



PHARMACY AND THERAPEUTICS COMMITTEE

DATE: June 25, 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. Samuel Currin, M.D. Mark Anderson, MD Allen Atchley, M.D Michael Harper, M.D	Karen Babb, PharmD Patrick Ellis, PharmD Lila Heet, PharmD Rhonda Poulson, RN Vickie Burger, Lab	Sandy Vredeveld, DPh Hannah Walker, RN Brian Jones, RD	Diona Brown, RN William Oellerich, M.D. Shannon Harris, RN Michael Stipanov, M.D. Scott Harbaugh, Finance Michelle Denham, RN Karen Regal, Supply Chain
		Rodney Elliott, PhT Nan Payne, RN Kevin Lewis, M.D Melissa Roden, RN	Matthew Russell, PharmD Megan Whittier, PharmD Tatum Daniel, 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 April 9, 2015 minutes were approved as submitted.		Complete
Therapeutic Interchanges and Formulary Decisions	<p>The following medications were reviewed:</p> <ol style="list-style-type: none"> 1. Custodial HTK (cardioplegia) – An update was provided regarding the use of Custodial HTK as a cardioplegia solution (approved for trial use in minimally invasive cases October 2014). Per David Middleton use beyond the trial population will not occur and single dose blood cardioplegia will be trialed for all patients. Recommended to continue to allow restricted use per the October 2014 decision. 2. Class Review – Antitussives: The CHI antitussive class review was reviewed. To comply with CHI's suggested formulary the following modifications to formulary were recommended: removal of Tussionex, triple combination products, Delsym, hycodan. The updated formulary interchange table was reviewed. 3. Vitamins – class review: The CHI vitamins class review was reviewed. The CHI class review is largely consistent with our existing formulary. Due to low use the following drugs were recommended for removal from formulary: Vitamin A injection, Vitamin C injection, ergocalciferol drops, calcium carbonate liquid formulation. In addition, Patrick explained that due to a recent price increase of phytonadione tablets he recommended that the hospital stop using the tablet formulation and instead use a liquid formulation compounded by the inpatient pharmacy (1 mg/ml liquid). 4. Respiratory Formulary Interchange – Patrick reviewed an updated therapeutic interchange list to incorporate newer products that have been released to the market. The formulary drugs of choice remain unchanged and the newer agents will be substituted to a therapeutically equivalent dose of a 	<ol style="list-style-type: none"> 1. Information - current use reserved for trial use as previously approved. 2. Formulary interchange approved 3. Formulary interchange approved 4. Formulary interchange approved 	<p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p>

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	<p>comparable formulary agent.</p> <p>5. Corlanor® (ivabradine) – New heart rate lowering agent indicated for a specific subset of HF patients. Studies have demonstrated a reduction in HF readmissions but no mortality benefit has been shown in clinical trials. Dr. Atchley recommended that based on current data that patients on stable therapy should not have their therapy interrupted but at this point it has no obvious role for new starts in the hospital setting.</p> <p>6. Opdivo® (nivolumab) – Immune modulating monoclonal antibody indicated for the treatment of advanced melanoma and squamous NSCLC. Dr. Stipanov recommended that this be added to formulary for outpatient use due to its unique mechanism of action and the promising data that has demonstrated superior survival rates as compared to standard regimens for numerous oncology diagnoses.</p> <p>7. Dyloject® (diclofenac injectable) – Injectable formulation of diclofenac (NSAID). Data was reviewed which has failed to demonstrate any statistically significant difference in regard to pain control or safety as compared to ketorolac. It was recommended to not add this agent to formulary and to interchange a therapeutically equivalent dose of ketorolac when/if ordered.</p> <p>8. Soliris® (eculizumab) – The draft Soliris inpatient protocol was reviewed. Patrick also reviewed with Drs. Chamberlain and Stipanov and both approved of the content and formatting. The protocol would allow for a single dose to be administered if the appropriate clinical criteria (as outlined in the protocol) are met. Dr. Pesce recommended that the protocol be approved for use.</p> <p>9. Beriner® (C1 esterase inhibitor) – C1 esterase inhibitor indicated for treatment of acute attacks of hereditary angioedema and off label use for severe ACE inhibitor associated angioedema. It was requested by Dr. Schatzman to add this to formulary for patients presenting with severe ACE induced angioedema or hereditary angiodema since no other reliable therapies exist for patients with airway compromise. Patrick recommended that if approved to formulary to only carry 3 vials (1500 units) since this would approximate a 20 unit/kg dose for a non-obese patient. Dr. Pesce also recommended that this be added to formulary and to limit formulary as recommended by Patrick.</p> <p>10. Vitamin D analogues – formulary interchange – Due to low use Patrick recommended that only one of the vitamin D analogues remain on formulary (doxercalciferol, paracalcitol). Due to cost it was recommended to only utilize paracalcitol and therapeutically interchange all orders for doxercalciferol to a therapeutically equivalent dose of the formulary agent. It was also recommended to remove both of the injectable formulations of the vitamin D analogues from formulary due to very low use. Dr. Chamberlain support this approach to these medications.</p> <p>11. Symbyax – formulary interchange – Combination olanzapine + fluoxetine product. Due to low use it was recommended to allow a formulary interchange utilizing the individual drug components per the manufacturer recommendations for converting from individual components to the combination product.</p> <p>12. Ketamine infusion for pain control – Patrick explained a request from Dr. Bartlett (anesthesia) to</p>	<p>5. Not approved for formulary addition</p> <p>6. Approved formulary addition</p> <p>7. Not approved for formulary addition</p> <p>8. Protocol approved</p> <p>9. Approved for formulary addition</p> <p>10. Formulary interchange approved</p> <p>11. Formulary interchange approved</p> <p>12. Information – added to August agenda for further discussion</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Pending</p>

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	<p>evaluate the possibility of utilizing sub-anesthetic doses of ketamine for a small subset of post-operative patients (opioid tolerant spine patients, etc.). The committee felt that this was a reasonable request and further discussion will occur with a potential protocol to be discussed at the August meeting with input from anesthesia.</p>		
Medication Use Evaluation	<p>Narcan® (naloxone) – An evaluation of all inpatient use of naloxone was reviewed to assess usage trends and opioid safety opportunities. The evaluation examined the precipitating causes necessitating the need for opioid reversal to assess for potential trends and opportunities related to opioid prescribing practices. Patrick explained that the two most common specialties associated with highest naloxone usage were the hospitalists and orthopedic surgery – as expected to the high volume of patients seen by these specialties. Among the hospitalist managed patients IV hydromorphone use was the most commonly implicated medication requiring eventual reversal with naloxone. Despite doses of 0.5-1 mg in all cases there were still 9 patients receiving hydromorphone who required naloxone for opioid reversal. Patrick suggested adding hydromorphone to the hospitalist admission orders with an option for opioid naïve (0.2-0.4 mg) and non-opioid naïve (0.5-1 mg) dosing. Dr. Dodson agreed that this seemed like a reasonable approach to help improve safety of hydromorphone dosing. Among the orthopedic surgery patients no clear trends were observed with the exception of polypharmacy being the leading cause of over sedation among this population of patients. It was noted that after widespread adoption of intra-operative use of local anesthetic tissue infiltration, the use of naloxone among total joint replacement patients has dropped considerably. Patrick also updated the committee on multi-disciplinary work that is ongoing to add standardized sedation assessments to the existing pain management policies for all patients receiving opioids.</p>	<p>Information – Hospitalist order set to be edited to include hydromorphone</p>	<p>Complete</p>
Medication Safety/Quality	<ul style="list-style-type: none"> • ADR Review (Jan-April 2015): Karen reviewed ADR data for this time period. One category 2 ADR was discussed but the committee felt that this patient did not meet criteria for MedWatch reporting. No other trends were observed other than narcotics being a major contributor to inpatient ADRs which was part of the previous naloxone MUE discussion. • Buprenex® (buprenorphine): Patrick raised for discussion some safety concerns related to an increased trend in observed ADRs related to buprenorphine. Six ADRs have been reported over the past 6 months in patients receiving buprenorphine. All of these ADRs were in post-operative spine patients and equated to a 20% ADR rate among these patients (reactions included hallucinations, over-sedation, psychosis). Dr. Pesce and the other members of the committee felt that there was not an obvious therapeutic need for buprenorphine and due to the potency of this medication (buprenorphine 0.3 mg = morphine 10 mg) and longer duration of effect as compared to other injectable opioids that this should be removed from formulary due to safety concerns. 	<p>Information</p> <p>Approved for formulary removal</p>	<p>Complete</p> <p>Complete</p>
Policy, Procedure & Protocols	<p>Inpatient IV Iron Dosing Protocol: A new IV iron dosing protocol was presented that offers a new dosing strategy for ferric gluconate complex that would allow this to be used as an alternative to iron dextran for total body iron replenishment. The publication that evaluated this dosing approach was</p>	<p>Protocol approved</p>	<p>Complete</p>

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	reviewed and the committee recommended the approval of this new protocol and dosing approach.		
Nutrition Support Team	<ul style="list-style-type: none"> • Food and Drug Policy – Brian explained that this policy was up for periodic review and no significant changes were made to the content of this policy. Recommended for approval. • Chyle Diet – An updated standard chyle diet was presented for use in patients with chyle leaks. Brian explained that physicians can request modifications to this standard diet if they feel changes are clinically appropriate otherwise this diet would serve as the new standard. • Oral Nutrition Supplements Med Pass Program – Brian updated the committee on work that is ongoing to improve wound healing and overall nutritional status in patients by incorporating the use of formulary nutritional supplements to be used by all patients when oral medications are administered to patients instead of juice or other products. 		

There being no further business, the meeting was adjourned at 8:00 A.M. The next P&T meeting is **August 13, 2015 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