkin lymphoma	**Follow Up** Informational Board members discussed the specific uses of CAR-T. Therapy will be given in select centers that follow defined protocols.

Action	**Conclusion/Recommendations:**
	• Looking Ahead
	  • DUR will continue to monitor the pipeline for the emergence of novel therapies (both oncology and non-oncology).
	  • In March 2017, Juno Therapeutics halted the development of its CAR-T after multiple patient deaths due to cerebral edemas.
	  • The trial was placed on hold once by the FDA and once voluntarily by the company.
	  • Anti-BCMA CAR-T cell therapy is being studied for the treatment of multiple myeloma.
	  • A first-in-class anti-Claudin18.2 CAR-T is being studied for the treatment of gastric and pancreatic cancers.
	  • Data should be emerging soon for human trials of CRISPR, a gene-editing approach that is being explored initially in cancer but could have potential in a host of gene-mediated diseases.
	  • Scientists are researching how to fine tune CAR-T therapies to avoid toxic side effects.
	• The U.S. government is considering setting new payment methods aimed at curbing costs for Medicare and Medicaid coverage of breakthrough medical treatments with very high prices, particularly novel gene-based therapies for cancer and other diseases, a top health official said on Thursday.
	• CMS does not negotiate prices or purchase drugs, but sets ground rules for the managed care companies and state Medicaid agencies that do.
		Conclusion
		Continue with monitoring as stated.

Agenda Item	Discussion	Conclusions/Follow Up
Pipeline Update	Pipeline Update Presentation	**Follow Up** Informational/Advisory

Action	**Discussion:**
	• Upadacitinib
	  • Proposed Indication: Treatment of moderate-to-severe AD in patients not adequately controlled with/intolerant to topical treatment
	  • Potential impact
	  • Approximately 14 million adults diagnosed with AD
		Conclusion
		Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
	• High-potency topical corticosteroids are SOC for moderate-to-severe AD • Upadacitinib 30 mg appears to have similar efficacy vs dupilumab* (no head-to-head data) • May be the first oral treatment for underlying cause of AD • Projected market entry • A specific timeline is not available • Ozanimod • Proposed Indication: Treatment of relapsing MS • Potential impact • Approximately 400,000 individuals with MS in US • Several disease-modifying agents available; agent selection individualized • Appears to have favorable safety profile vs fingolimod • Projected market entry • An NDA submission is expected by the end of 2017	

Agenda Item	Discussion	Conclusions/Follow Up
Hemophilia Clinical Update	**Discussion:** • Discuss background information on hemophilia and von Willebrand disease (VWD) as well as the various agents available for treatment. • Evaluate recent utilization and cost data for antihemophilic agents in MassHealth members. • Present an in-depth review of the PCC/FFS utilizers. • Discuss challenges with management of hemophilia. • Introduce newly approved agents and products in the pipeline. • Review recommendations to current MassHealth management.	**Follow Up** Informational Board members discussed that there are different types of hemophilia have separate treatments and some members may not be followed in treatment centers.
Action	**Conclusion/Recommendation:** • Continue to allow hemophilia agents to remain off prior authorization. • Re-assessing practice as new agents come to market. • Potentially implement yearly audit of pharmacy providers. • Utilize current practice of Alabama Medicaid as a reference.	**Conclusion** Proceed with recommendations as stated.

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Update	MassHealth Update	**Follow Up** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Action	**MassHealth Update** • Re-procure managed-care organization contracts. • Accountable-care organizations (ACO) ➢ Identified 18 contractors for ACO model ➢ Six ACOs are participating in pilot for direct contract with MassHealth ➢ Target date is March 1, 2018 ➢ Readiness review practice model o Transitions of care: 10 of thousands shifting form one model to another o Prioritization schedule to understanding new system **Pharmacy Program** • Budget ➢ High cost of medications • Regulations changes in process ➢ Dispensing fee on Medicaid Prescriptions is $10.02. New regulations proposed to reduce fee to $9.02 – on hold. ➢ CMS Waiver 1115 which is posted on the website has also made the news. Arizona has also submitted similar waiver. ▪ Create flexibility in formulary management • Abuse Deterrent Opioids ➢ Convening a workgroup to take a step forward to manage opioids in Massachusetts • Pediatric Behavioral Medication Initiative ➢ Working with foster care population and Department of Children and Families • Hepatitis C – new preferred products strategy identified • Contracting Strategies ➢ Seeking to be faster/more efficient ➢ Exploring outcomes based contracting ➢ Signed contracts for new preferred drugs that go into effect on January 1, 2018.	**<u>Conclusion</u>** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
MHDL Update	MassHealth Drug List (MHDL) Updates	**<u>Follow Up</u>** Informational/Advisory
Action	Discussed new drug additions and changes that will go into effect on January 8, 2018. • There will be eight new drugs added to the drug list and all will require PA. • Four drugs will be removed from the Brand Name Preferred to Over Generic list. • Five drugs will be added to the Brand Name Preferred Over Generic list. • One drug will be removed from the Over-the-Counter Drug list.	**Conclusion** Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
DUR Operational Update	Quarterly Operational Statistics	**Follow Up** Informational/Advisory

Action	• Prior Authorization (PA) Requests – average 7,500 per month
	• Call Volume – 7,500 calls per month, peak September 2016 with 8,092 calls
	• Abandonment rate about 1.5%
	• Average answered call wait time – 12 seconds
	• Overall call time for answered calls – 3 minutes and 52 seconds
	  ➢ Goal under four minutes
	• Pharmacy Edits
	  • Refill too soon was (40%)
	  • Prior authorization required (36%)
	  • DUR Reject Error (18%)
	  • CSMP Lock In (1%)
	• Appeals average 10 to 11 per month
	• Provider outreach
	  ➢ Average 8 to 10% of PA volume
	• Top 10 PA medications
	  ➢ Aripiprazole
	  ➢ Clonidine
	  ➢ Lyrica
	  ➢ Methylphenidate
	  ➢ Lantus
	  ➢ Harvoni
	  ➢ Oxycodone
	  ➢ Botox
	  ➢ Clindamycin
	  ➢ Risperidone
	• PA turn-around time during business hours
	  ➢ Statutory mandate is 24 hours
	  ➢ 60% done in six hours
	  ➢ 99.9 within 24 hours
	• PA turn-around time during non-business hours
	  ➢ 85% done in six hours
	  ➢ 99% within less than nine hours
		Conclusion
		Informational/Advisory

Agenda Item	Discussion	Conclusions/Follow Up
Alzheimer's Agents Quality Assurance Analysis	Presentation was deferred.	**Follow Up** N/A

Meeting adjourned at 8:00 PM.

Respectfully submitted by: Vincent Palumbo, Director of DUR

Date: _____