Pharmacy & Therapeutics Committee Meeting

SCN Board Room + Zoom

September 14, 2023 7:00 a.m.

Next Meeting Date: November 9, 2023 at 7:00 a.m.

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CHI Memorial Hospital Georgia

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: June 15, 2023
LOCATION: Zoom

CALLED TO ORDER: 7:00 a.m.
ADJOURNED: 7:39 a.m.

Voting Member Attendance:				Non-Voting Member Attendance:		Guests:
X	**Nathan Chamberlain, MD- Chairman**		Matthew Kodsi, MD- Quality	X	**Karen Babb, PharmD- Manager**	**Joseph Oh, Pharmacy Resident**
X	**Mark Anderson, MD- Infectious Disease**	X	**Aditya Mandawat, MD- Cardiology**		Jamie Barrie, PharmD- Manager, HX	**Jordan Tynes, Pharmacy Resident**
X	**Justin Blinn, MD- Anesthesiology**	X	**Daniel Marsh, PharmD- Director of Pharmacy**	X	**Kenneth Dyer, PharmD- Operations Manager**	**Chris D'Amico, Pharmacy Resident**
X	**David Dodson, MD- Hospitalist**		Chad Paxson, MD- Intensivist	X	**Rodney Elliott- Purchasing**	**Hallie Butler, Pharmacy Resident**
X	**Karen Frank, RN- Quality**		James Wahl, MD- Hospitalist, GA		Lori Hammon, RN- Quality	
	Sherry Fusco, RN- CNO		Richard Yap, MD- Hospitalist	X	**Shannon Harris, RN- Infection Prevention**	
	F. Lee Hamilton, MD- Hospitalist			X	**Kevin Hopkins, RT- Director of Resp Therapy**	
	William Haren, MD- Psychiatry				Rachel Kile, PharmD- Clinical Manager	
				X	**Carey Smith, RPh- Manager, GA**	
					Ingrid Wright, Clinical Dietician	

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 March minutes were approved as submitted.	Approved	Complete
Old Business	A. **CommonSpirit Health P&T Committee Decision Brief:** teclistamab-cqyv (Tecvalyi) is a monoclonal antibody used for patients with multiple myeloma. It was moved from non-formulary status to restricted formulary in May 2023 to the outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Tecvalyi still lacks a specific reimbursement J-code (anticipated summer 2023). The EHR design/build for Tecvalyi is being coordinated to assist sites that may need to use this therapy for appropriate individuals. This is an ongoing process at our facility. The current local process has Tennessee Oncology administer Tecvalyi in their office followed by admission to CHI Memorial Hospital for monitoring of possible neurologic and cytokine release syndrome toxicities.	Informational	Complete
	B. System P&T also approved levetiracetam doses up to 1.5 gm should be administered as IV push. Currently Memorial gives doses up to 1 gm IV push. Will work to allow doses of up to 1.5 gm to be given as IV push. Approved by the local committee.	Informational	Complete
	C. System P&T shared new Controlled Substance Management policies. These will be reviewed and adopted by the local diversion committee.	Informational	Complete

Formulary Decisions & Therapeutic Interchanges	A. **Vibegron (Gemtesa):** Vibegron selectively activates the B3 adrenergic receptor within the bladder to relax th detrusor smooth muscle and increase bladder capacity. It is the second B3 agonist to be approved for the indication of overactive bladder with symptoms of urinary incontinence, urgency, and urinary frequency in adults. Vibegron obtained FDA approval in 2020 based on: ● EMPOWUR trial demonstrated significant reduces in micturitions, urgency episodes and urge incontinence while increasing volume per micturition when compared to placebo Mirabegron is currently on CHI Memorial and Commonspirit Health formulary. No head-to-head trials have been conducted to assess the differences of safety and efficacy of vibegron and mirabegron. However, study results demonstrate with vibegron: ● A lower risk of drug interactions ● Lower incidence rates of increased blood pressure ● A quicker onset of efficacy At the time of this review, vibegron is more expensive than the tablet formulation of mirabegron. It is recommended to adopt the CommonSpirit Health system P&T committee decisions to formulary decisions below including an automatic pharmacist or EHR therapeutic interchange of vibegron 75 mg PO daily to mirabegron 25 mg PO daily. ● Formulary, restricted Mirabegron to patients who are unable to take antimuscarinic agents and/or continuation from home ● Non-formulary: Vibegron	Approved	Complete
	B. **Drug shortage update [Solu-cortef (hydrocortisone)]**: Solu-cortef is currently a critical shortage item due to manufacturing delays. Unfortunately a potential alternative, Solu-medrol, is also in shortage for most formulations. The pharmacy was able to procure Solu-medrol 1 gram vials from which we are drawing up 40 mg syringes. Solu-medrol can be used as an alternative to Solu-cortef, but lacks mineralocorticoid activity (does not provide benefits for blood pressure support in adrenal insufficiency and septic shock patients). A new LMA displays when a provider attempts to order Solu-cortef: ● Hydrocortisone 100 mg (IV/PO) = methylPREDNISolone 20 mg + fludrocortisone 0.2 mg It is recommended to formulary approve the pharmacist automatic interchange for orders of Solu-medrol 125 mg to Solu-medrol 120 mg in order to utilize three of the compounded 40 mg syringes while the 125 mg vials are unavailable during the current shortage.	Approved	Complete
	C. **Electrolyte Replacement Guidelines (Potassium Update):** the current guideline states that if a potassium level is less than or equal to 2.9, replacement can only be accomplished using IV replacement, unless IV access is not available. Every 10 mEq of IV potassium replacement requires a 1 hour infusion time and 50-100 mL of fluids. To replace 80 mEq of potassium per the protocol for K < 2.9, a total infusion of 8 hours and 400-800 mL of fluid would be needed. To minimize fluid overload and reduce the time to achieve normalized potassium levels, it is proposed to allow for utilization of a hybrid of both oral or per tube replacement and IV replacement if the patient is able. The proposed verbiage on the order set for potassium	Approved	Complete

	level of 2.9 or less would read as: • Patients with no IV access: 80 mEq oral potassium • Patients with IV access and able to take PO: 40 mEq oral potassium, followed by 40 mEq IV potassium • Patients unable to take PO: 80 mEq IV potassium P&T committee approves the above recommendation. There was discussion on addressing other areas of improvement on the electrolyte protocol, specifically on how the orders are worded to have the most direct pathway for nurses to use when conducting electrolyte protocol order. The phosphate order pieces related to potassium have not been altered as part of this recommendation.		
Pharmacy Resident Research	A. **Evaluation of weight-based vs fixed dosing of Kcentra in management of DOAC associated bleeding**: This retrospective study demonstrated no statistically significant difference in achieving hemostasis between the two dosing strategies while allowing for a decreased average dose per patient by nearly 1500 units. Utilizing the fix-dosing of Kcentra is a more cost effective alternative, allowing for a cost savings of over $60,000 when comparing study periods. There are currently no modifications to the CHI Memorial Antithrombotic Reversal and Surgical Management Guidelines recommended.	Informational	Complete
	B. **Impact of pharmacy-led beta-lactam allergy clarification and delabeling**: The antimicrobial stewardship team approved of a beta-lactam allergy guideline to assist clinicians in prescribing antibiotics for inpatients with reported allergic reactions to penicillin or cephalosporin antibiotics. Resources available include a patient allergy assessment tool questionnaire, allergic reaction risk category chart, cross-reactivity matrix, and test dosing procedures (PO and IV). This retrospective study resulted in 167 pharmacy interventions in January 2023 and showed there are substantial opportunities for delabeling with approximately 40% of patients' allergies being categorized as either minimal or low-risk reactions. 72% of patients had their reaction occur >10 years ago. Lastly, 43% of patients had a previous beta-lactam prescription in the last year, further reinforcing the ability for these patients to be capable of utilizing a beta-lactam or penicillin in their therapy to optimize care.	Informational	Complete
	C. **Impact of pharmacist intervention on discharge antibiotic therapy for community acquired pneumonia (CAP)**: It has been shown increasing total antibiotic duration beyond 5 days in clinically stable patients with CAP has no benefit. A pharmacist driven initiative was implemented to target patients with a diagnosis of CAP. Ultimately, implementation of this initiative, particularly at the point of discharge, decreased both total duration of antibiotics and discharge duration of antibiotics by one day. All interventions related to duration of therapy and 100% of those interventions were accepted.	Informational	Complete

There being no further business, the meeting was adjourned at 7:39 a.m. The next P&T meeting is **August/September with a specific date TBD**.

Respectfully submitted,
Daniel Marsh, Director of Pharmacy

Approved by,
Nathan Chamberlain, MD, Chairman

CSH SYSTEM PHARMACY AND THERAPEUTICS COUNCIL DECISION BRIEF

July 2023 Decisions

NOTE: Local/divisional P&T committees may implement more restrictive statuses

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
ublituximab-xiiy	Treatment of relapsing Multiple Sclerosis		BRIUMVI		Restrictions: Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
fecal microbiota spores, live-brpk (oral)	Prevention of recurrent *Clostridioides difficile* infection			VOWST		Within 60 days of System P&T Committee approval
fecal microbiota, live-jslm (rectal)	Prevention of recurrent *Clostridioides difficile* infection		REBYOTA		Restrictions: Outpatient setting subsequent to payer approval for the FDA-approved indication of prevention of recurrence of CDI 48-72 hours after completing a standard course of antibiotic treatment	Within 90 days of System P&T Committee approval
lenacapavir sodium	Treatment of human immunodeficiency virus type 1		SUNLENCA		Restrictions: Ambulatory clinic setting • Initiation of therapy is restricted to ID/HIV specialist or other provider with experience in HIV management • Administer at an appropriate injection setting by medical professional (local site to determine site based on community HIV resources) • Not to be initiated in the inpatient setting	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
brexpiprazole	Treatment of agitation associated with dementia due to Alzheimer's Disease		REXULTI		Restrictions: Agitation associated with dementia due to Alzheimer's disease (AD) that has not responded to interventions with less risk (e.g. pain management or behavioral interventions) or continuation of home therapy for AD indication. EHR/HOS recommendation: Employ order questions to ensure used for dementia due to Alzheimer's disease	Within 90 days of System P&T Committee approval
omaveloxolone	Treatment of Friedreich ataxia in adults and adolescents ≥16 years of age			SKYCLARYS		Within 60 days of System P&T Committee approval
trofinetide	Treatment of Rett syndrome in adults and peds >/=2			DAYBUE		Within 60 days of System P&T Committee approval
felbamate tablets	Treatment of seizures	FELBATOL, FELBAMATE			EHR/HOS recommendation to include: Tablets may be crushed and administered via feeding tube	Within 90 days of System P&T Committee approval
rasburicase	To prevent hyperuricemia	ELITEK 1.5mg injection			EHR/HOS recommendation to include: standardization of order sets and EHR orders to reflect system approved dosing Link to rasburicase standard	Within 90 days of System P&T Committee approval
				ELITEK 7.5mg injection		Within 60 days of System P&T Committee approval
antitussive - multi AHFS class review	To prevent or relieve a cough	dextromethorphan polistirex, DELSYM				Within 90 days of System P&T

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
						Committee approval
			GUAIFENESIN-CODEINE		Restricted to use in adults	Within 90 days of System P&T Committee approval
				promethazine/phenylephrine HCl/codeine, PROMETHAZINE VC-CODEINE	Link to therapeutic interchange	Within 90 days of System P&T Committee approval
				PROMETHAZINE-CODEINE	Link to therapeutic interchange	Within 90 days of System P&T Committee approval
		Link to all antitussive class data				
skin and mucus membranes topicals - multi AHFS class review	Miscellaneous indications	CLINDAMYCIN 2% CREAM				Within 90 days of System P&T Committee approval
	Miscellaneous indications	GENTAMICIN 0.1% OINTMENT				Within 90 days of System P&T Committee approval
	Miscellaneous indications	MICONAZOLE 2% TOPICAL POWDER, CREAM, OINTMENT				Within 90 days of System P&T Committee approval
	Miscellaneous indications	UREA 20%, 40% CREAM				Within 90 days of System P&T Committee approval
		Link to skin and mucous membrane antimicrobial topicals class data Link to skin and mucous membrane non-antimicrobial class data (no changes)				

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
multi AHFS class review **ENZYMES** **DEVICES** **DISINFECTANTS FOR NON-DERMATOLOGIC USE** **ELECTROLYTIC, CALORIC AND WATER BALANCE** **AUTONOMIC MEDICATIONS** **SMOOTH MUSCLE RELAXANTS**	Multiple uses	No formulary changes - Link to full data				Within 60 days of System P&T Committee approval
bevacizumab-maly	To treat age related macular degeneration and multiple cancers		ALYMSYS		Almysys is the preferred bevacizumab biosimilar Restrictions • Outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization (Reference product should only be used if a biosimilar is not payor approved) Link to biosimilar preferred products	Within 90 days of System P&T Committee approval
bevacizumab - bvzr	To treat age related macular degeneration and multiple cancers		ZIRABEV		Zirabev is the secondary bevacizumab biosimilar Restrictions • Outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization (Reference product should only be used if a biosimilar is not payor	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
					approved) Link to biosimilar preferred products	
ritonavir-boosted nirmatrelvir	COVID-19 treatment		PAXLOVID		Restrictions: • Inpatient - treatment of COVID-19 positive patients • Outpatient – unrestricted use	Within 90 days of System P&T Committee approval
remdesivir	COVID-19 treatment		VEKLURY		Restrictions: • Inpatient - treatment of COVID-19 positive patients • Outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization	Within 90 days of System P&T Committee approval
baricitinib	COVID-19 treatment		OLUMIANT		Restrictions: • Treatment of COVID-19 positive patients (non COVID-19 indications are non-formulary)	Within 90 days of System P&T Committee approval
tocilizumab	COVID-19 treatment		ACTEMRA		Restrictions: • Inpatient - Treatment of COVID-19 positive patients (non COVID-19 inpatient use is non-formulary) • Outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization	Within 90 days of System P&T Committee approval
sarilumab	COVID-19 treatment		KEVZARA		Restrictions: • Inpatient - Treatment of COVID-19 positive patients (non COVID-19 inpatient use is non-formulary) • Outpatient setting for FDA-approved indications or payor-approved off-label indications	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
					subsequent to insurance approval or prior authorization	
tofacitinib	COVID-19 treatment		XELJANZ		Restrictions: • Inpatient - Treatment of COVID-19 positive patients (non COVID-19 inpatient use is non-formulary) • Outpatient setting for FDA-approved indications or payor-approved off-label indications	Within 90 days of System P&T Committee approval
bamlanivimab - etesevimab	Antiviral monoclonal antibody			bamlanivimab - etesevimab		Within 90 days of System P&T Committee approval
bamlanivimab	Antiviral monoclonal antibody			bamlanivimab		Within 90 days of System P&T Committee approval
casirivimab 600mg plus imdevimab 600mg	Antiviral monoclonal antibody			REGEN COV		Within 90 days of System P&T Committee approval
etesevimab	Antiviral monoclonal antibody			etesevimab		Within 90 days of System P&T Committee approval

THERAPEUTIC INTERCHANGES

Antitussives	
Ordered	**Provided**
Promethazine 6.25 mg-codeine 10 mg/5 mL syrup	Dextromethorphan-guaifenesin 10 mg-100 mg/5 mL oral syrup at same frequency
Promethazine VC-Codeine or generic 6.25 mg-5 mg-10 mg/5 mL oral syrup	Dextromethorphan-guaifenesin 10 mg-100 mg/5 mL oral syrup at same frequency

Preferred biosimilars

	Bevacizumab	Rituximab	Infliximab	Trastuzumab	Pegfilgrastim	Filgrastim/Tbo-filgrastim
Preferred biosimilar	Alymsys (preferred) Zirabev (secondary)	Truxima	Renflexis	Ogivri	Fulphila	Nivestym Granix
Non-preferred biosimilars	Mvasi	Ruxience Riabni	Inflectra Avsola	Kanjinti Trazimera	Udenyca Ziextenzo	Zarxio

Indication Comparison for New Formulary Biosimilars

Per the CHI Memorial Biosimilar policy, new biosimilars that have been FDA approved for the same indications as the reference product (RP) will be automatically added to hospital formulary if the RP is currently approved as a formulary agent.

Any formulary restrictions currently in place for the RP will be applied to the biosimilar medication.

Alymsys (bevacizumab-maly) 4/2022 Package Insert	**Avastin (bevacizumab) 9/2022 Package Insert**
Alymsys is a vascular endothelial growth factor inhibitor indicated for the treatment of: ● Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. ● Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. ○ Limitations of Use: Alymsys is not indicated for adjuvant treatment of colon cancer. ● Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment. ● Recurrent glioblastoma in adults. ● Metastatic renal cell carcinoma in combination with interferon alfa. ● Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan. ● Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens	**Avastin** is a vascular endothelial growth factor inhibitor indicated for the treatment of: ● Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. ● Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. ○ Limitations of Use: Avastin is not indicated for adjuvant treatment of colon cancer. ● Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment. ● Recurrent glioblastoma in adults. ● Metastatic renal cell carcinoma in combination with interferon alfa. ● Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan. ● Epithelial ovarian, fallopian tube, or primary peritoneal cancer: ○ in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, for stage III or IV disease following initial surgical resection ○ in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant

	recurrent disease who received no more than 2 prior chemotherapy regimens ○ in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Avastin as a single agent, for platinum-sensitive recurrent disease ● Hepatocellular Carcinoma (HCC) ○ in combination with atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy

DRUG SHORTAGE MANAGEMENT

BACKGROUND/RATIONALE:

The medications included in this summary are currently experiencing, or have recently experienced, a critical drug shortage and require Pharmacy & Therapeutics Committee review.

MEDICATION #1: Nystatin powder 15 gm bottles

Summary: Nystatin powder is currently a critical shortage item. On September 8, 2023 the P&T Committee chairman, CMO, and Hospitalist Medical Director emergently approved the automatic interchange by pharmacists of nystatin to miconazole powder at the same dosing frequency.

Recommendation: It is recommended to formally approve the pharmacist emergent automatic interchange for orders of nystatin powder to miconazole powder during times of nystatin powder shortage.

Medications for COVID-19: September 2023 Update

Emergency Use Authorization (EUA) Medications		
	Current Process	**Recommended Action**
Tocilizumab (Actemra)	Pharmacist automatic therapeutic interchange to either product based on product availability	Maintain current process
Baricitinib (Olumiant)		
Bamlanivimab/etesevimab	Federal government (HHS) manages supply and determines which product will be shipped to each state. State of TN then allocates mAb to select sites. Use of agent determined by activity against current variant(s) of concern (VOC).	Maintain current process
Casirivimab/imdevimab (Regen-COV)		
Sotrovimab		
Bebtelovimab		
Nirmatrelvir and ritonavir (Paxlovid)*	Formulary (stocked by retail pharmacy) Allow continuation of the patient's own home supply upon hospital admission, if ordered to continue by the admitting physician. Federal government (HHS) manages supply and determines which product will be shipped to each state. State of TN then allocates products to select sites.	Maintain current process
Molnupiravir	Non-formulary. Federal government (HHS) manages supply and determines which product will be shipped to each state. State of TN then allocates products to select sites.	Maintain non-formulary status

*Per the PAXLOVID fact sheet: “Should a patient require hospitalization due to severe or critical COVID-19 after starting treatment with PAXLOVID, the patient should complete the full 5-day treatment course per the healthcare provider’s discretion.”

COVID-19 Vaccines		
	Current Process	**Recommended Action**
Pfizer-BioNTech COVID-19 Vaccine	Non-formulary	Maintain current process
Pfizer-BioNTech COVID-19 Bivalent BOOSTER Vaccine	Non-formulary	Maintain current process
Moderna COVID-19 Vaccine	Non-formulary	Maintain current process
Janssen (J&J) COVID-19 Vaccine	Non-formulary	Maintain current process

Use/Restriction Criteria Approved by COVID-19 Medications Subcommittee

Remdesivir Criteria: Inpatients (updated 2/1/22)**:** 5 (FIVE) day course of IV remdesivir (200 mg IV x 1 dose, followed by 100 mg IV daily x 4 days) or until hospital discharge, whichever comes first.

Inclusion criteria:

- COVID-19 (+)
- ≤5 days since symptom onset or positive test (whichever comes first)

Exclusion criteria:

- No greater than 5L of supplemental oxygen to maintain an O2 Sat of 92%
- ALT > 5x ULN
- If the provider determines the patient has end stage comorbidities, it is reasonable to withhold remdesivir and the palliative care screening tool is available to assist with decision making regarding therapy initiation.

~~-Renal function must be tested prior to starting remdesivir. Remdesivir should be used with caution in patients with an eGFR <30 mL/min (dose has not been studied & the infusion may cause further injury)~~

-If patient does not meet the specified criteria but you feel your patient may benefit from remdesivir, ID approval must be obtained.

Ritonavir-boosted nirmatrelvir (Paxlovid) Criteria: Inpatients (updated 2/9/23)**:**

Inclusion criteria:

- Diagnosis of COVID-19 with mild to moderate symptoms
- <= 5 (FIVE) days since symptom onset or positive test (whichever comes first)
- High risk of progressing to severe COVID-19

Exclusion criteria:

- Hospitalized due to COVID-19
- eGFR < 30mL/min (dosage adjustment required for eGFR < 60mL/min)
- Severe Hepatic Impairment (Child-Pugh Class C)
- High risk for serious toxicity due to drug interactions unmanageable via therapy modification

Remdesivir Criteria: Incidental COVID+ (symptomatic) while admitted for non-COVID diagnosis (updated 4/12/22)**:**
(SOTROVIMAB preferred, when available/effective against VOC)

3 (THREE) day course of IV remdesivir (200 mg IV x 1 dose, followed by 100 mg IV daily x 2 days) or until hospital discharge, whichever comes first.

Inclusion criteria:

- COVID-19 (+) with mild to moderate symptoms
- ≤7 (SEVEN) days since symptom onset or positive test (whichever comes first)
- High risk of progressing to severe COVID-19
- Patient is not a candidate for sotrovimab or ritonavir-boosted nirmatrelvir due to specific patient factors and/or drug availability

Exclusion criteria:

- Hospitalized due to COVID-19
- ALT > 5x ULN
- If the provider determines the patient has end stage comorbidities, it is reasonable to withhold remdesivir and the palliative care screening tool is available to assist with decision making regarding therapy initiation.

~~-Renal function must be tested prior to starting remdesivir. Remdesivir should be used with caution in patients with an eGFR <30 mL/min (dose has not been studied & the infusion may cause further injury)~~

-If patient does not meet the specified criteria but you feel your patient may benefit from remdesivir, ID approval must be obtained.

Sotrovimab Criteria (approved 4/12/22):
Update [4/5/2022] 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

Inclusion criteria:

- COVID-19 (+) with mild to moderate symptoms
- <= 10 (TEN) days since symptom onset or positive test (whichever comes first)
- High risk of progressing to severe COVID-19

Exclusion criteria:

- Hospitalized due to COVID-19

Bebtelovimab Criteria (approved 4/12/22):
Update [11/30/2022] Bebtelovimab is not currently authorized for emergency use in the U.S. because it is not expected to neutralize Omicron sub-variants BQ.1 and BQ.1.1.

Inclusion criteria:

- COVID-19 (+) with mild to moderate symptoms
- <=7 (SEVEN) days since symptom onset or positive test (whichever comes first)
- ONLY if none of the preferred therapies are available, feasible to deliver, or clinically appropriate (e.g., due to drug-drug interactions, concerns related to renal or hepatic function)

Exclusion criteria:

- Hospitalized due to COVID-19

Heparin Drip Order Clarification

Situation

Nursing staff have recently questioned the need to wait for lab results before initiating a heparin drip based on the following order on the Heparin Drip Order MCT order set:
"Notify physician before initiating protocol if baseline aPTT is GREATER than 50 or INR is GREATER than 2, or platelets are LESS than 100,000".

Background

In June, pharmacy management was notified by nursing managers regarding this situation. The nursing order in question has been present on the order set since we were "on paper" with Meditech order sets.

Assessment

Pharmacy management brought the question forward to the CMO and ED physician leadership, who also discussed it with intensivist and hospitalist physician leadership.

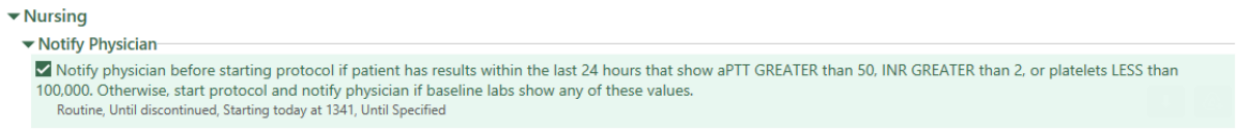
Recommendation

Physician leadership recommended the following modification to the nursing order:

Notify physician before starting protocol if patient has results within the last 24 hours that show aPTT GREATER than 50, INR GREATER than 2 or platelets LESS than 100,000. Otherwise, start protocol and notify physician if baseline labs show any of these values.

The purpose of this change will:
1. Make it clear that beginning a heparin infusion prior to baseline lab results is appropriate.
2. Verify the provider is aware of significant lab values that may be already present.
3. Provide instruction for what nursing should do if significant baseline laboratory values return.

The changes have already been updated in Epic.



Methocarbamol (Robaxin) Dose Limits

Situation

In July, an IRIS report was submitted because a patient had an active order for IV methocarbamol every eight hours that started over 1 week prior.

The order in the EHR defaults to a 3 day limit, but this limit can be removed and was in this situation.

Background

A pharmacist received a call from the patient's nurse requesting the medication to be sent for the next dose. Upon entering the chart, the pharmacist noticed that the patient was on this medication for about a week too long.

Assessment

According to the package insert, IV methocarbamol should be administered at a maximum dose of 3 grams per day for no more than 3 consecutive days with a 48 hour washout period, due to the polyethylene glycol component in the formulation.

In response, the following actions were taken immediately:

- The IV methocarbamol order instructions in the EHR were updated to include the following statement:
  Maximum dose: 3 g/day for no more than 3 consecutive days. If condition persists, may repeat course of therapy after a drug-free interval of 48 hours.

- A pharmacist alert in Theradoc was developed to fire once an order for IV methocarbamol has been active for more than 72 hours. These real time alerts are reviewed twice daily.

Epic functionality for limiting max doses and durations are limited due to the nuanced nature of the calculations for max daily dose and duration, in addition to requiring cross market approvals.

Recommendation

It is recommended to grant approval for pharmacists to:

1. Automatically discontinue active orders for IV methocarbamol once the order is active for more than 3 consecutive days, OR
2. If the original order is for longer than 3 days, pharmacists may limit the order to 3 days.

Providers may re-order after a 48 hr washout period.

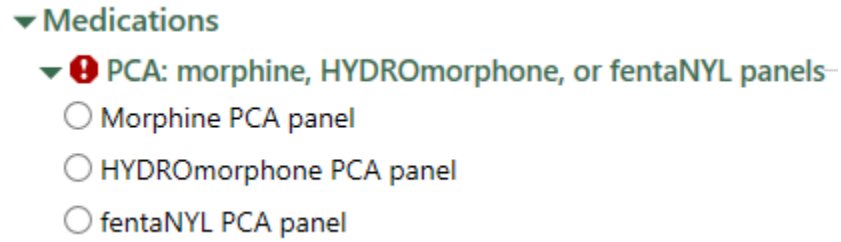
Patient Controlled Analgesia (PCA) Medication Use Evaluation

Situation

Nursing elevated questions regarding Patient Controlled Analgesia (PCA) orders to their managers and this was brought to the nurse manager meeting. The question was concerning the dose of Patient Controlled Analgesia for patients who are elderly or may be particularly sensitive to opiates. A medication use evaluation was conducted based on this feedback. The results were presented at the Medication Safety Committee and the recommendation from that committee was to get provider input regarding suggested recommendations.

Background

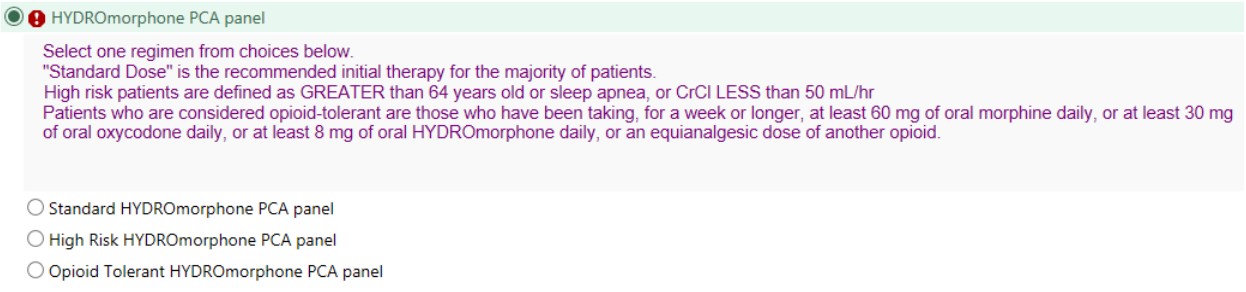
Our current PCA order set (PCA Standard Infusion MCT) has the option to choose from three different agents:



Once an agent is selected the provider is presented with the following guidance text:

Select one regimen from choices below.
"Standard Dose" is the recommended initial therapy for the majority of patients.
High risk patients are defined as GREATER than 64 years old or sleep apnea, or CrCl LESS than 50 mL/hr
Patients who are considered opioid-tolerant are those who have been taking, for a week or longer, at least 60 mg of oral morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral HYDROmorphone daily, or an equianalgesic dose of another opioid.

And then the provider will select the appropriate panel for the patient

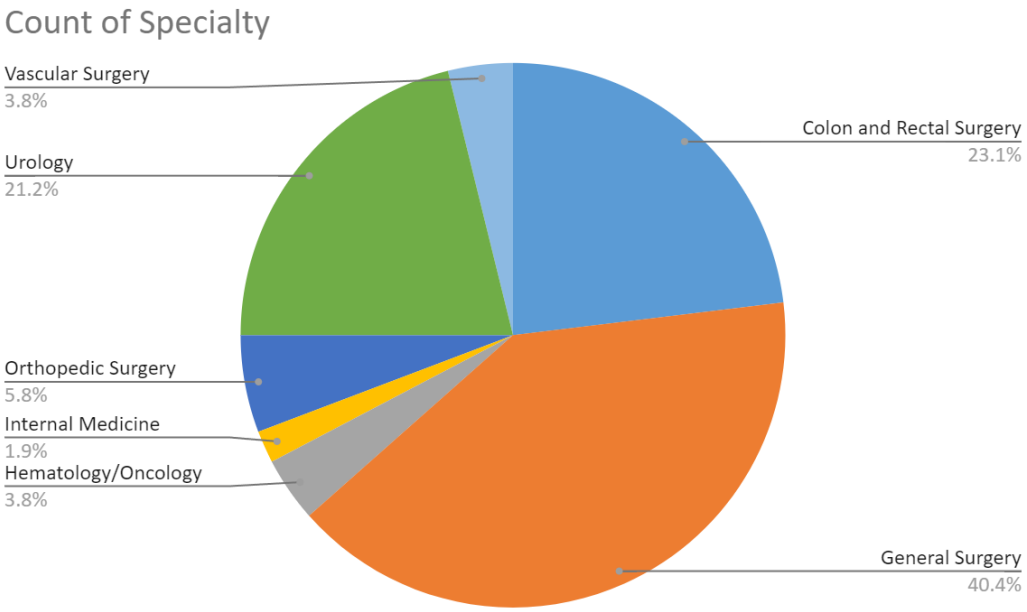


The MUE examined all PCA orders placed from June through mid August 2022, which was a total of 114 orders.

Assessment

According to the criteria in the PCA order set, 50 of these 114 orders were ordered outside of the suggested criteria- mostly because “standard dose” was ordered but the patient qualified for “high risk” due to age, OSA or RF (If the patient was on hospice or comfort measures, those orders were not included in the count).

The vast majority of these orders came from post-op order sets. This pie chart is the breakdown of orders by specialty and only included the 50 orders that were deemed to be different from what the recommendations suggest.



There were two other important findings:

- Narcan use was assessed during the MUE, only used on 2 patients. Both of those patients had a higher dosed panel than suggested by the order set.
- Another assessment of the MUE was to review if the patient had PRN pain medications available on the MAR while the PCA orders were active. It was found that 49 out of the 114 orders still had PRN pain medications on the MAR that did not come from the PCA order set.

Recommendation

There were several recommendations that were suggested as a result of the MUE discussed in the Medication Safety Committee meeting:

- It's unclear if selection is an intentional choice vs "favorites" on postoperative order sets. So it's unclear if provider education is a solution.
- Should it be part of the order set to discontinue all other PRN opiates unless ordered at the same time as the PCA?
- Should it be part of the orders to change the orders to the "high risk" dosing panel if the patient meets the criteria automatically? Exclusions to this might include:
    - Providers who do not order a PCA directly from order set ("custom" orders)
    - Hospice, palliative care and/or end of life orders from critical care
- Would it be beneficial to place the panels in order of low-medium-high order rather than starting with the medium choice (standard) at the top?

SEDATIVE/HYPNOTIC MEDICATION USE EVALUATION

BACKGROUND:

At a prior P&T Committee meeting when the Sedative/Hypnotics for Sleep policy was reviewed. The primary outcome of this policy is to ensure sedatives/hypnotics for sleep in hospitalized patients will be used safely and in an effort to reduce the risk of fall and injury, especially in the elderly population of patients.
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 medication use evaluation (MUE) was performed from January to March 2023 to examine the use of potentially inappropriate medications elderly patients receiving them *around bedtime* in 56 inpatients ages 65 years or older with a documented fall incident. There is substantial evidence that shows an increased fall and fracture risk in elderly patients with insomnia that use sedative/hypnotic medications to treat their symptoms. The purpose of the MUE was to reassess a prior fall study from over 10 years ago that was used to create the current policy that states that no sedative/hypnotics for sleep be administered to any patient greater than 65.

METHODS/RESULTS:

Am MUE was performed evaluating medications that are present on both the American Geriatrics Society (AGS) Beers Criteria list and the hospital formulary that could possibly be utilized off-label for sleep. This analysis excluded drugs already being monitored on the fall-risk policy.

The 31 medications analyzed were lorazepam, midazolam, pentobarbital, phenobarbital, trazodone, doxepin, amitriptyline, nortriptyline, mirtazapine, gabapentin, alprazolam, clonidine, clonazepam, quetiapine, pregabalin, carbamazepine, diazepam, rotigotine, ropinirole, pramipexole, desipramine, ketamine, promethazine, clobazam, tizanidine, clomipramine, cyclobenzaprine, imipramine, orphenadrine, methocarbamol, and olanzapine.

The data collected was then filtered to only include the medications that were scheduled and administered between the hours 8 p.m. and midnight, but not necessarily scheduled “for sleep” or “at bedtime”.

There were 56 patients ages 65 or older with a documented fall from January to March 2023. Of the 56 patients studied, 38 patients received a potentially inappropriate medication. 19 of the 38 patients were given medication between 8 p.m. and midnight with a scheduled dose around bedtime, and 5 of those 19 patients received the medication within 24 hours prior to the documented fall (Table 1). Three patients received gabapentin, 1 received midazolam, and 1 received clonidine and methocarbamol.

Table 1

Facility	Event Local Time	Medication	Incident Subtype	Age	Gender	Fall Assessment at Time of Fall (Risk Score)	Home Med or CIWA?
Georgia	00:00	Clonidine 0.1 mg PO q6 PRN HTN Methocarbamol 500 mg PO BID	Accidental Fall	89	Female	Low (35)	
Hixson	03:15	Gabapentin 300 mg PO TID	Accidental Fall	76	Male	High (85)	Home med 1200 mg BID (admitted for falls)
Hixson	14:40	Gabapentin 600 mg PO every 8 hours	Accidental Fall	65	Female	High (85)	CIWA
Glenwood	21:20	Gabapentin 800 mg PO BID	Anticipated Physiological Fall	65	Female	High (70)	Home med
Glenwood	01:50	Midazolam 1 mg IV	Accidental Fall	65	Male	High (95)	

DISCUSSION:

Approximately 9% of patients 65 years of age or older who fell from January to March 2023 received a potentially inappropriate medication around bedtime within the 24 hours prior to the fall.

It is difficult to decipher the true cause of fall for the 5 patients that fell after receiving a potentially sedating medication. There are multiple factors that can contribute to the mobility of elderly patients which can only be assessed after their baseline ambulatory capabilities are understood.

- Are there safer sleep medication alternatives to those currently on formulary? Which agents are included on the system formulary to be considered for adoption locally?
    - Would hospitalist education be helpful on these safer alternatives, if available?
- Should the current sedative/hypnotics for sleep policy be revised to also focus on sleep safety?
    - i.e. guidelines for prioritizing appropriate medication selection for sleep; increased fall monitoring/precautions if certain medications are active on the MAR?
    - The Fall Risk Assessment and Prevention policy states, under Standard/Universal Fall Interventions, "Consider additional interventions based on effects of medications administered (i.e. pain narcotics, **sleep aides**, blood pressure altering, and diuretics)".

CSH Formulary:

☒Formulary, Unrestricted

- Eszopiclone
- Melatonin immediate-release tablets and capsules
- Trazodone
- Temazepam
- Diphenhydramine (use only in patients less than 65 years old)
- Zolpidem 5mg

☒Formulary, Restricted; Zolpidem 10mg

- Continuation of home therapy

☒Non-Formulary

- Ramelteon
- Suvorexant
- Zaleplon

Sedative Hypnotic Therapeutic Interchange

Medication Ordered	Dose Ordered	Formulary Medication	Frequency
Zolpidem CR (Ambien CR)	6.25 mg or 12.5mg	Zolpidem (Ambien) 5mg	As ordered
Ramelteon (Rozerem)	8mg	Melatonin 3 mg	
Zaleplon (Sonata)	5mg	Eszopiclone (Lunesta) 1 mg	
		OR	
		Zolpidem (Ambien) 5 mg	
	10mg	Eszopiclone (Lunesta) 2 mg	
		OR	
		Zolpidem (Ambien) 5 mg	
Suvorexant (Belsomra)	10mg	Eszopiclone (Lunesta) 1 mg	
		OR	
		Zolpidem (Ambien) 5mg	
	20mg	Eszopiclone (Lunesta) 2 mg	
		OR	
		Zolpidem (Ambien) 5 mg	

CHI Memorial Formulary:

Sedative/Hypnotics for Sleep	
ORDERED	**SUBSTITUTION**
Ramelteon (Rozerem®) 8 mg	Melatonin® 3 mg
Zaleplon (Sonata®) 5 mg	Zolpidem (Ambien®) 5 mg
Zaleplon (Sonata®) 10 mg	Zolpidem (Ambien®) 5 mg
Triazolam (Halcion®) 0.25 mg	Zolpidem (Ambien®) 5 mg
Eszopiclone (Lunesta®) 1 mg	Zolpidem (Ambien®) 2.5 mg
Eszopiclone (Lunesta®) 2 mg	Zolpidem (Ambien®) 5 mg
Eszopiclone (Lunesta®) 3 mg	Zolpidem (Ambien®) 5 mg
Flurazepam (Dalmane®) 15 mg or 30 mg	Zolpidem (Ambien®) 5 mg
Estazolam (Prosom®) 1 mg or 2 mg	Temazepam (Restoril®) 15 mg
Temazepam (Restoril®) 7.5 mg	Zolpidem (Ambien®) 5 mg
Temazepam (Restoril®) 15 mg or 30 mg	Temazepam (Restoril®) 15 mg
Zolpidem CR (Ambien CR®) 6.25 mg or 12.5 mg	Zolpidem (Ambien®) 5 mg
Suvorexant (Belsomra®) 10 mg	Zolpidem (Ambien®) 5 mg
Suvorexant (Belsomra®) 20 mg	Zolpidem (Ambien®) 5 mg

POLICY

Title: **BIOSIMILAR MEDICATIONS – FORMULARY MANAGEMENT**			
		Page **1** of **2**	
Policy Number: MM-05470		Date Last reviewed/Revised: 9/23	Valid Until: 9/26
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Departments		Review Period: every 3 years	

OUTCOME:
To outline the process for formulary additions of new biosimilar therapies and utilization processes for both inpatient and outpatient settings.

DEFINITIONS:

A. Biosimilar: A biologic medication that is highly similar, with no clinically meaningful differences to an already FDA approved biologic in terms of safety profile, purity, and potency of the product.
B. Reference Product: A reference product (RP) is the single biological product, already approved by the FDA, against which a biosimilar product is compared. A proposed biosimilar product is compared to and evaluated against a reference product to ensure that the product is highly similar and has no clinically meaningful differences.
C. Interchangeable Biosimilar: A biosimilar that has met additional FDA requirements for interchangeability that may be substituted without the intervention of the health care provider who prescribed the reference product.

POLICY:

A. Formulary Approval:
New biosimilars that have been FDA approved for the same indications as the RP will be automatically added to hospital formulary if the RP is currently approved as a formulary agent. Any formulary restrictions currently in place for the RP will be applied to the biosimilar medication. New biosimilars with indications different than the RP will be reviewed by the Pharmacy and Therapeutics committee for formulary consideration.

Information regarding automatic approval, as described above, for new biosimilar additions to formulary will be brought for information review before the Pharmacy and Therapeutics Committee. This includes any modifications of any existing treatment protocols, etc.

PROCESS:

A. Inpatient utilization of biologics – formulary biosimilar available:
The most cost-effective formulary biosimilar agent may be substituted for the RP as an automatic interchange by the pharmacist (provider notification not required).

B. Outpatient utilization of biologics – formulary biosimilar available (without interchangeable designation):
    a. **Patients treatment naïve to ordered RP**:
    Patients previously not treated at Memorial infusion centers with the ordered RP will not be accepted for outpatient treatments if insurance authorizes utilization of biosimilar medication for FDA-approved or off-label indications. If the patient's insurance allows multiple biosimilars of a given RP, the most cost-effective formulary biosimilar will be utilized pending insurance prior authorization. New provider orders will be required in order to proceed with the biosimilar conversion.
        i. Exception: If biosimilar medication is not allowed per insurance policy, the RP may be utilized following prior-authorization obtainment.

b. **Patients currently receiving RP therapy at a Memorial infusion center (Insurance authorizes use of biosimilar for FDA-approved or off-label indications):**
If/when a new biosimilar medication is approved to formulary, all patients on existing therapy with the corresponding RP will be evaluated for possible biosimilar conversion. Each provider will be contacted to assess for clinical appropriateness of possible biosimilar conversion. If the ordering provider provides evidence suggesting that a biosimilar conversion is clinically inappropriate (jeopardizes clinical efficacy, safety, etc.) the patient may remain on therapy with RP. New provider orders will be required in order to proceed with the biosimilar conversion.

c. **Patients currently receiving RP therapy at Memorial infusion center (Insurance does not authorize use of biosimilar)**
In situations where biosimilar use is not permitted secondary to insurance restrictions, patients may remain on RP therapy and insurance status will be periodically reevaluated for future conversion opportunities.

C. Outpatient utilization of biologics – formulary biosimilar available (interchangeable)
   a. For biosimilars that are designated by the FDA as interchangeable products, the most cost-effective, insurance approved interchangeable biosimilar will be automatically substituted by the pharmacist. Provider notification is not necessary or required when executing conversions for interchangeable biosimilars.

D. Patient Education:
All outpatients transitioning to a biosimilar medication will receive pharmacist education on the conversion prior to changing therapies.

Key Contact: Pharmacy Directors
Approved/Reviewed by: Pharmacy and Therapeutics Committee, Nursing Professional Practice Committee (NPPC), Chief Nursing Officer
Related Forms/Policies: Formulary Policy (MM-05428)
Date First Effective & Revision/Review dates: (8/20) (9/23)

CHI Memorial

Look Alike/Sound Alike Drug List

Drug Name	Drug Name	Potential Errors	Prevention Strategies
CeleBREX®	CeleXA® and CereBYX®	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
clomiPHENE	clomiPRAMINE	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Do NOT store next to each other.
cloNIDine	KlonoPIN®	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Diamox®	Diuril®	Similar names	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR
DOBUTamine	DOPamine	Similar names	1. Tall man letting in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
DOXOrubicin *Liposomal*	DOXOrubicin *Conventional* and DAUNOrubicin	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Do NOT store next to each other. 3. Name alert on MAR
Humalog®	Kenalog®	Similar names	1. Pyxis pop-up warning. 2. Do NOT store next to each other.
hydrOXYzine	hydrALAzine	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Keppra®	Ketamine	Similar names	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR 4. Witness required for ketamine
metroNIDAZOLE	metFORMIN	Similar names and strengths	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
MuciNEX®	MucoMYST®	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
oxyCODONE controlled-release	oxyCODONE immediate-release	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
PHENobarbital	PENTobarbital	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Do NOT store next to each other.
Plavix®	Pradaxa®	Similar names and strengths	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR
predniSONE	prednisoLONE	Similar names	1. Tall man lettering in Pyxis, Epic & Carousel. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Remicade®	Rituxan®	Similar names	1. Tall man lettering in Epic. 2. Do NOT store next to each other. 3. Name alert on MAR
VeRSED®	VeCURONium®	Similar names	1. Tall man lettering in Pyxis 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR

Antimicrobial Subcommittee Meeting
8/17/2023
Time: 12:00-1:00pm
Meeting Minutes

Attendees	Dr. Mark Anderson, Dr. Hal Hill, Dr. Paul Cornea, Dr. Lee Hamilton, Linda Johnson

Agenda Item	Highlights

Beta-lactam allergy clarification and delabeling project report	• Pharmacy-led beta-lactam allergy clarification protocol led to 167 interventions during 1 month period
	  ○ Most common intervention was allergy clarifications by MHTs
	• Substantial opportunity for de-labeling with approximately:
	  ○ 40% of patients' allergies later classified as an adverse reaction or a low-risk allergic reaction
	  ○ 72% of patients reported an allergy that occurred >10 years ago
	  ○ 43% of patients with beta-lactam allergies had previously received penicillins and cephalosporins
	Planning to present data to outpatient physician groups to encourage penicillin test dose challenges in patients with low risk allergies

Pharmacist Intervention on discharge antibiotic therapy for CAP	• In January 2023, a new CAP pharmacist evaluation document was created and implemented through education and workflow changes
	  ○ Goal: Optimize antibiotic therapy with a focus on reducing duration of therapy at discharge
	• Decentralized pharmacist reviewed CAP patients and made recommendations to providers encouraging them to switch to an appropriate agent, route, dose and duration of therapy
	• The median duration of total antibiotics & discharge antibiotics decreased by one day in the post-intervention group
	• Most pharmacist interventions were related to duration of antibiotics
	• Majority of the discharge antibiotics were deemed appropriate, although most appropriate in post-intervention (91.7% and 97.3%, respectively)
	• 40.5% of patients in the post-intervention group had pharmacist interventions
	  ○ 100% of interventions were accepted

UA/Urine culture Criteria Update in EPIC	• CSH will be adding indications to all urine culture (UA w/ reflex & urine culture) orders • All UAs and urine cultures will live in a panel • We voted to remove UA with reflex to culture order from the following order sets: MCT ED nursing protocols quick list, MCT IP Cardiology admission, MCR IP Gen Common Labs, MCT IP Neu Stroke Intracranial hemorrhage (intraparenchymal), MCT IP CC ECMO, MCT IP Gen Diabetic ketoacidosis (DKA), MCT IP Neu Stroke non TPA & TIA, MCT IP Pat preoperative testing, MCT IP Ren Peritoneal dialysis)
Rebyota	• Fecal microbiota rectal instillation (approved Nov 2022) • Indicated for prevention of recurrent C diff infection within 72 hours after treatment with standard drugs such as PO vanco or fidaxomicin • PUNCH CD3 study: treatment success at 8 weeks was 71.4% for Rebyota and 62.4% for placebo • Storage: requires ultracold freezer or store in fridge up to 5 days; cannot refreeze after thawing • Adverse effects: abdominal pain, discomfort, diarrhea • Cost ~ $9,000 • CSH P&T: restricted to outpatient setting subsequent to payer approval • Places near us who can do it: TwelveStone home infusion, OptivRx infusion center in Knoxville • Concerns with doing it at Memorial: order through specialty Rx, storage, room to administer it, terminal clean of the room post-admin, different method of admin than what we currently do, reimbursement? • Dr. Anderson and Linda to discuss further with outpt infusion administrators and GI to formulate final plan

VOWST	• Fecal transplant oral capsules (approved April 2023; not yet available for purchase) • Indicated for prevention of recurrent C diff infection within 48-96h after treatment with standard drugs such as PO vanco or fidaxomicin • ECOSPOR III: CDI recurrence at 8 weeks was 12% with VOWST and 40% with placebo • Adverse effects: GI Symptoms • Cost ~ $17,500 • CSH P&T: non-formulary • Company offers patient assistance programs for uninsured and underinsured. May also be an opportunity for copay assistance for commercially insured patients

Other Topics	• Discussed focus area for antimicrobial stewardship
	  ○ Cellulitis
	  ○ Aspiration Pneumonia
	• AUC based vanco dosing coming soon
	• Next Meeting topics: Xacduro, Rezzayo