



PHARMACY AND THERAPEUTICS COMMITTEE

DATE: February 9, 2017
 LOCATION: Private Dining Room

CALLED TO ORDER: 7:00 A.M.
 ADJOURNED: 8:00 A.M.

Members Present:		Members Absent:	Guests:
Richard Pesce, M.D. David Dodson, M.D. Mark Anderson, MD Allen Atchley, M.D. Richard Yap, M.D. Helen Kuroki, MD Nathan Schatzman, M.D. Lee Hamilton, M.D.	Sandy Vredevelde, DPh Patrick Ellis, PharmD Lila Heet, PharmD Susan Fuchs, RD Karen Babb, PharmD	Nan Payne, RN Melissa Roden, RN Shannon Harris, RN Michael Stipanov, M.D. Nathan Chamberlain, M.D. Scott Harbaugh, Finance Avni Kapadia, M.D. Jeffrey Mullins, M.D. Jamie Barrie, PharmD Patty Hicks, RN	Shane Church, PharmD Meredith Tate, PharmD Justin Reinert, PharmD Jenny Gibson, PharmD Jonathan Cobb, Student

This meeting will be convened under the protection of the Tennessee Statute 63-6-219 and the Health Care Quality Improvement Act of 1986, Public Law 99-660. All information, case reviews, meeting minutes, statistics and correspondence are confidential and protected. Included in that protection are those that are involved in the review of the information. Any discussion of this information outside the realm of Peer Review constitutes a breach and violates the protection of the persons involved in the breach.

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Minutes	The October 13, 2016 minutes were approved as submitted.	Approved	Complete
CHI MUE Committee	<p>The following medications were reviewed:</p> <p>1. CHI MUE Committee Decision Brief: The medications that were reviewed at the October & November national MUE committee meeting were reviewed with the committee. The only two items that required local P&T review are the following:</p> <p>A. <u>Calcitonin injection restrictions:</u> Memorial has previously reviewed calcitonin utilization (April 2015 P&T) and educated prescribers on appropriate use and pharmacists screen all orders for appropriateness and communicate with prescribers regarding questionable orders. Memorial's current criteria for use are consistent with the national MUE criteria and no changes were recommended to the current process. Patrick will provide repeat education for the hospitalists at their next scheduled meeting.</p> <p>B. <u>Levalbuterol:</u> The national MUE has designated this medication as a formulary restricted medication that allows use in certain clinical scenarios although this has been non-formulary at Memorial for many years. Dr. Pesce recommended that this remain as a non-formulary medication at Memorial.</p>	<p>No change recommended</p> <p>Affirmed non-formulary status</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p>
Therapeutic Interchanges and Formulary Decisions	1. Tecentriq® (atezolizumab) – A new PDL-1 directed monoclonal antibody indicated for the treatment of urothelial carcinoma & NSCLC. Although this agent is similar to other formulary agents (Opdivo, Keytruda) it is the first of these agents to be approved for treatment of	Approved	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	<p>advanced/refractory urothelial cancer. It was recommended by Dr. Stipanov to approve this for outpatient infusion use only for the labeled indication or other insurance approved off label indications.</p> <p>2. Cetylev® (N-acetylcysteine) – New effervescent tablet formulation of NAC for acute APAP overdose. Pharmacokinetic (PK) data comparing this to traditional liquid/oral formulations of NAC has shown no clinically meaningful differences in any PK parameter. Patrick recommended that this be designated non-formulary and the oral/liquid formulation of NAC be substituted for any Cetylev orders due to a higher cost and lack of data demonstrating superiority for this new formulation.</p> <p>3. Relistor® (methylnaltrexone) oral formulation – New oral formation of existing sub-cutaneous formulary version of Relistor (peripheral acting mu-opioid receptor antagonist - PAMORA). Movantik® (naloxegol) is currently the only oral PAMORA on formulary. Although no head to head studies exist comparing oral Relistor to Movantik, the available data does suggest that the time of onset and efficacy of these two medications is very comparable and based on this information it was recommended to utilize and automatic therapeutic interchange in which all Relistor (oral) orders will be substituted to a therapeutically equivalent dose of Movantik.</p> <p>4. Ophthalmic Glaucoma Agents Class Review – A formulary interchange for the following classes of ophthalmic agents has been suggested by the national MUE committee: alpha agonists, beta blockers, carbonic anhydrase inhibitors. The clinical efficacy among these various agents are all similar in regard to their ability to lower IOP with the only difference being some minor differences in adverse effect profiles between products. Patrick stated that most of the patients on these medications are continuation of home therapies and a therapeutic interchange could be utilized and patients intolerable to the formulary agent(s) or who wish to stay on their home therapies could utilize their home supply per the formulary policy. It was recommended to designate the following products as the formulary agents for these classes with all other orders to be substituted to a therapeutically equivalent dose of the formulary agent: brimonidine 0.2%, timolol 0.25 & 0.5%, dorzolamide 2%. All other formulary medications would be designated as “non-formulary”. Patrick will work with our ophthalmologists that utilize apraclonidine for certain eye surgeries to ensure that this substitution will be appropriate for these indications before removing this agent from formulary.</p> <p>5. Blood factor products for inherited bleeding disorders – A review of the available clotting factors for both hemophilia and VWD were reviewed. Patrick discussed this review with Dr. Stipanov and he approved designating specific products as the formulary agents of choice for each clotting disorder. If a specific brand of clotting factor is requested the pharmacy will discuss with the provider the potential substitution to ensure this is appropriate for the ordered indication. The below process was discussed and approved by Dr. Stipanov. <u>Hemophilia A (Factor VIII)*</u></p> <ul style="list-style-type: none"> No specific product requested – Alphanate (human derived factor VIII) will be utilized 	<p>Non-formulary, therapeutic interchange approved</p> <p>Non-formulary, therapeutic interchange approved</p> <p>Therapeutic interchange approved</p> <p>Approved</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p>

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	<ul style="list-style-type: none"> • Recombinant product requested – Xyntha (recombinant factor VIII) will be utilized • Anti-inhibitor coagulant complex – FEIBA (human factors II, VII, IX, and X) <i>FEIBA will be ordered on an as needed basis for patients with hemophilia with inhibitors or in patients with acquired inhibitors to other clotting factors</i> <p><u>Hemophilia B (Factor IX)*</u></p> <ul style="list-style-type: none"> • No specific product requested – Bebulin (human derived factor IX) will be utilized • Recombinant product requested – Benefix (recombinant factor IX) will be utilized • Anti-inhibitor coagulant complex – FEIBA (factors II, VII, IX, and X) <i>FEIBA will be ordered on an as needed basis for patients with hemophilia with inhibitors or in patients with acquired inhibitors to other clotting factors</i> <p><u>Von Willebrand Disease (vWF)*</u></p> <ul style="list-style-type: none"> • No specific product requested – Humate-P (human derived vWF) will be utilized <p><i>*If a specific product is requested by name the prescriber will be contacted and the above product offered as a potential alternative</i></p> <p>6. Specialty Pharmacy Medications – Specialty pharmaceuticals are generally high cost maintenance medications for patients with rare and/or chronic diseases. The distribution system for these medications are typically dispensed as patient specific prescriptions direct to the patient from specialty pharmacy distributors. During a recent formulary review it was discovered that several “specialty” medications are currently on formulary without any restrictions for their use. It was recommended to designate these as “non-formulary, specialty” medications and for patients to utilize their own medications if these are home, maintenance medications. When these are ordered as new therapies it was recommended that the inpatient pharmacy along with case management and the medication patient assistance coordinator to navigate through the appropriate contracted specialty pharmacies to arrange for new medication orders to be filled as a direct to patient order when possible rather than these being ordered and dispensed directly from the inpatient pharmacy. This would help to ensure that the patient’s ongoing therapy is insurance approved and can be continued once discharged and eliminates the need for the hospital to assume the total cost of therapy for their brief inpatient stay. The following drugs were recommended for this new “non-formulary, specialty” designation: sorafenib, erlotinib, dasatinib, imatinib, sunitinib, thalidomide, temozolomide, etoposide oral, cyclophosphamide oral, capecitabine, macitentan, ambrisentan, bosentan.</p>	Approved	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Medication Safety	<ol style="list-style-type: none"> 1. Hypoglycemia Management – The hypoglycemia protocol has been updated to more accurately reflect current evidence based recommendations for treatment of hypoglycemia. The protocol was shared for informational purposes. Patrick also asked the committee if the protocol should automatically be available for ALL patients on oral or injectable hypoglycemic agents so the pharmacologic treatment options would be available on the EMAR if/when needed. Currently the hypoglycemia protocol is only attached to hospital protocols such as SQ correctional insulin protocols, insulin drip protocols, etc. The committee recommended that this would be a best practice and suggested that this recommendation be forwarded on to MEC for approval as a standing order for any applicable patient. 2. Hypertonic Saline – Dr. Hamilton shared with the committee a recent event in which a patient was incorrectly started on 3% NS based on an erroneous lab value. He questioned the committee regarding if this therapy should somehow be restricted in order to prevent future patient safety issues due to inappropriate utilization or lack of follow up laboratory values. The committee was unable to reach consensus on specific restriction criteria and it was recommended for pharmacy to develop (in collaboration with nephrology and Dr. Hamilton) appropriate use criteria that pharmacists can use to evaluate appropriateness when this therapy is ordered. Additionally, hospitalist education will be developed based on the use criteria that are to be developed. The appropriate use criteria will be reviewed at the April 2017 P&T meeting. In the interim Patrick agreed to prepare preliminary education on appropriate use to the pharmacy staff to utilize until the final use criteria is developed and approved. 3. Perioperative Medication Management – Dr. Schatzman discussed some recent literature that suggests that continuation of ACE/ARBs during the preoperative period can be correlated with both procedural hypotension and an increased risk of myocardial injury. After discussion, the committee supported Dr. Schatzman’s recommendation and approved the proposal to modify the existing <i>Pre-Anesthesia Orders</i> to include holding ACE/ARBs for 24 hours prior to surgery. Dr. Kuroki recommended that an educational document be prepared and distributed to the medical staff prior to roll out. Drs. Atchley and Schatzman agreed to work with Patrick on the development of this document for distribution to the full medical staff prior to roll out of this new process. 4. ADRs May to August 2016 – Karen reviewed the ADRs and noted that no ADRs for this time period would need to be reported to the FDA’s Medwatch program. No other significant trends were noted. 	<p>Information only – Recommendation to be forward to MEC for approval</p> <p>Usage criteria to be developed and reviewed at April meeting</p> <p>Approved – education document to be developed</p> <p>Information only</p>	<p>Pending</p> <p>Complete</p> <p>Pending</p> <p>Pending</p> <p>Complete</p>
Medication Use Evaluation	Pharmacy Discharge Service – Program Update: Patrick shared with the committee a recent change to the pharmacy process in an effort to increase the scope and the number of patients seen by pharmacists prior to discharge. The pharmacists will be collaborating with the discharge LPNs to review the final discharge medication orders for accuracy and counsel the patients prior to their discharge. Instead of focusing on only high LACE score patients the pharmacists will focus on ANY patients whose discharge is being prepared by the discharge LPNs. Preliminary findings have demonstrated higher	Information only	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	productivity for the pharmacists involved in this work and an ability to screen more patients prior to discharge. Patrick asked the committee for feedback as this work progresses so these efforts can best be utilized to have the greatest impact (high risk disease states, bundle patients, etc.).		
Policy & Procedure	Look-Alike, Sound-Alike Policy – Modifications to this policy were approved.	Approved	Complete
Protocols	IV Iron Replacement – max dose consideration Nicotine Replacement Protocol	Tabled to next meeting Tabled to next meeting	Pending Pending

There being no further business, the meeting was adjourned at 8:00 A.M. The next P&T meeting is **April 13, 2017 at 7:00 a.m.**

Respectfully submitted,
Sandy Vredevelde, D.Ph. Director of Pharmacy
Patrick Ellis, Pharm.D Pharmacy Clinical Coordinator

Approved by,
Richard Pesce, M.D. Chairman