CHI Memorial
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PHARMACY AND THERAPEUTICS COMMITTEE

DATE: May 12, 2022 CALLED TO ORDER: 7:00 a.m.
LOCATION: Private Dining Room ADJOURNED: 8:00 a.m.

Voting Member Attendance:				Non-Voting Member Attendance:		Guests:
X	**Nathan Chamberlain, MD- Chairman**	X	**Matthew Kodsi, MD- Quality**	X	**Karen Babb, PharmD- Manager**	**Tina Mathew, Pharmacy Resident**
	Mark Anderson, MD- Infectious Disease	X	**Aditya Mandawat, MD- Cardiology**		Jamie Barrie, PharmD- Manager, HX	**Doug Dertien, Pharmacy Resident**
X	**Justin Blinn, MD- Anesthesiology**	X	**Daniel Marsh, PharmD- Director of Pharmacy**	X	**Chris Chastain- Admin Coordinator**	**Jessica Duke, Pharmacy Resident**
X	**David Dodson, MD- Hospitalist**	X	**Chad Paxson, MD- Intensivist**		Kenneth Dyer, PharmD- Operations Manager	**Gabby Hall, Pharmacy Student**
	Karen Frank, RN- Quality		Vimal Ramjee, MD- Cardiology	X	**Rodney Elliott- Purchasing**	**Drew Smith, Pharmacy Student**
	Sherry Fusco, RN- CNO		James Wahl, MD- Hospitalist, GA	X	**Lori Hammon, RN- Quality**	
	F. Lee Hamilton, MD- Hospitalist	X	**Richard Yap, MD- Hospitalist**	X	**Shannon Harris, RN- Infection Prevention**	
	William Haren, MD- Psychiatry				Kevin Hopkins, RT- Director of Resp Therapy	
				X	**Rachel Kile, PharmD- Clinical Manager**	
				X	**Farrah Reidt- Clinical Nutrition**	
				X	**Carey Smith, RPh- Manager, GA**	

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 February 2022 minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	**March 2022 Decision Brief:** The medication decisions that were approved at the CommonSpirit Health System P&T committee meeting were reviewed. All new system formulary medications or changes were either consistent with existing CHI Memorial formulary decisions or are described in the "Formulary Decisions & Therapeutic Interchanges" section of the minutes below, or will be reviewed at an upcoming P&T committee meeting.	Approved	Complete
Old Business	**A. Sedatives-Hypnotics for Sleep Policy:** At the February meeting, Rhonda recommended a best practice review for sleep in hospitalized patients. Doug Dertien provided a summary of the available literature, which is unfortunately lacking, however there is support for limiting the use of zolpidem in patients 65 years and greater. Dr. Paxson recommended revisiting the use of other medications ordered for sleep/sedation, such as benzodiazepines. Dr. Kodsi asked if a stepwise algorithm for sleep medications would be helpful. A workgroup will meet to review with Dr. Paxson, and will be sure to include a member of Memorial's Fall Prevention Team. No policy changes will be made at this time.	Informational	Complete
Formulary Decisions & Therapeutic Interchanges	**A. Pneumococcal vaccines:** The ACIP and CDC released new pneumococcal vaccine recommendations in January in light of the two new pneumococcal immunizations (Prevnar 20 and Vaxneuvance) entering the market. Rachel reviewed the monograph for newly developed pneumococcal 20-valent conjugate (Prevnar 20) vaccine and it was recommended to be added to formulary with the following restrictions for use:	Approved	Complete

	a. Post-splenectomy with no pneumococcal vaccination history b. Patients 65 years and older or with underlying medical conditions or other risk factors who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown AND where continuation of care is not likely (e.g. homeless) The committee also reviewed and approved the following formulary statuses for additional pneumococcal vaccines: a. Pneumococcal conjugate vaccine 15 valent (Vaxneuvance): Non-formulary b. Pneumococcal conjugate vaccine 13 valent (Prevnar 13): Non-formulary c. Pneumococcal polysaccharide vaccine 23 valent (Pneumovax 23): Formulary, with restrictions to post-splenectomy patients who have already received Prevnar 13		
	B. Post-splenectomy vaccines: Rachel presented the updated Post-Splenectomy Vaccine Schedule and Post-Splenectomy Vaccine Guidelines for patients which reflect utilization of the pneumococcal 20-valent conjugate (Prevnar 20) vaccine as the initial pneumococcal vaccine (replacing Prevnar 13). The schedule was also updated to reflect the ACIP and CDC recommendations if the patient has already received prior pneumococcal vaccination.	Approved	Complete
	C. Bezlotoxumab (Zinplava): Bezlotoxumab is a human monoclonal antibody approved for the reduction of the recurrence of Clostridioides difficile infection (CDI). The 2021 Infectious Diseases Society of America (IDSA) update on the management of CDI suggests bezlotoxumab as an adjunctive treatment with standard of care antibiotics for patients with a recurrent CDI episode within the last 6 months. It is a single IV infusion and the safety and efficacy of repeat administrations have not been studied. Heart failure occurred more frequently with bezlotoxumab in clinical trials. Infusion-related reactions are also likely. It was recommended to adopt the recommendation of the ASP Subcommittee and approve bezlotoxumab to formulary with restrictions as follows: a. Restricted to outpatient infusion only (subsequent to insurance approval or prior authorization) for patients with any of the following risk factors: i. ≥ 65 years old ii. History of one or more CDI episode in the past 6 months iii. Immunocompromised status iv. ≥2 points on the Zar score for severity ▪ 1 point each is given for age >60 years; temperature >38.3°C; albumin level <2.5 mg/dL; WBC count >15,000 cells/mm3 ▪ 2 points are given for endoscopic evidence of pseudomembranous colitis; treatment in ICU v. Dose: 10mg/kg (max: 1,000 mg) x 1 dose during administration of active CDI treatment.	Approved	Complete

	vi. Adjunctive therapy to prevent recurrent CDI. Use caution in patients with underlying congestive heart failure (CHF).	Approved	Complete
	D. C. diff treatment guidelines: Linda Johnson reviewed the updates to the CDI Clinical Pathway/Treatment Guidelines. Updates include the addition of fidaxomicin for first or subsequent recurrences, non-fulminant; bezlotoxumab as adjunctive therapy for outpatient use; and considerations for fecal microbiota transplantation and secondary prophylaxis with oral vancomycin. Routine use of probiotics is discouraged.	Approved	Complete
	E. Cobicistat (Tybost): Linda presented the drug monograph for cobicistat. Cobicistat is a pharmacokinetic (PK) enhancer for certain protease inhibitors and non-nucleoside reverse transcriptase inhibitors. Ritonavir is also utilized as a PK enhancer and is on formulary, but there are important PK distinctions between the two agents. Significant issues can arise when switching from cobicistat to ritonavir in certain patients with multiple comorbidities and concomitant medications. It was recommended to approve cobicistat (Tybost) to formulary with restrictions as follows: a. Ordering or approval by Infectious Disease for new therapy initiation b. Any provider may order to continue a patient's established home medication	Approved	Complete
	F. Rifaximin (Xifaxan): Rachel presented the anticipated cost savings (~$68,000 annually based on historical utilization) by converting all doses of 550 mg to 600 mg utilizing three 200 mg tablets instead of one 550 mg tablet. It was recommended to designate the rifaximin (Xifaxan®) 550 mg tablet as non-formulary and approve an automatic therapeutic interchange to convert all doses of 550 mg to 600 mg.		
	G. Anifrolumab-fnia (Saphnelo): Jessica Duke presented this new drug monograph. Anifrolumab-fnia is the first type 1 interferon (IFN) antagonist monoclonal antibody approved for adults with moderate to severe systemic lupus erythematosus (SLE) already receiving standard therapy. There is an increased risk of respiratory infections, infusion-related reactions, and herpes zoster with this medication compared to placebo. Memorial Rheumatologists have requested access to this medication for a few patients already and will be informed of the formulary decision. It was recommended to approve to formulary with the following restriction(s): Outpatient setting subsequent to insurance approval or prior authorization for FDA approved indications or payer approved off-label indications.	Approved	Complete
	H. Pafolacianine (Cytalux): Pafolacianine is a folate analog conjugated to a near-infrared (NIR) fluorescent dye. It is a novel imaging agent that targets folate receptors, which may be overexpressed in ovarian cancer. Pafolacianine is an adjunct for intraoperative identification of malignant lesions in adult women with a diagnosis, or high clinical suspicion, of ovarian cancer. Pafolacianine assists optical imaging during surgery by absorbing light in the NIR region and emitting fluorescence. It is not included in the NCCN ovarian cancer guidelines. In a phase 3 trial, 26.9% of patients in the study had a confirmed ovarian cancer lesion detected, but the patient-level false-positive rate was 20.2%. Based on unknown and limited drug supply, need for a capital	Approved	Complete

	purchase of equipment, and limitations in current evidence, it was recommended that pafolacianine should not be added to the formulary at this time and the formulary status may be revisited once the supply chain issues are addressed.		
	I. Olanzapine/samidorphan (Lybalvi) to olanzapine-Therapeutic interchange: Olanzapine/samidorphan is the only second generation (atypical) antipsychotic and opioid antagonist combination medication, and was formulated specifically to decrease weight gain associated with olanzapine monotherapy. It is approved for the treatment of adults with schizophrenia and bipolar I disorder. Olanzapine/samidorphan is contraindicated in patients taking opioids or those who are undergoing acute opioid withdrawal. A seven day course of Lybalvi is $267.12, and a 7 day course of the highest dose of olanzapine (20 mg) is $5.36. Based on the specialized place in therapy, lower cost treatment options with similar efficacy, and contraindications with opioids, it was recommended to classify olanzapine/samidorphan as non-formulary. An automatic therapeutic interchange from olanzapine/samidorphan to the corresponding olanzapine monotherapy dose was also recommended.	Approved	Complete
	J. Erythropoietin stimulating agents: Recently, the manufacturer of Retacrit communicated an expected supply disruption of Retacrit. It was recommended to temporarily add Epogen and Procrit to formulary for use only when Retacrit is unavailable or the required dose cannot be made with the on-hand vial size(s) of Retacrit. An automatic pharmacist therapeutic interchange from Retacrit to Epogen or Procrit, based on product availability, was recommended while Retacrit is in short supply.	Approved	Complete
	K. Azelastine hydrochloride nasal spray: Azelastine nasal spray is currently a non-formulary medication, but the patient may use their own home supply, if available. Due to the workflow burden on staff and unlikely clinical significance of holding this medication for the duration of a hospitalization, It is recommended to designate azelastine nasal spray as non-formulary and will not be continued during hospitalization. New medication orders will be rejected at pharmacist order verification.	Approved	Complete
	L. Medications for COVID-19: Rachel reviewed the updates to the Medications for COVID-19 guidelines approved by the COVID medications subcommittee. It was recommended to add nirmatrelvir and ritonavir (Paxlovid) to formulary with restrictions for use; update the 3 day remdesivir course use criteria (for Incidental COVID+ (symptomatic) while admitted for non-COVID diagnosis); and updated the sotrovimab use criteria (note Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant). Bebtelovimab was also added to formulary with restriction criteria.	Approved	Complete

Medication Use	**A. Collagenase ointment (Santyl):** Tina Mathew, pharmacy resident, presented the results of her medication use evaluation. She concluded that implementation of restriction criteria for prescribing and dispensing unit doses of Santyl was a cost-effective choice for our institution and the practices will be continued. **B. Angiotensin II (Giapreza):** Jessica Duke, pharmacy resident, presented the results of her medication use evaluation. The results demonstrated that out of 12 included patients over 19 months, there was high prescriber adherence to restriction criteria for use, however in-hospital mortality was 100% and there was suboptimal nursing titration of the medication. Medication administration instructions in the EHR have been revised to further limit titration errors, and additional EHR enhancements are planned to ensure optimal administration and monitoring is achieved. Angiotensin II will remain on formulary and a subsequent MUE will be performed following the implemented changes.	Approved Approved	Complete Complete
Policies	**A. Hypertonic Saline (Sodium Chloride) for Adults:** Policy changes to reflect updates in alignment with development of the Hyperosmolar Therapy Order set were reviewed.	Approved	Complete

There being no further business, the meeting was adjourned at 8:00 a.m. The next P&T meeting is **August 11, 2022 @ 7:00 a.m.**

Respectfully submitted,
Daniel Marsh, Director of Pharmacy; Rachel Kile, PharmD, Pharmacy Clinical Manager

Approved by,
Nathan Chamberlain, MD, Chairman