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PHARMACY AND THERAPEUTICS COMMITTEE

DATE: August 8, 2019 CALLED TO ORDER: 7:00 A.M.
LOCATION: Private Dining Room ADJOURNED: 8:01 A.M.

Members Present:		**Members Absent**:		**Guests**:
Nathan Schatzman, M.D	Patrick Ellis, PharmD	Nan Payne, RN	Karen Babb, PharmD	Bradley Proctor, PharmD
Chad Paxson, MD	Karen Babb, PharmD	Shannon Harris, RN	Michael Stipanov, M.D.	Kameron Blair, PharmD
Mark Anderson, MD	Daniel Marsh, PharmD	David Dodson, M.D	Vimal Ramjee, M.D	Matthew Green PharmD
Richard Yap, M.D.	Rhonda Hatfield, CNO	Scott Harbaugh, Finance		Casey O'Neal PharmD
Nathan Chamberlain, M.D	Susan Fuchs, RD	Jamie Barrie, PharmD		Juddy Ombara- student
F. Lee Hamilton, MD	Rodney Elliott	Allen Atchley, M.D.		Sarah Gentry- 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 May 2019 minutes were approved as submitted.	Approved	Complete
CHI System P&T Committee	**1. May & July Decision Briefs-** The medications that were reviewed at the May & July system P&T committees were reviewed. All new system formulary medications or changes were either consistent with existing Memorial formulary decisions or are described in the "Therapeutic Interchanges and Formulary Changes" section of the minutes below. The class reviews outlined below are CHI system P&T reviews completed for the intent of formulary standardization opportunities across the entire CHI system. **a. Estrogen Class -** The following medications were recommended for non-formulary status. Each of the medications are very low use (< 30 doses per year). i. Premarin vaginal cream: will be interchanged to estradiol cream ii. Menest (esterified estrogens): may use home supply **iii.** Estropipate: may use home supply **b. Rectal Products Class** - The following medications were recommended for non-formulary status. Both medications have zero recent utilization. **i.** Cortifoam rectal foam (hydrocortisone acetate 10% 15 gm aerosol can) ii. Epifoam rectal foam (hydrocortisone/pramoxine) c. **Constipation Medications** – Formulary restriction to be implemented with Epic go-live: i. Amitiza (lubiprostone) and Linzess (linaclotide): Restrict usage to continuation	Approved in entirety	Complete

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	of home medications only; no new starts during hospitalization. This will be accomplished by limiting these two medications to the "pharmacy" medication preference list only and removing from the "facility" preference list. **d. Miscellaneous Medications -** The following medications were recommended for non-formulary status. i. Co-enzyme Q-10 (ubiquinone) capsule: Coenzyme Q10 is no longer recommended for statin-associated muscle symptoms (SAMS). The ACC/AHA 2018 Guideline on the Management of Blood Cholesterol assigned a Class of Recommend of III (no benefit). Change to non-formulary status and classify as an herbal medication: do not continue during hospitalization if a home medication and new orders for coenzyme Q10 will not be verified. **ii.** Diclofenac potassium tablet: Change to non-formulary status and do not allow continuation of home medication. Recommend interchange to alternative oral NSAID if needed.		
Old Business	**1. ISMP 2018-2019 Best Practices- Injectable promethazine –** Rachel spoke with IV team leadership to discuss the potential for underreporting of tissue injury due to promethazine at our institution, as this is not a known issue currently. The IV team has not received any reports of tissue injury or extravasation due to promethazine. No changes to current practice are recommended at this time. **2. Alternatives to Opioids (ALTO) protocol for inpatient expansion –** The committee's discussion on inpatient expansion focused effective means for nursing education, patient location for monitoring, modification of the current ketamine low dose for pain policy, and incorporation into Epic. Rachel will work with Rhonda to ensure a robust nursing education plan is developed. No restrictions on inpatient location, although lidocaine infusion does require cardiac monitoring. The committee approved modification of the "Ketamine Low Dose (Sub-Anesthetic Dosing) For Pain" policy to remove all verbiage that currently restricts patient location and ordering provider for ketamine intermittent/IVP dosing and nasal administration. Ketamine IV infusion will maintain its restrictions to specific clinical areas and providers. Rachel will work with the Epic builders to learn how this protocol can be built.	Information only Update to be shared at next meeting	Complete Complete
Therapeutic Interchanges and Formulary Decisions	**1. Sodium zirconium cyclosilicate (Lokelma**) – Oral potassium binder for the initial and maintenance treatment of hyperkalemia in adults. Nine times greater potassium binding than SPS, but no head to head trials against any potassium binders. Efficacy studies (against placebo) demonstrated significant decreases in potassium from baseline to 48 hours. Dr. Chamberlain was supportive of adding a potassium binder to formulary. It was recommended to approve to formulary with the following restrictions: a. Management of severe hyperkalemia (K ≥ 6.0mEq/L). Not be used as monotherapy for emergent treatment of life-threatening hyperkalemia because of its delayed onset of	Approved	Complete

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	action. b. If patient intolerant to or failed therapy with SPS (Kayexalate) c. Continuation of home therapy d. Patients using Veltassa (patiromer) as a home medication may use their own supply during hospitalization. If home supply is unobtainable, the physician will be contacted to discuss an appropriate substitution to Lokelma, if indicated.		
	2. Digoxin immune Fab (Digifab) – Updated restriction criteria for use in patients with life-threatening or potentially life-threatening toxicity and lower dose guidelines were reviewed and approved. The new dosing calls for 1-2 vials of Digifab initially and if the patient is still symptomatic after 60 min, repeat the 40-80 mg (1-2 vials) dose, and sooner if patient is clinically unstable.	Changes approved	Complete
	3. Bevacizumab biosimilars – The committee reviewed the monograph for Mvasi (bevacizumab-awwb), a biosimilar for the reference product, Avastin. Mvasi has demonstrated similar clinical efficacy as Avastin and was approved for all indications as Avastin with the exception of ovarian, fallopian tube, or primary peritoneal cancers. Mvasi and other bevacizumab biosimilars, generally more cost-effective than the reference product, were approved to formulary for outpatient use for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Avastin will now have the following restrictions: If a bevacizumab biosimilar is not available or payer-approved, may be used outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. TN Oncology providers have reviewed and approved this recommendation. The Epic treatment regimen for Avastin will have the following order instructions added: "Pharmacy may substitute biosimilar product per P&T committee approved restriction criteria."	Approved	Complete
	4. Trastuzumab biosimilars – The committee reviewed the monograph for two trastuzumab biosimilars for the reference product, Herceptin. Kanjinti and Ogivri are among the first several biosimilars to be approved as therapy for HER2-positive metastatic breast cancer and have demonstrated that safety, efficacy, and clinical outcomes did not differ from the reference product. Kanjinti is currently available for purchase, but Ogivri is not yet available. Kanjinti and other trastuzumab biosimilars, generally more cost-effective than the reference product, were approved to formulary for outpatient use for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Herceptin will now have the following restrictions: If a trastuzumab biosimilar is not available or payer-approved, may be used outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. TN Oncology providers have reviewed and approved this recommendation. The Epic treatment regimen for Herceptin will have the following order instructions added: "Pharmacy may substitute biosimilar product per P&T committee approved restriction criteria."	Approved	Complete
	5. Pentamidine (Pentam) IV – Rachel presented recommendations for new order restriction criteria		

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	and set dosing guidelines for IV pentamidine. Pentamidine is an antifungal agent FDA approved for treatment of PJP. Off-label use includes prevention of PJP in non-HIV infected patients and for trypanosomiasis infection. IV pentamidine has severe adverse effects associated with its use, therefore a new ordering "panel" will be built in Epic (during optimization) which will include restriction criteria, nursing interventions, required labs, and medication orders including pentamidine 4 mg/kg (max 300 mg) IV along with supportive medications. Ordering will be limited to infectious disease physicians OR for use as an alternative agent to PO TMP-SMX for PJP prophylaxis in hematology/oncology patients. The restriction criteria and dosing guidelines can be implemented immediately. 6. **Prednisolone to methylprednisolone Formulary Interchange –** Due to low usage and higher cost compared to methylprednisolone, it was recommend to remove prednisolone oral products from formulary and interchange all orders for prednisolone to methylprednisolone tablets at a twenty percent dose reduction. Rachel reviewed the proposed therapeutic interchange. Methylprednisolone has slightly higher anti-inflammatory activity relative to hydrocortisone than prednisolone (5 to 4, respectively). This will provide a 98% cost savings per dose. 7. **Latanoprostene bunod (Vyzulta) to latanoprost (Xalatan) Formulary Interchange -** Latanoprostene bunod (Vyzulta) 0.024% ophthalmic solution is a new prostaglandin analog indicated for the reduction of intraocular pressure in patients with open angle glaucoma or ocular hypertension. It was recommended to add Vyzulta ophthalmic solution to the existing formulary interchange table for prostaglandin analogs and substitute all orders for Vyzulta to latanoprost ophthalmic solution (Xalatan) at the same dosage. 8. **Atomoxetine (Strattera) Formulary Removal –** It was recommended to remove atomoxetine (Straterra) from formulary due to low usage and lack of clinical need to decrease inventory costs. 9. **Potassium chloride oral product packet to effervescent tablet conversion –** Rachel reviewed the cost savings plan to convert the existing oral potassium packet products to an effervescent tablet. The major impact will be the electrolyte replacement protocol and there are no anticipated changes in efficacy.	Approved Approved Approved	Complete Complete Complete
Protocols and Orders	1. **Antibiotic Dosing for CRRT-** Rachel reviewed proposed antibiotic dosing guidelines for patients on CRRT. The Antimicrobial Stewardship Program subcommittee as well as Dr. Galphin previously reviewed and approved these guidelines. To ensure adequate antibiotic concentrations in patients on CRRT, it was recommended to adopt the guidelines for inclusion into the existing pharmacist renal dose adjustment protocol. The guidelines include loading, maintenance, and high dose options. All pharmacists will be educated on the appropriate use of the guidelines, but use will be primarily with the ICU pharmacists, and pharmacists will write orders for dose adjustments per P&T protocol. 2. **Alcohol Withdrawal Benzodiazepine "Light" Protocol Final Results –** Rachel reviewed the final results of the data collected comparing the use of the traditional alcohol withdrawal protocol to the	Approved Approved	Complete Complete

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	newly implemented benzodiazepine (BZD)-sparing protocol. Data was collected on 20 patients per protocol group. 75% of patients in the BZD-sparing protocol group received the gabapentin taper. The primary outcomes evaluated were total daily dose of lorazepam and average daily CIWA score. The total daily dose of lorazepam and average daily CIWA score was lower for all patient days in the benzodiazepine-sparing protocol treated patients. Length of stay was also lower at 7.7 vs 9.4 days. Secondary outcomes demonstrated less transfers to ICU, intubations, and most notably, lethargy/sedation (10% vs 65%) in the benzodiazepine-sparing protocol treated patients. The committee discussed retiring the traditional alcohol withdrawal protocol in light of the results of the BZD-sparing protocol, inclusion of required medications on the BZD-sparing protocol vs traditional, and prescribers' ability to order medications from the traditional protocol as individual meds outside of the order set, if required (e.g. lorazepam drips). The committee motioned to immediately retire the traditional order set and move forward in Meditech and Epic with only the BZD-sparing order set.		
Policy & Procedure	The below policy was reviewed as part of the ongoing policy review process: 1. **PRN Orders-** This policy was updated to remove non-formulary medications and correct spelling and grammatical errors. Because all of the medications included within this policy are built in Epic with a required PRN field that is defaulted to the listed indications, the committee approved to retire this policy when Epic is implemented in November.	Approved	Complete- policy will be retired in November

There being no further business, the meeting was adjourned at 8:01 A.M. The next P&T meeting is **October 10, 2019 at 7:00 a.m.**

Respectfully submitted,
Patrick Ellis, PharmD, Director of Pharmacy
Rachel Kile, PharmD, Pharmacy Clinical Manager

Approved by,
Nathan Schatzman, M.D., Chairman