



## PHARMACY AND THERAPEUTICS COMMITTEE

DATE: April 9, 2015  
 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. Nathan Chamberlain, M.D. Samuel Currin, M.D.	Karen Babb, PharmD Michelle Denham, RN Patrick Ellis, PharmD Lila Heet, PharmD Karen Regal, Supply Chain Rhonda Poulson, CNO Scott Harbaugh, Finance	Melissa Roden, RN Sandy Vredevel, DPh Hannah Walker, RN	Diona Brown, RN Rodney Elliott, PhT Matthew Russell, PharmD Megan Whittier, PharmD Nick Martin, Student Vickie Burger, Lab Brian Jones, RD Nan Payne, RN Shannon Harris, RN Kevin Lewis, M.D. William Oellerich, M.D. Michael Harper, M.D Allen Atchley, M.D Michael Stipanov, M.D. Mark Anderson, M.D

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
<b>Minutes</b>	The February 12, 2015 minutes were approved as submitted.		Complete
<b>Therapeutic Interchanges and Formulary Decisions</b>	<p>The following medications were reviewed:</p> <ol style="list-style-type: none"> <li>1. <b>Anti-fungal Class Review</b> – The CHI antifungal class review was reviewed. CHI will be completing medication class reviews for the purpose of standardizing formularies across the various CHI hospitals. The CHI antifungal review is the first of these reviews and it is largely consistent with the existing Memorial formulary. The only necessary change to formulary is to transition to the use of Ambisome instead of Abelcet due to a recent contracting change which results in Ambisome being the most cost effective lipid based amphotericin product available at this time. Dr. Anderson is aware of this formulary change and is agreeable to this formulary modification.</li> <li>2. <b>EpiPen (epinephrine auto-injector)</b> – The formulary status of EpiPen auto-injectors was discussed. Patrick recommended that these be removed from formulary now that a standardized anaphylaxis protocol is available for use throughout all clinical areas. The allergic reaction/anaphylaxis standing orders can be utilized in lieu of the use of EpiPen auto-injectors.</li> <li>3. <b>Endothelin Receptor Antagonist Class Review</b> – Oral agents approved for treatment of patients with pulmonary arterial hypertension. Due to the REMS requirements for each medication, patients must be enrolled in the REMS program specific to each medication and thus patients must be maintained on their home therapy and not switched to alternate therapies while hospitalized.</li> </ol>	<ol style="list-style-type: none"> <li>1. Approved</li> <li>2. Information</li> <li>3. Not approved for formulary addition</li> </ol>	<p>Complete</p> <p>Complete</p> <p>Complete</p>

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	<p>Due to the cost associated with these medications and their infrequent use it was recommended by Dr. Pesce for patients to utilize their own supply (dispensed by pharmacy) and for these to only be ordered in the event that a patient is not able to supply their own medications while hospitalized.</p> <p>4. <b>Zerbaxa® (ceftolozane/tazobactam)</b> – New cephalosporin/beta-lactamase inhibitor combination approved for the treatment of cUTI and intra-abdominal infections. The available in-vitro susceptibility data shows that this antimicrobial may prove beneficial for the niche treatment of certain MDR <i>Pseudomonas</i> infections. It was recommended to approve for formulary addition with restriction to ID physicians or proven cases of susceptibility in the setting of multi-drug resistance on a case by case basis per Antimicrobial Stewardship Team.</p> <p>5. <b>Avycaz® (ceftazidime/avibactam)</b> – New cephalosporin/beta-lactamase inhibitor combination. Although only limited clinical data is available for this medication it was approved via an accelerated FDA approval pathway due to its unique ability to provide coverage for certain MDR organisms. The addition of avibactam allows this antimicrobial to inhibit most broad spectrum beta-lactamase enzymes including most carbapenemases. It was recommended to approve for formulary addition with restriction to ID physicians or proven cases of susceptibility in the setting of multi-drug resistance on a case by case basis per Antimicrobial Stewardship Team.</p> <p>6. <b>Soliris® (eculizumab)</b> – Eculizumab is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. The cost of the drug is \$6,086.66 per each 300 mg vial. Due to the cost and the need for appropriate lab tests for accurate diagnosis the development of a protocol was discussed. All physicians were in agreement that an order set/protocol is needed to ensure that appropriate diagnosis is made and that necessary lab tests are expedited to assist in diagnosis of aHUS. Patrick agreed to develop a draft protocol and it will be reviewed with the committee members at the next meeting.</p> <p>7. <b>Toujeo® (U-300 insulin glargine)</b> – A concentrated 300 unit/ml formulation of insulin glargine (Lantus) only available in a pre-filled insulin pen. The Toujeo pen has been specially designed for Toujeo, therefore no dose conversion is required and it can be converted to Lantus or other long acting insulin as a 1:1 conversion. It has been recommended by CHI that all facilities designate this</p>	<p>4. Approved with restriction</p> <p>5. Approved with restrictions</p> <p>6. Protocol to be developed</p> <p>7. Formulary interchange approved</p>	<p>Complete</p> <p>Complete</p> <p>Pending</p> <p>Complete</p>

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	<p>product as non-formulary and substitute Levemir for Toujeo. Dr. Dodson agreed that due to a lack of clear clinical benefit and risk of errors associated with concentrated insulin products to automatically interchange Levemir on a unit to unit basis in the event that Toujeo is ordered.</p>		
<p><b>Medication Use Evaluation</b></p>	<ol style="list-style-type: none"> <li>1. <b>Miacalcin Injection (calcitonin-salmon)</b> Pricing of injectable calcitonin recently increased by an extremely large amount and a medication use evaluation was conducted to determine calcitonin usage trends to determine if opportunities to decrease use exist. The MUE highlighted the need for physician education on the recent price increase and to recommend bisphosphonates as 1<sup>st</sup> line agents for treatment of mild to moderate hypercalcemia. The use as a pain control measure for compression fracture was also discussed. Due to the price increase the committee felt that education is necessary to discourage this practice and to encourage the use of nasal calcitonin for this indication. Patrick will follow up and coordinate education.</li> <li>2. <b>Timing of Antibiotic Administration-Sepsis</b> – An evaluation of patients admitted to the ED with confirmed sepsis was conducted to evaluate the timing of antibiotic administration in relation to the recommendations from the <i>Surviving Sepsis Campaign</i> guidelines. The most recent guidelines also include a recommendation that IV antibiotic therapy should be started within the first hour of recognition of severe sepsis after initial cultures have been obtained. The sampling of data collected from patients in this review reveal that some opportunities for shortening the time to initial antibiotic administration do exist at both campuses. Overall (including both facilities), 78% of all patients received their first dose of any antibiotic greater than 60 minutes following their initial triage time. The initial antibiotic choice was also evaluated for appropriateness. In many situations the initial empiric antibiotic was appropriate based on the patient’s suspected source of infection, however some patients were prescribed therapies that may not have been optimal based on local resistance patterns, etc. Rhonda explained that electronic prescribing of first dose antibiotics in the ED might enable quicker administration of the first dose antibiotic and this would be explored for feasibility. It was also recommended to standardize the initial antibiotic choices to mirror the Sepsis Admission Orders to provide a higher likelihood that the most optimal first dose antibiotic is ordered based on the suspected site of infection. Patrick will f/u with Rhonda and assess potential opportunities.</li> <li>3. <b>Exparel Orthopedics Review</b> – Patrick reviewed a February memorandum from CHI Clinical Leadership Council that has “prohibited” Exparel in all procedures except for total knee replacements although details have yet to emerge on how this effects pre-existing use outside of knee surgeries. Patrick</li> </ol>	<ol style="list-style-type: none"> <li>1. Information</li> <li>2. Information</li> <li>3. Information</li> </ol>	<p>Pending</p> <p>Pending</p> <p>Pending</p>

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	also shared Memorial's data related to TKA procedures and this information will also be shared with the surgeons. Recent data suggests that conventional local anesthetics (ropivacaine) may offer similar results to Exparel.		
<b>Medication Safety/Quality</b>	<b>ADR Review</b> – Karen reviewed ADR data from July-December 2015. One category 3 ADR was discussed and this will be reported to the FDA Medwatch program. A continued trend of opioid related ADRs was observed and a multidisciplinary group is evaluating the use of opioids and this work will be presented at the next meeting.	Information	Complete
<b>Policy, Procedure &amp; Protocols</b>	<ul style="list-style-type: none"> <li>• <b>P&amp;T Policy</b> – Edits to the existing P&amp;T policy were presented. The content of the policy is largely unchanged but a few additions were made to conform to the standardized P&amp;T policy.</li> <li>• <b>Prescription Pad Security</b> – Melissa initiated some discussion regarding the need for improved security measures to prevent theft and inappropriate use of hospital prescription pads. No clear recommendations were made but further discussion will continue and also via other multidisciplinary committees.</li> </ul>	<p>Approved</p> <p>Information</p>	<p>Complete</p> <p>Pending</p>

There being no further business, the meeting was adjourned at 8:00 A.M. The next P&T meeting is June 25, 2015

Respectfully submitted,

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

Approved by,

Richard Pesce, M.D. Chairman