Pharmacy & Therapeutics Committee Meeting

Conference via Zoom Only

June 15, 2023 7:00 a.m.

Next Meeting Date: TBD at 7:00 a.m.

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: March 30, 2023 CALLED TO ORDER: 7:02 a.m.
LOCATION: SCN Boardroom ADJOURNED: 7:37 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**	**Teresa Brown, RN (proxy for CNO)**
X	**Mark Anderson, MD- Infectious Disease**	X	**Aditya Mandawat, MD- Cardiology**		Jamie Barrie, PharmD- Manager, HX	**Joseph Oh, Pharmacy Resident**
X	**Justin Blinn, MD- Anesthesiology**	X	**Daniel Marsh, PharmD- Director of Pharmacy**	X	**Kenneth Dyer, PharmD- Operations Manager**	**Jordan Tynes, Pharmacy Resident**
X	**David Dodson, MD- Hospitalist**	X	**Chad Paxson, MD- Intensivist**	X	**Rodney Elliott- Purchasing**	**Chris D'Amico, Pharmacy Resident**
X	**Karen Frank, RN- Quality**		James Wahl, MD- Hospitalist, GA		Lori Hammon, RN- Quality	**Hallie Butler, Pharmacy Resident**
	Sherry Fusco, RN- CNO	X	**Richard Yap, MD- Hospitalist**	X	**Shannon Harris, RN- Infection Prevention**	**Deb McKaig, Pharmacy Administrative Coordinator**
	F. Lee Hamilton, MD- Hospitalist			X	**Kevin Hopkins, RT- Director of Resp Therapy**	**Spencer Elliott, Pharmacy Student**
	William Haren, MD- Psychiatry			X	**Rachel Kile, PharmD- Clinical Manager**	**Sara Corum, Pharmacy Student**
				X	**Carey Smith, RPh- Manager, GA**	**Neely Hodge, Pharmacy Student**
				X	**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 February minutes were approved as submitted.	Approved	Complete
Old Business	**A. Hydralazine IV orders:** Following incidences of patients receiving PRN IV hydralazine for appropriate blood pressure parameters resulting in subsequent elevated heart rate issues, it was proposed to add hold instructions in all as needed injectable hydralazine orders. A vote was conducted following the December P&T meeting, with the majority selecting Option 1 - a default in administration instructions to hold for heart rates exceeding 100 beats per minute. These instructions are currently live in EPIC. The default administration instructions are editable if the provider desires to not include in the order.	Informational	Complete
	B. Clinimix E: Clinimix E is a standardized, commercially available parenteral nutrition product. This week the utilization of Clinimix went live. a. Clinimix is not the same as ProcalAmine as Clinimix requires a central line b. Clinimix still follows the same clinical necessity as TPN c. Clinimix should not be requested if the intended duration of parenteral nutrition is less than 7 days	Informational	Complete

Formulary Decisions & Therapeutic Interchanges	**A. Spesolimab-sbzo (Spevigo):** Spevigo is a humanized monoclonal antibody that inhibits IL-36 signaling by binding to the interleukin-36 receptor (IL-36R). Binding of Spevigo to IL-36R prevents subsequent activation of IL-36R by ligands and downstream activation of pro-inflammatory and pro-fibrotic pathways. Dermatology office in Hixson requested a review of this drug. The CommonSpirit Health System P&T committee has reviewed this medication and approved for formulary. Spevigo obtained FDA approval in September 2022 for acute flares of generalized pustular psoriasis (GPP) based on: ● Effisayil-1 study demonstrated 54% of patients in treatment group vs 6% in placebo had no visible pustules at week 1 after treatment Warnings and precautions for Spevigo include: ● Increased risk of infections; do not initiate during any clinically important active infection ● Hypersensitivity reactions (including DRESS) and infusion-related reactions; discontinue immediately ● Evaluate patients for TB prior to treatment ● Do not concurrently administer live vaccines with Spevigo It was recommended that due to the significant cost (up to $102,266 per disease flare) and rarity of GPP in the United States, Spevigo should be added to formulary, but with restrictions to outpatient settings for FDA-approved indications or payer-approved off-label indications subsequent to insurance for approval or prior authorizations. Having this medication available in the outpatient may help prevent future hospitalizations.	Approved	Complete
	B. Aminolevulinic acid (Gleolan): Gleolan is the first and only FDA-approved optical imaging agent for use during fluorescence-guided surgery (FGS) in patients with glioma as an adjunct for the visualization of malignant tissue during surgery. In October 2021, the CHI Memorial P&T committee voted to approve Gleolan to formulary. Gleolan is a weight-based medication dosed at 20 mg/kg. Currently, patients are being charged for the full amount of the Gleolan vial (1 vial = 1500 mg) even if patients do not require the full vial. Gleolan does not allow for wastage to be charged by the hospital, so Memorial is required to charge the patient for the full vial regardless. Solution: other CommonSpirit facilities using Gleolan have adopted a fixed-dosing strategy:: ● Patient weight <= 120 kg = 1500 mg (1 vial) ● Patient weight >120 kg = 3000 mg (2 vials) In a review of patients who have received Gleolan since early 2022, 4 patients weighing less than 120 kg have received Gleolan, therefore those patients would receive one 1500 mg vial. One of the four patients would have a substantial dose change as the fixed dose of 1500 mg is ~32% less than the administered dose. Dr. Ranjith Babu has reviewed the data and approved the fixed-dose strategy. It was recommended to adopt the above fixed dosing strategy with approval for the pharmacist to round to the nearest vial size.	Approved	Complete
	C. Sulfadiazine: Sulfadiazine is an oral antibiotic with FDA approval for treatment of toxoplasmosis encephalitis in combination with pyrimethamine and prophylaxis of rheumatic fever in patients with a penicillin allergy. In the past 6 months, there have been no inpatient orders for sulfadiazine tablets (60 tablets = $884). Dr. Anderson added he has seen little utilization of this drug during his career and supported the recommendation to remove sulfadiazine tablets from formulary. Patients will be allowed to continue their own home medication. If a case suspicious of toxoplasmosis encephalopathy were to arise, Memorial would go through non-formulary channels of obtaining the drug. This would not delay care as the diagnostic testing typically takes 2-3 days to result which would allow time to obtain sulfadiazine if needed.	Approved	Complete
	D. Acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL: Acetaminophen with codeine is indicated for pain management of mild to moderate pain where treatment with an opioid is appropriate. In February 2023, acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL oral liquid unit dose became unavailable for purchase from our standard distributor due to manufacturer discontinuation (40 count unit dose	Approved	Complete

	package). The only option for purchase is a 100 count package at a higher price. The previous 12 months of utilization showed only 3 doses were administered. ● Alternative oral liquid options for mild to moderate pain on formulary including acetaminophen, ibuprofen, and hydrocodone with acetaminophen ● Due to low utilization, Dr. Champion (ED) approved removal from formulary It was recommended to approve the removal of acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL from formulary. **E. Drug shortages update:** Duoneb (ipratropium 0.5 mg/albuterol 2.5 mg per 3 mL) is currently a critical shortage item. On March 7th, 2023, the P&T Committee chairman emergently approved the automatic interchange by pharmacists from Duoneb to the separate components, ipratropium and albuterol, as individual nebulized medications. Since emergent approval, the pharmacy has received some backorders, but remains in critical shortage. In collaboration with respiratory therapy leadership, orders for Duoneb are slowly being integrated back into patient care on 5N, 6N, and 7N only due to RRT staffing as separating Duoneb into separate components hosts its own problems for RRT: ● Nebulizing the separate medications doubles the nebulization time by the RRT due to double the amount of drug volume ● Increases time by roughly 15 minutes per treatment and is requiring an additional 3 RRT's workload volume per day It was recommended to formally approve the pharmacist emergent interchange during times of Duoneb shortage. There was discussion on how to potentially address this issue. One recommendation is to evaluate the true need to have ipratropium and albuterol for a patient. There is an option in the Adult General Admission MCT order set under "Medications" → "Respiratory" that allows for the selection of albuterol by itself.	Approved	Complete
Policies	**A. Methicillin Resistant Staphylococcus Aureus (MRSA) nasal PCR - Pharmacy Ordering :** Reviewed policy with no updates needed. The MRSA rapid nasal PCR has been shown to have high negative predictive value (95-99%) for MRSA pneumonia and has been safely used to de-escalate vancomycin therapy in studies as well at Memorial Hospital. The positive predictive value for the MRSA nasal PCR is low (~40%). Therefore should not be used for escalation of therapy, especially if the patient is clinically improving on current non-MRSA antimicrobial therapy. Another reminder that the MRSA nasal PCR is only for pneumonia and not for other indications. This policy has decreased the need for vancomycin and has decreased the average days of therapy from 4 days to 2 days.	Approved	Complete
Miscellaneous	**A. Report: Pharmacist Clinical Interventions, Serious Significance Level:** Rachel reviewed the "serious" significance level interventions made by pharmacist staff. The committee had no recommendations based on this review.		

There being no further business, the meeting was adjourned at 7:39 a.m. The next P&T meeting is **June 15, 2023 via ZOOM only.**

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

Approved by,
Nathan Chamberlain, MD, Chairman

CSH SYSTEM PHARMACY AND THERAPEUTICS COMMITTEE DECISION BRIEF

March 2023 Decisions

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

Medication Name	Medication Used For	Formulary Decision				Restrictions and Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary	Do Not Stock		
dextromethorphan & bupropion	Major depressive disorder			AUVELITY			Within 60 days of System P&T Committee approval
spesolimab	Generalized pustular psoriasis		SPEVIGO			Restrictions: Outpatient use Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Inpatient use • Dermatology or rheumatology consult required • Diagnosis of moderate-to-severe GPP flare defined as: GPPGA total score of ≥3, new or worsening pustules, a GPPGA pustulation sub-score of ≥2, and ≥5% of body-surface area with erythema and the presence of pustules AND Presence of systemic symptoms: fever, and/or asthenia, and/or myalgia, and/or elevated C-reactive	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision				Restrictions and Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary	Do Not Stock		
						protein, and/or leukocytosis with peripheral blood neutrophilia (above ULN) • Patients that have failed treatment with ≥1 non-FDA approved historical first-line therapy: Cyclosporine, oral retinoid, infliximab, methotrexate • Patient is clinically unstable for discharge and delay of treatment will lead to poor patient outcomes	
elacestrant	Estrogen receptor positive breast cancer			ORSERDU			Within 60 days of System P&T Committee approval
pirtobrutinib	Mantle cell lymphoma			JAYPIRCA			Within 60 days of System P&T Committee approval
methylene blue	Treatment of acquired methemoglobinemia. Diagnostic agent for various purposes including sentinel lymph node mapping.	METHYLENE BLUE, 1%					Within 90 days of System P&T Committee approval
				PROVAY BLUE, 0.5%		Link to therapeutic interchange	Within 60 days of System P&T Committee approval
teclistamab-cqyv	Multiple myeloma			TECVAYLI		Notes: Teclistamab is not anticipated to have a reimbursement code until summer 2023. Thus, until a	Within 60 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision				Restrictions and Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary	Do Not Stock		
						reimbursement code is available, teclistamab will be non-formulary. However, due to the likelihood of possible use prior to this time, the EHR design/build for Tecvayli will be coordinated to assist sites that may need to use this therapy for appropriate individuals prior to formal P&T approval. Additionally, operational guidance will be developed to assist sites with management of cytokine release syndrome and operational coordination of the required inpatient observation period following the step-up dosing schedule.	
difelikefalin	Chronic kidney disease pruritis			KORSUVA			Within 60 days of System P&T Committee approval
Lecanemab	Alzheimer's disease				LEQEMBI	Only facilities considered to be tertiary neurology care centers are allowed to procure and administer aducanumab and lecanemab. An application process will ensure division and facility clinical and operational leaders understand and meet the care requirements for any non-formulary requests for this therapy. Link to the application	Within 60 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision				Restrictions and Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary	Do Not Stock		
Nusinersen	Spinal muscular atrophy		SPINRAZA			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
Lipid emulsion (fish oil based)	Parenteral nutrition		OMEGAVEN			Restrictions: • Pediatric and neonatal patients with parenteral nutrition-associated cholestasis or intestinal failure-associated liver disease (IFALD) evidenced by conjugated bilirubin > 2 mg/dL despite a reduced dose of soy oil-based lipid emulsion (SOLE), failed trial of SMOFlipid, and who are predicted to require PN for at least an additional 30 days. • SMOFlipid® should be initiated and failed prior to starting Omegaven.	Within 90 days of System P&T Committee approval
AHFS Class Review: Antitoxins, toxoids, vaccines, Dental agents, gold compounds, nonhormonal contraceptives, radioactive agents	Various indications	Multiple decisions – no changes				Link to formulary status for all class representatives	Within 90 days of System P&T Committee approval
AHFS Class Review: Ophthalmic antimicrobials	Ophthalmic infections	Multiple decisions				Link to formulary status for all class representatives	Within 90 days of System P&T Committee

Medication Name	Medication Used For	Formulary Decision				Restrictions and Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary	Do Not Stock		
						Link to therapeutic interchanges	approval

THERAPEUTIC INTERCHANGES

Methylene blue dye	
Ordered	**Provided**
Provay blue 0.5% 10ml ampule	Methylene blue 1% 10ml vial

Ophthalmic antimicrobial drops	
Ordered	**Provided**
Tobrex 0.3 % eye drops	Tobramycin 0.3 % eye drops at the same dose and frequency as ordered
TobraDex 0.3%-0.1% eye drops	Tobramycin 0.3%-dexamethasone 0.1% eye drops at same number of drops and frequency
Maxitrol 3.5 mg/mL-10,000 unit/mL-0.1% eye drops,suspension Maxitrol 3.5 mg/g-10,000 unit/g-0.1 % eye ointment	Neomycin-polymyxin-dexameth 3.5 mg/mL-10,000 unit/mL-0.1% eye drops at the same dose and frequency as ordered
Polytrim 10,000 unit-1 mg/mL eye drops	Polymyxin B sulfate 10,000 unit-trimethoprim 1 mg/mL eye drops at same number of drops and frequency as ordered
AK-Poly-Bac 500 unit-10,000 units/gram eye ointment	Bacitracin-polymyxin B 500 unit-10,000 unit/gram eye ointment at same number of drops and frequency
Moxifloxacin 0.5 % viscous eye drops	Moxifloxacin 0.5 % eye drops at same number of drops and frequency as ordered
Ciloxan 0.3 % eye drops	Ciprofloxacin 0.3 % eye drops at same number of drops and frequency as ordered
Ocuflox 0.3 % eye drops	Ofloxacin 0.3 % eye drops at same number of drops and frequency as ordered
Vigamox 0.5 % eye drops	Moxifloxacin 0.5 % eye drops at same number of drops and frequency as ordered
Blephamide10%-0.2%eye drops, suspension Bleph-10 10 % eye drops	Sulfacetamide-prednisolone 10 %-0.23 % (0.25 %) eye drops at same number of drops and frequency as ordered

CommonSpirit

CSH System Pharmacy and Therapeutics (P&T) Committee
Meeting Date: March 16, 2023
DECISION BRIEF

Tertiary Neurology Center Application to Procure and Administer Aducanumab-avwa (Aduhelm) or Lecanemab-irmb (Legembi)

Adacanumab-avwa and lecanemab-irmb are unique medications with evidence to support use in a small subset of Alzheimer's (AD) patients. Both are non-formulary, however non-formulary criteria have been composed In order to assure they are used in accordance with an evidence based approach. Only facilities considered to be tertiary neurology care centers are allowed to procure and administer aducanumab and lecanemab-irmb. The application process will ensure division and facility clinical and operational leaders understand and meet the care requirements. The person completing this form is attesting that the following resources are in place at:

_____ _____
Name of Facility/Center City, State

Resources required for the appropriate use of aducanumab or lecanemab within Commonspirit

• Clinicians skilled in the detection and recognition of early AD

• Individuals with lumbar puncture expertise or amyloid PET access
  ○ CLIA-certified laboratory available for CSF measurements, or
  ○ Experts in amyloid PET interpretation

• Infusion resources (office/clinic; general infusion center; home infusion with visiting nurse
• MRI access
• Experts proficient in clinical recognition and management of ARIA on MRI
• Genetic counseling available for patients with questions regarding implications of APOE genotyping and interpretation of genetic testing

Patients believed to be candidates for therapy with aducanumab or lecanemab will be assessed by a physician with specialty training in the diagnosis and treatment of dementia. No direct external referrals will be accepted.

An approved prior authorization (PA) is required before aducanumab or lecanemab is administered for all patients with pharmacy or medical benefit coverage that requires one in order for it to be reimbursed.

An **Aducanumab/Lecanemab Patient Selection Consensus Committee** will be created and include:

- Dementia specialist (neurologist or neuropsychiatrist),
- Neuroradiologist
- Neuropsychologist
- Nurse or Nurse manager

Monitoring for Amyloid Related Imaging Abnormalities

All neuroimaging will be performed at the same facility to ensure consistency of scans and to ensure that neuroradiologists experienced in monitoring for ARIA-H and ARIA-E are analyzing the scans.

_____ _____
Signature Date

_____ _____
Print Name Title

Please send completed application to the Divisional VP of Pharmacy for approval

EHR Guidance

EXECUTIVE SUMMARY

The Infectious Diseases Society of America (IDSA) guidance document recommends high dose ampicillin/sulbactam IV (Unasyn) as a treatment option for some Carbapenem-Resistant Acinetobacter (CRAB) infections.[1] Most non-ID specialist healthcare professionals are not familiar with high dose Unasyn regimens. Additionally, there is not a suggested renal adjustment process within the IDSA guidance document. Standard dosing and renal adjustment guidance would facilitate timely CRAB treatment when needed. Once approved a standard may be build within EHRs.

RECOMMENDATIONS

- Restrict high dose Unasyn to ID approval (for facilities that have ID consult readily available) for CRAB infection not involving the urinary tract

EHR build:
Ampicillin/sulbactam IV dosing:
For albumin of 2.5 and greater
CrCl 15-30, 3 gm q 8 hours with 4 hour infusion
CrCl 31-59, 6 gm q 8 hours with 4 hour infusion
CrCl 60-89, 6 gm q 6 hours with 4 hour infusion
CrCl > 90, 9 gm q 8 hours with 4 hour infusion

For albumin less than 2.5
CrCl 15-30, 3 gm q 12 hours with 4 hour infusion
CrCl 31-59, 6 gm q 12 hours with 4 hour infusion
CrCl 60-90, 6 gm q 8 hours with 4 hour infusion
CrCl > 90, 9 gm q 8 hours with 4 hour infusion

Implementation Date Recommended implementation date is within 120 days of System P&T Committee approval.

CommonSpirit

CSH System Pharmacy and Therapeutics (P&T) Committee
Meeting Date: March 16, 2023
DECISION BRIEF

Guideline Update: surgical antimicrobial prophylaxis

EXECUTIVE SUMMARY

Infection risk is high in patients with an open fracture. The current CommonSpirit Health surgical antimicrobial antimicrobial prophylaxis guidelines for adults do not include open fracture antimicrobial prophylaxis recommendations. Data is limited to guide evidence based recommendations for open fracture antimicrobial prophylaxis compared to other surgical prophylaxis recommendations. In response to a request (Peri-op Council) to add recommendations for open fracture antimicrobial prophylaxis to the CommonSpirit Health surgical antimicrobial prophylaxis guidelines, SCrPT (System clinical pharmacy team) ID composed recommendations. The SCrPT ID recommendations were based on current clinical guidelines, studies completed since the guidelines were last updated, and utilization of susceptibility data for more rare infection types. Alternatives for patient allergies were included as well as typical lengths of therapy. SCrPT (System clinical pharmacy team) ID is composed mostly of ID pharmacists and ID physicians. Recommendations were also reviewed and accepted by the Peri-op council. These recommendations will be added to the current Surgical Prophylaxis Guideline already approved by CommonSpirit Health P&T committee

RECOMMENDATION

Add the following open fracture antimicrobial prophylaxis recommendations to the CommonSpirit Health surgical antimicrobial prophylaxis guidelines:

Open Fracture (type I or II): Cefazolin (alt for cephalosporin allergy vancomycin)
Antibiotics should be discontinued 24 hours after successful wound closure

Open Fracture (type III no gross contamination): Ceftriaxone OR Gentamicin+Cefazolin or for allergy to cephalosporins Gentamicin+Vancomycin
Antibiotics should be continued for 72 hours after injury or not more than 24 hours after soft tissue coverage has been achieved

Open Fracture (type III with clostridial concern/farm exposure): same as type III plus Metronidazole or Penicillin G 2 MU IV Q 4 hours
Antibiotics should be continued for 72 hours after injury or not more than 24 hours after soft tissue coverage has been achieved

* If fresh or saltwater injury, consider piperacillin/tazobactam instead of ceftriaxone/gentamicin
** For all, if MRSA is a concern, consider adding vancomycin
*** For practical considerations, particularly in a delay getting into the OR, ceftriaxone is safer to redose immediately pre-op than gentamicin and thus favored.
**** Extended interval high dose aminoglycoside dosing is acceptable

Implementation Date Recommended implementation date is within 90 days of System P&T Committee approval

Oncology Clinical Institute (OCI) position statement: antimicrobial prophylaxis for targeted oncology treatments

OCI POSITION STATEMENTS ARE BEST PRACTICE RECOMMENDATIONS

Antimicrobial Prophylaxis for Targeted OncologyTreatments

Recommendations from the Oncology Clinical Institute

Background
Cancer patients have an increased risk of infection due to both their disease process and treatment. There is evidence to support the increased risk of specific infections in patients receiving select targeted agents. The use of prophylactic antimicrobials against herpes simplex, varicella zoster and *Pneumocystis jiroveci* pneumonia have proven effective in reducing the incidence of infection. The recommendations below are based on the NCCN Guidelines for the Prevention and Treatment of Cancer-Related Infections v3.2022. Consult NCCN Guidelines for specific recommendations regarding CMV surveillance and prevention strategies in select populations.

Recommendations

PJP = *Pneumocystis jirovecii* pneumonia ACV = acyclovir VZV = varicella zoster virus

Medication class	Medications	HSV/VZV Recommendations	PJP Prophylaxis
Ubiquitin-proteasome pathway inhibitors	Bortezomib (Velcade) Carfilzomib (Kyprolis) Ixazomib (Ninlaro)	**Recommend** VZV prophylaxis with valacyclovir during active therapy with proteasome inhibitors and 6 weeks* after the last dose. Risk of herpes zoster infection is 10-22%.	Not applicable
CD38 target	Daratumumab (Darzalex) Isatuximab (Sarclisa)	**Recommend** HSV/VZV prophylaxis within 1 week after starting treatment and continued for 3 months following treatment. Risk of herpes zoster infection is 2-5%.	**Consider** PJP prophylaxis
CD52 target	Alemtuzumab (Campath)	**Recommend** HSV/VZV prophylaxis minimum of 2 months after completion of alemtuzumab and until CD4 ≥ 200 cells/mcL	**Recommend** PJP prophylaxis minimum of 2 months after completion of alemtuzumab and until CD4 > 200 cells/mcL
CD319 target	Elotuzumab (Empliciti)	**Recommend** HSV/VZV prophylaxis	Not applicable
CCR4 target	Mogamulizumab (Poteligeo)	**Recommend** HSV/VZV prophylaxis	**Recommend** PJP prophylaxis
Alkylating agents	Temozolomide (Temodar) + radiation	Not applicable	**Recommend** PJP prophylaxis for duration of treatment

Medication class	**Medications**	**HSV/VZV Recommendations**	**PJP Prophylaxis**
PI3K Inhibitors	Copanlisib (Aliqopa) Idelalisib (Imbruvica) Duvelisib (Copiktra) Alpelisib (Piqray)	Not applicable	**Recommend** PJP prophylaxis
Janus kinase (JAK) inhibitors	Ruxolitinib (Jakafi) Fedratinib (Inrebic	**Consider** HSV/VZV prophylaxis	**Consider** PJP prophylaxis depending on additional risk factors
CD30 target	Brentuximab (Adcetris)	**Consider** HSV/VZV prophylaxis	**Consider** PJP prophylaxis
CD19 CD3 target	Blinatumomab (Blincyto)	**Consider** HSV/VZV prophylaxis	**Consider** PJP prophylaxis
Bruton tyrosine kinase (BTK) inhibitors	Acalabrutinib (Calquence) Ibrutinib (Imbruvica) Zanubrutinib (Brukinsa)	**Consider** HSV/VZV prophylaxis depending on additional risk factors	**Consider** PJP prophylaxis depending on additional risk factors
CD20 target	Obinutuzumab (Gazyva) Ofatumumab (Arzerra) Rituximab	**Consider** HSV/VZV prophylaxis	**Consider** PJP prophylaxis if concomitant therapy increases risk of PJP (eg, prednisone >20mg daily x 4 weeks)
Purine analogs	Fludarabine (Fludara) Cladribine (Leustatin)	**Consider** HSV/VZV prophylaxis during active therapy	**Consider** PJP prophylaxis during chemotherapy and continued at least 6 months after treatment and until CD4 >200
mTOR inhibitors	Everolimus (Afinitor) Sirolimus (Rapamune) Temsirolimus (Torisel)	Not applicable	**Consider** PJP prophylaxis depending on additional risk factors

Dosing Regimens

PJP Regimens	**Antiviral Regimens**
TMP/SMX DS 1 tab po TIW ***OR***	Acyclovir 400-800 mg po BID **OR**
TMP/SMX SS 1 tab po QD	Valacyclovir 500 mg po BID (preferred over oral ACV for VZV)
*TMP/SMX is most effective agent for PJP prophylaxis **Dose modification is required for impaired renal function CrCl < 30 ml/min = Reduce 1 DS tab TIW to 1 SS tab TIW	*There is variability in prophylactic doses of ACV used in clinical trials in patients with hematologic malignancies. **Dose modification is required for impaired renal function CrCl < 25 ml/min = Acyclovir 200 mg po BID CrCl < 30 m/min = Valacyclovir 500 mg po QD

TMP/SMX = trimethoprim-sulfamethoxazole
** Consider TMP/SMX desensitization, dapsone, or aerosolized pentamidine for patients intolerant to TMP/SMX

CSH SYSTEM PHARMACY AND THERAPEUTICS COMMITTEE DECISION BRIEF

May 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		
teclistamab-cqyv	Multiple myeloma		TECVAYLI		Restriction criteria: 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
teplizumab	Type 1 diabetes		TZIELD		Restriction criteria: 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
tremelimumab-actl	Unresectable hepatocellular carcinoma and non-small cell lung cancer		IMJUDO		Restriction Criteria: Outpatient setting for FDA-approved indication subsequent to insurance approval or prior authorization	Within 90 days of System P&T Committee approval
mirvetuximab soravtansine-gynx	Ovarian cancer		ELAHERE		Restriction Criteria: 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
nitazoxanide	Cryptosporidiosis			Nitazoxanide oral solution		Within 60 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		

			Nitazoxanide tablets		Restriction Criteria: For the treatment of Cryptosporidiosis
					• immunocompetent patients/non-HIV with non-self-limiting diarrhea
					  ○ nitazoxanide 500 mg BID x 3 days
					• in patients with HIV, who have persistent symptoms despite ART
					  ○ nitazoxanide 500-1000 mg orally twice daily for up to 14 days
					  ○ Once the diarrhea has resolved, treatment can be discontinued.
					• other immunocompromised (non-HIV) hosts in which reduced immunosuppression is not feasible
					  ○ nitazoxanide can be trialed for Cryptosporidiosis in doses up to 500-1000 mg BID x 14 days
						Within 90 days of System P&T Committee approval

adagrasib	advanced or metastatic non-small cell lung cancer			KRAZATI		Within 60 days of System P&T Committee approval
olutasidenib	acute myeloid leukemia			REZLIDHIA		Within 60 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		
deucravacitinib	moderate-to-severe plaque psoriasis			SOTYKTU		Within 60 days of System P&T Committee approval
bexagliflozin	Type 2 diabetes			BRENZAVVY	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
injectable levetiracetam	Seizures			Levetiracetam premade bags for infusion		Within 90 days of System P&T Committee approval
		Levetiracetam intravenous vials			Doses up to 1.5 gm should be administered via IV push; considerations of IV push administration for doses exceeding 1.5 gm can be determined at the market level based on operational considerations, etc.	Within 90 days of System P&T Committee approval
EENT DRUGS, MISCELLANEOUS ANTIALLERGIC AGENTS CORTICOSTEROIDS (EENT) LOCAL ANESTHETICS (EENT) VASOCONSTRICTORS	Throat and nasal topical medications for various uses	PHENASEPTIC				Within 90 days of System P&T Committee approval
		CHLORASEPTIC				Within 90 days of System P&T Committee approval

CommonSpirit

CSH System Pharmacy and Therapeutics (P&T) Committee
Meeting Date: May 18, 2023
DECISION BRIEF

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
ANTI-INFEFCTIVES (EENT) **MOUTHWASHES AND GARGLES** **LOCAL ANESTHETICS (EENT)** **DRUGS (EENT)**			Topical cocaine 4% solution		Restriction Criteria: Restrict for refractory epistaxis in patients w/o cardiac history	Within 90 days of System P&T Committee approval
		Multiple products, no changes			Link to all class representative formulary status data	Within 60 days of System P&T Committee approval
Fluorescite/ fluorescein sodium intravenous injection	dye for cystoscopy	Fluorescite/ fluorescein sodium intravenous injection				Within 90 days of System P&T Committee approval
Indigotindisulfonate sodium/ indigo carmine injection	dye for intraoperative cystoscopy		Indigotindisulfonate sodium/ indigo carmine injection		Restriction criteria Use as a second line agent for cystoscopy when fluorescein sodium is not available. Fluorescein sodium is the formulary preferred dye for cystoscopy.	Within 90 days of System P&T Committee approval
DIAGNOSTIC AGENTS	Multiple diagnostic uses	Multiple products, no changes			No changes, Link to formulary status data	Within 60 days of System P&T Committee approval
HEAVY METAL ANTAGONISTS	Multiple uses	Multiple products, no changes				
LOCAL ANESTHETICS (PARENTERAL)	Local anesthesia	Multiple products, no changes				
OXYTOCICS	Stimulation of labor	Multiple products, no changes				
PHARMACEUTICAL AIDS	Medical device, bulk	Multiple products, no changes				

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
	product or supply					

THERAPEUTIC INTERCHANGES

Bexagliflozin	
Ordered	**Provided**
Bexagliflozin 20mg	Empagliflozin 10mg

Policy template: controlled substance management – acute care

TEMPLATE
COMMONSPIRIT POLICY TEMPLATE FOR LOCAL USE/ADOPTION

FACILITY NAME
Policy and Procedure

SUBJECT: Controlled Substance Management
☐ National/System Offices ☒ Acute Care Facilities ☐ Non-Acute Care Facilities

DEPARTMENTS: Pharmacy, Nursing, and Providers.

POLICY: Controlled Substance Management

PURPOSE: To establish guidelines for the procurement, receiving, dispensing, security and record keeping of all controlled substances and reduce the potential for drug diversion at CommonSpirit Health Hospitals.

DEFINITIONS:

DEA Registrant: The officer of the organization who signed, or is authorized to sign, the most recent application for DEA Registration renewal. Often, this is the same person who grants Power of Attorney to allow other individuals to order controlled substances via DEA form 222 and/or Controlled Substance Ordering System (CSOS).

Signer Power of Attorney (POA): Once on file with the DEA, the Pharmacist-in-charge (PIC) will be authorized to sign and communicate to the DEA on the hospital officer's behalf. A signer POA does not authorize "ordering". If the PIC with this POA leaves the organization, the hospital should revoke the PIC's "signers" POA on file with the DEA.

Ordering Power of Attorney (POA): Pharmacist with the ordering POA is authorized to order Schedule II controlled substances (CIIs) for the registrant (i.e. hospital) via DEA form 222 for patient use pursuant to an order by a provider. This POA is issued by the DEA Registrant (officer of the organization) and remains valid in the event the hospital officer leaves the organization. All Power of Attorney authority and paperwork are maintained on site at the pharmacy. There may be variability based on jurisdiction. If that exists, retain documentation.

CSOS Coordinator: The principal coordinator is required for each DEA Registration number enrolled in the CSOS program. Only one Principal Coordinator and one Alternate Coordinator may be enrolled in CSOS for any one DEA Registration number. Once on file with the DEA, the coordinator is authorized to sign and communicate to the DEA on the Registrant's behalf. The coordinator can also have responsibility for ordering through a POA.

CSOS Power of Attorney (POA): Any individual authorized to electronically order CII controlled substances via CSOS by the registrant or the CSOS principal/alternate coordinator. If the hospital officer leaves the organization, the POAs and DEA applications signed by the officer continue to be valid

Discrepancy resolution: Occurs when the cause of the controlled substance discrepancy is known and the cause accounts for the controlled substance variance.

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Drug Diversion: Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.[1] Prescription drug diversion may occur at any time as prescription drugs are distributed from the manufacturer to wholesale distributors, to pharmacies, or to the patient.[2] Members of the medical profession may also be involved in diverting prescription drugs for recreational purposes, relief of addictions, monetary gain, self-medication for pain or sleep, or to alleviate withdrawal symptoms.

PROCEDURE:

1) **POWER OF ATTORNEY (POA)**: issued and signed by the registrant (hospital officer). If the hospital officer leaves the organization, the POAs and DEA applications signed by the officer continue to be valid. All Power of Attorney authority and paperwork are maintained on site at the pharmacy. There may be variability based on jurisdiction. If that exists, retain documentation.
2) Pharmacist-in-charge (PIC) determines the maximum number of pharmacists who will be granted POA authority to execute orders for CIIs.
   - **i)** A POA may be granted to other pharmacy staff as allowed by law. https://www.deaecom.gov/poa.html
   - **a)** Signers POA
     - **(1)** The officer of each organization or each pharmacy should be the current signatory on the DEA application. The officer of each corporation over the pharmacy may delegate the signatory by completing the power of attorney form naming the pharmacy individual who is authorized to sign the applications on behalf of the pharmacy.
     - **(2)** All required fields of the Hospital POA form are completed legibly
     - **(3)** The hospital officer and the PIC review and sign the POA
     - **(4)** File a copy of the completed POA within the hospital pharmacy for 2 years or as stipulated by state requirements
     - **(5)** Submit the signers POA to the DEA if required
     - **(6)** Once on file with the DEA, the PIC is authorized to sign and communicate with the DEA on the hospital's behalf.
   - **ii)** Ordering POA
     - **(1)** The registrant is required to sign the POA designating the individual to sign DEA Form 222 on behalf of the pharmacy.
     - **(2)** Complete all required fields of the Hospital POA form legibly.
     - **(3)** The POA applicant and the PIC review and sign the POA
     - **(4)** File a copy of the completed POA within the hospital pharmacy
     - **(5)** Once on file with the DEA, the POA applicant is authorized to order CIIs on behalf of the hospital.
   - **b)** Revocation of POAs
     - **i)** The revocation section of the ordering POA must be completed within seven (7) days of an individual's departure.
     - **ii)** A copy of the revoked POA should be provided to the departing individual.
     - **iii)** File the revoked POA within the hospital pharmacy for a minimum of two (2) years (or INSERT time period if longer).
3) **ORDERING CONTROLLED SUBSTANCES**
   - **a)** Either a Drug Enforcement Administration (DEA) Form 222 or its electronic DEA form equivalent is required to order CIIs.
     - **i)** Each DEA form 222 must be signed and dated by the person authorized to sign a

registration application or a person granted power of attorney to sign a Form 222. https://www.deadiversion.usdoj.gov/online_forms_apps.html

ii) Each Controlled Substance Ordering System (CSOS) is completed electronically by the person authorized to sign a registration application or a person granted power of attorney to sign via CSOS.

4) **RECEIVING CONTROLLED SUBSTANCES**

a) Upon receipt, the package is confirmed sealed and the count, condition, and identification of the controlled substances are verified by a pharmacist, or pharmacy technician where permitted by law. *Ideal standard is the receipt of the controlled substances by an individual who did not place the order.

i) The Department of Pharmacy will maintain documentation of the receipt of all controlled substances, depending on state law.

b) The invoice is checked against the controlled substances received, dated and signed by the licensed person receiving the controlled substances. If received by a pharmacy technician, the invoice must be reviewed and co-signed by a pharmacist.

i) Invoices for CIIs will be maintained separately from all other records.

ii) Invoices for Schedules III, IV, and V controlled substances (CIII-CV) will be maintained in a single file separately from all other records.

c) The pharmacist will fill out the DEA Form 222 for all CIIs, indicating the actual number of packages received and date received, sign the form or complete electronically if using CSOS and make a copy to retain.

i) Executed DEA Form 222's will be maintained in a file separately from all other records.

ii) A copy of the supplier's invoice may be attached to the DEA Form 222.

d) The controlled substances will be immediately stored in the locked controlled substance vault and/or in the secure vault (CSM or equivalent) of the automated dispensing machine (ADM); or under constant surveillance. .

e) Upon stocking controlled substances into the pharmacy ADM, a Stocking Receipt will be created and used to reconcile controlled substances received against the invoice.

i) After reconciliation, attach the Stocking Receipt to the dated and signed invoice.

ii) Any discrepancies in shipment must be identified immediately and reported (same day) to the wholesaler and the Pharmacist-in-Charge.

5) **STORAGE OF CONTROLLED SUBSTANCES**

a) The PIC or designee will restrict access to authorized personnel to areas in which controlled substances are stored.

i) Within the Department of Pharmacy, controlled substances will be stored in a securely locked area.

(1) Access to this area is available only to registered pharmacists employed or contracted by the hospital.

(2) A pharmacy technician assisting in the preparation and dispensing of controlled substances may be granted access to this area.

ii) Controlled substances that are kept at the nursing unit will be secured in the ADM or other securely locked cabinet.

b) The PIC or designee will perform monthly inspections to ensure security of controlled substances (or in accordance with state regulation).

6) **INVENTORY OF CONTROLLED SUBSTANCES**:

a) The Department of Pharmacy will maintain a perpetual inventory system through the ADM for all controlled substances.

b) Each time controlled substances are received, dispensed, returned to the pharmacy, or otherwise removed from or added to the inventory, the transaction will be recorded on

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the perpetual inventory through the ADM, including:

i) Name and strength of controlled substance

ii) Date

iii) Amount

iv) Area dispensed to or received from

v) Balance on hand will be verified through the ADM

c) A physical inventory of controlled substances in the pharmacy is recommended monthly, but required to be performed quarterly, by two licensed pharmacy staff members.

i) The physical inventory will be compared to the computed balance in the perpetual inventory and any discrepancies will be reconciled.

ii) The PIC must be notified if a discrepancy is unresolved.

d) A new physical inventory of all controlled substances within the facility will be taken at least every two (2) years as required by DEA regulations.

i) The physical inventory report will be dated, timed and signed by two licensed staff members with at least one as a pharmacist.

(1) The biennial inventory will include controlled substances:

(a) Stocked in the pharmacy

(b) Stocked in the ADMs throughout the facility

(c) Expired controlled substances removed from stock but still in control of the registrant

(d) Any other controlled substances under the Pharmacy Department's control

ii) When a medication not previously listed as a controlled substance is scheduled, or a controlled substance is rescheduled, the controlled substance will be inventoried as of the effective date of scheduling or change in scheduling.

7) **DISPENSING OF CONTROLLED SUBSTANCES**:

a) Controlled substances will be dispensed from the pharmacy to the nursing units through the ADM.

i) In the event that a controlled substance cannot be stocked in an ADM, such items will be supplied to the nursing station as individual patient doses and must be secured.

b) Controlled substances will be delivered by licensed pharmacy personnel to the nursing unit and stocked in the ADM.

i) The process will be a validated process that mitigates the risk for diversion.

c) Individual doses of controlled substances dispensed by the pharmacy will be delivered by authorized pharmacy personnel to the patient care unit.

i) The licensed individual (within their scope of practice) receiving the dose will sign the delivery form.

d) The PIC or designee will review controlled substance dispensing and restocking along with ADM return transactions reconciling any discrepancies using the ADM reconciliation/exception report at minimum weekly.

i) ADM reconciliation/exception reports will be maintained onsite by the pharmacy for a minimum of two (2) years or as defined by policy.

8) **CONTROLLED SUBSTANCE DISCREPANCIES:**

a) Any discrepancies in the controlled substance count will be investigated within 24 hours and an action plan regarding reconciliation within 72 hours (specify facility process) will be completed barring any extenuating circumstances (e.g., investigate healthcare staff on vacation post event). If extenuating circumstances arise, the division CNO and division pharmacy VP will be notified within 72 hours of the incident.

b) Staff Responsibilities

i) When notified by the ADM system of a controlled substance discrepancy, the user

should perform a witnessed cycle count, if necessary, to validate/correct the count.
- ii) The user and a witness should document/resolve the discrepancy by entering the findings/reason for the discrepancy in the "document discrepancy area" of the ADM (if the reason for the discrepancy is known).
- iii) A discrepancy resolution is the known cause of the discrepancy and accounts for the controlled substance variance (i.e. error in the counting or removal). If staff is unable to determine the cause of a discrepancy, the discrepancy should be left unresolved and the pharmacy should be notified to assist with the investigation.

c) Nurse Manager's (or designee) Responsibilities
- i) The Nurse Manager (or designee) will review the discrepancies for each patient care unit to ensure the proper use of the ADM system.
- ii) It is the responsibility of the Nurse Manager to monitor ALL discrepancies for appropriate resolutions.

d) Chief Nursing Officer (CNO) Responsibilities
- i) The CNO will receive a monthly report of all discrepancies and resolutions, in addition to the Statistical Usage Report (i.e. Anomalous Usage Report).
- ii) The CNO will follow up with each Nurse Manager (or designees) to ensure appropriate and timely resolution of all discrepancies.

e) Pharmacy's Responsibilities
- i) The PIC, or designee will monitor and review all discrepancies to ensure appropriate resolution.
- ii) The PIC or designee will follow up with the Nurse Manager or designee on all discrepancies which are unresolved or resolved inappropriately.
- iii) For discrepancies inappropriately documented in the ADM system, the pharmacy will maintain manual documentation of the investigation/resolution.
- iv) Discrepancies resulting in a significant loss of a controlled substance will be reported to the DEA, Board of Pharmacy and any other regulatory agency as required by state law by the PIC or designee in accordance with State and Federal regulations. Prior to reporting to the DEA and Board of Pharmacy, the PIC or (designee) will notify the CEO or designee, the Chief Nursing Officer (or designee), Chief Medical Officer (or designee), the system VP of Pharmacy Enterprise and the division VP of Pharmacy Enterprise. The report will be made within 48 hours of discovery.

f) Joint Responsibilities
- i) For discrepancies which are unresolved or resolved inappropriately, the PIC, CNO and Nurse Manager will work in collaboration to resolve appropriately in a timely manner.

9) ADMINISTRATION OF CONTROLLED SUBSTANCES

a) At the time the dose is needed for administration, the administering nurse will remove the medication from the ADM.

b) The administering nurse must document administration of each dose of controlled substances on the Medication Administration Record or as otherwise appropriate in the medical record.

c) If the package size removed from the ADM is *greater than the ordered dose*, the remaining controlled substance must be wasted in a timely manner in the presence of a second licensed person who serves as a witness in the ADM.

10) RETURNING OF CONTROLLED SUBSTANCES

a) Unused and unopened controlled substances may be returned to the ADM with a witness. The returned item and the printed receipt (if provided) will be placed in the secured ADM return bin or (INSERT if defined by the pharmacy).

b) Individually dispensed doses of controlled substances not stocked in an ADM, will be

returned to the pharmacy (INSERT if specific process for your facility).

c) Returned controlled substances will be placed in the controlled substance vault and/or in the secure vault (CSM or equivalent) and returned to stock through the pharmacy ADM as appropriate.

d) No open or partially used syringes, vials, or other medication forms of controlled substances to be returned to the pharmacy.

11) WASTING OF CONTROLLED SUBSTANCES
- i) The wastage will be recorded through the ADM to include:
  - **(1)** Patient name
  - **(2)** Controlled substance being wasted
  - **(3)** Dose given
  - **(4)** Amount unused and/or wasted
- ii) The wasted controlled substance is to be documented at the time it is physically wasted.
- iii) A controlled substance is not considered wasted until the waste is documented and the controlled substance has been destroyed.
- iv) Reconciliation of waste will be monitored through the ADM (unreconciled waste report) or manually.
- v) A report of unreconciled waste will be sent, as necessary, to the unit manager for investigation.
  - **(1)** The unit manager will provide follow up on each unreconciled waste to the PIC or designee.
- vi) Anesthesia must complete the post-case reconciliation of all transactions from the anesthesia workstation/or manual alternative.
  - **(1)** Unused and unopened medications may be returned to the ADM
  - **(2)** Partially administered doses must be wasted as described above
- vii) Procedural areas that waste controlled substances outside of the ADM must have a daily reconciliation process that validates documentation of a witness to the waste.

12) CONTROLLED SUBSTANCE ACCESS:

a) Keys for refrigerator lock boxes will be stored in and accessed through the ADM.

b) Access to the ADM will be issued by the pharmacy department

c) Monitoring of the ADM access will be reconciled with terminations, at a minimum, on a monthly basis.

13) EXPIRED CONTROLLED SUBSTANCES:

a) A pharmacist (or other pharmacy personnel as allowed by state regulations) will routinely check all ADMs and the controlled substance vault and/or in the secure vault (CSM or equivalent) for the presence of expired controlled substances.

b) Controlled substances require a witness to remove the expired medication or validation through the CSM.

c) Expired controlled substances will be removed from the ADM using the "expired/recall" function.

d) Expired controlled substances in the controlled substance vault and/or in the secure vault (CSM or equivalent) will be removed from the vault and processed as an expired medication. *Expired compounded controlled substances will be destroyed and documented on Form 41.

e) Expired controlled substances will be returned to the controlled substance vault and/or in the secure vault (CSM or equivalent) designated expired area and will be recorded through the ADM system.
- i) Expired CIIs will be stored separately from CIII-V.

f) Expired controlled substances will be transferred to a DEA registered reverse distributor

who handles the disposal of controlled substances.

g) The reverse distributor will issue an official DEA Form 222 or the electronic equivalent for the transfer of the controlled substances.

h) The pharmacy will maintain a record of distribution that lists:
- **i)** Controlled substance name
- **ii)** Dosage form
- **iii)** Strength
- **iv)** Quantity
- **v)** Date transferred

i) The pharmacy will compare the controlled substances listed on the DEA Form 222 to the expected list of controlled substances to be transferred. Any discrepancies will be reconciled.

j) The pharmacy will compare the report of CIII-V on the vendor return report to the expected list of controlled substances to be transferred. Any discrepancies will be reconciled.

14) MONITORING OF CONTROLLED SUBSTANCES

a) The Pharmacy Director, PIC or designee will monitor, review and evaluate controlled substance usage patterns, individual activity reports, statistical usage reports and discrepancies. This can be done in one of two ways:
- **i)** Diversion detection software
- **ii)** Manual monitoring process. If a manual process is used, the frequency is outlined in the table below.

Audit Type	Frequency
Statistical Usage Report	Monthly
Specific Activity Reports Random selections for each nursing unit	Monthly
Waste	Monthly
Discrepancies	Weekly

b) Diversion monitoring reports will also be sent to the Nurse Manager (or designee) for investigation and follow up or when pharmacy staff require further information.

c) When requested by pharmacy staff, the Nurse Manager will review and investigate and report all findings to the Pharmacy Director, PIC or Designee within fourteen (14) days; if no findings report as none.

d) A record of the review will be maintained for two (2) years or as defined by policy onsite by the pharmacy.

e) A monthly report of all purchases of controlled substances from all vendors will be compared to the report of the controlled substances stocked in the pharmacy vault. Any discrepancies will be reconciled.

f) The Pharmacy Director, PIC or designee will complete a monthly controlled substance compliance audit.

15) DIVERSION OF CONTROLLED SUBSTANCES

a) No prescription medication or controlled substance may be sold, transferred, or otherwise distributed, except as allowed by law, and as authorized by written policy or by the appropriate individual charged with such responsibility. All employees must strictly adhere to all laws, regulations, and hospital policies & procedures with regard to procurement, distribution, storage, administration, documentation and destruction of

prescription medications and controlled substances.

b) The hospital has a responsibility to investigate and intervene when there is a report and/or suspicion of drug diversion. The hospital has a multidisciplinary process to respond to reported or suspected diversions. Investigations should be accurate, detailed, objective and specific. Documentation of the investigation is imperative as well as confidential and revealed only to the appropriate authorities.
- **i)** The multidisciplinary process may include designated representatives from the following areas:
  - **(1)** Pharmacy Administration
  - **(2)** Nursing Administration
  - **(3)** Human Resources Administration
  - **(4)** Risk Management
  - **(5)** Hospital Administration
  - **(6)** Security (ad hoc)
  - **(7)** Medical Staff Administration (ad hoc)
  - **(8)** Advanced Practice Provider lead (ad hoc)
  - **(9)** Legal (ad hoc)
- **ii)** Roles and Responsibilities
  - **(1)** Pharmacy Administration
    - **(a)** The Pharmacy Director, PIC or designee will monitor, review and evaluate controlled substance usage patterns, individual activity reports, statistical usage reports and discrepancies.
    - **(b)** Retrospective audits of a user may be conducted in order to identify patterns and/or discrepancies.
    - **(c)** The Pharmacy Director, PIC or designee may participate in investigative interviews involving suspected diversion. In addition, the Pharmacy Director is responsible for reporting all theft/loss or suspicion of drug diversion to the State Board of Pharmacy and the DEA as appropriate.
  - **(2)** Nursing Administration
    - **(a)** The CNO or designee will assist with diversion investigation and chart review as needed.
    - **(b)** The CNO/designee will act as liaison with nursing personnel, including registry.
    - **(c)** In addition, the CNO is responsible for ensuring regulatory reporting to the appropriate licensing board for all known or suspected drug diversions or unexplained losses of controlled substances.
  - **(3)** Human Resources Administration:
    - **(a)** The Director of Human Resources or designee will facilitate investigative interviews with the employees, and act as liaison with the appropriate unions for represented employees.
    - **(b)** In addition, they will be responsible for all employment issues and maintaining all pertinent documentation in the employee's record.
  - **(4)** Risk Management
    - **(a)** The Risk Manager will assist with diversion investigation and chart review as needed in collaboration with the CNO and COO.
    - **(b)** The Risk Manager is responsible for required regulatory reporting of any adverse events related to a known or suspected drug diversion.
  - **(5)** Hospital Administration
    - **(a)** Hospital administration will assist in the review and resolution of all known or suspected incidents of drug diversion.

(6) Security Staff
- (a) Security will provide assistance when a request is made by a member of the Drug Diversion Team.
- (b) The Director of Security or their designee may be requested to assist with, and conduct interviews or investigations of drug diversions.
- (c) At no time will security officers force an employee to submit to a search or touch the employee without their consent.
  - (i) If there is reasonable suspicion to believe that a particular individual may be in possession of materials in violation of this policy, security officers may conduct a search of the employee (with their consent), their work area, lockers, personal items, and vehicle if the vehicle is parked on property owned and/or operated by CommonSpirit Health, and with the employee or owner's consent.
  - (ii) All searches shall be witnessed by a second party.

(7) Medical Staff Administration (ad hoc)
- (a) Information for any suspected incidence of drug diversion involving a member of the medical staff will promptly be reported to Medical Staff Administration for appropriate follow up/resolution by the President of the Medical Staff in accordance with the Medical Staff Bylaws, Rules and Regulations, and Medical Staff Policy. Appropriate reporting will be done to any applicable state or licensing board

iii) Suspected Drug Diversion Investigation

(1) All employees are expected to report knowledge/suspicion of drug diversion
- (a) Employees should report any known or suspected drug diversion incidents to their manager/director.
- (b) Department managers/Directors will notify the Pharmacy Director or designee for further follow up.

(2) The Pharmacy Director or designee will initiate a preliminary investigation.
- (a) The Pharmacy Director or designee may also initiate an investigation based on the ongoing monitoring and auditing of controlled substance usage performed by the pharmacy.

(3) If, after review of the preliminary investigation, drug diversion is suspected or cannot be excluded as a possibility, the Pharmacy Director or designee will initiate the multidisciplinary drug diversion investigation process

(4) An employee suspected of drug diversion may be placed on administrative leave while the investigation is in process. No decision regarding employment is made until the investigation has been completed and management and Human Resources have been consulted. Suspected diversion involving a member of the medical staff will be reported to Medical Staff Administration

(5) An investigation of the suspected diversion incident will be conducted and will include, but not limited to, review of controlled substance dispensing records, medication administration records (MARs), orders, nursing notes, records of waste, pain assessments, and staff interviews.

(6) Once the investigation is completed, for nursing associates, the nursing manager, in consultation with the CNO and Human Resources, will make the decision regarding any disciplinary action, up to and including termination. For pharmacy associates, the pharmacy director, in consultation with the Division VP of Pharmacy and Human Resources, will make the decision regarding any disciplinary action, up to and including termination, in consultation with Human Resources. For medical staff, the President of the Medical Staff will follow up with

members of the medical staff in accordance with the Medical Staff Bylaws, Rules and Regulations, and Medical Staff Policy.

(7) The hospital will report all known or suspected cases of drug diversion to the appropriate licensing board. Incidents of known or suspected drug diversion may also be reported to local law enforcement authorities as appropriate.

16) **REPORTING OF LOSS OR THEFT OF CONTROLLED SUBSTANCES**
- **a)** Discovery of theft or significant loss of a controlled substance must be reported immediately (within 24 hours of discovery) to the local DEA field office and Board of Pharmacy (as required by each state's Board of Pharmacy) by the Pharmacy Director or designee in accordance with State and Federal regulations.
  - **i)** Prior to reporting to the DEA and Board of Pharmacy, the PIC or (designee) will notify the CEO (or designee), the Chief Nursing Officer (or designee), the Chief Medical Officer (or designee), the system VP of Pharmacy Enterprise and the division VP of Pharmacy Enterprise.
- **b)** When determining whether a loss is significant, the following factors should be considered:
  - **i)** The actual quantity of controlled substances lost;
  - **ii)** The specific controlled substance lost;
  - **iii)** Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substance.
  - **iv)** A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and if known.
  - **v)** Whether the specific controlled substances are likely candidates for diversion.
  - **vi)** Local trends and other indicators of the diversion potential of the missing controlled substance.
- **c)** A DEA Form 106 will be completed regarding such theft or loss.
  - **i)** If, after the initial notification to the DEA, the investigation of the theft or loss determines no such theft or loss of controlled substance occurred, a DEA Form 106 does not need to be filed. However, the DEA must be notified in writing of this fact in order to resolve the initial report and explain the decision to not file a DEA form 106. https://www.deadiversion.usdoj.gov/21cfr_reports/theft/DEA_Form_106.pdf
- **d)** Thefts will be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.
- **e)** Loss or theft of controlled substances will also be reported to the state Board of Pharmacy as required.
- **f)** Significant losses will be reported in accordance through the Event Reporting System.

REFERENCES:

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- Thompson. (2011). *Controlled Substance Handbook*. Washington, DC: Thompson Publishing Group.
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- Clark, J. et al (2022). ASHP Guidelines on Preventing Diversion of Controlled Substances. Am J Health-Syst Pharm. 79(24):2279-2306. https://doi.org/10.1093/ajhp/zxac246
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- New, K. (2020). Drug diversion regulatory requirements and best practices. Patient Safety and Quality Health Care. Retrieved from https://www.psqh.com/analysis/drug-diversion-regulatory-requirements-and-best-practices/

APPROVERS/DATE APPROVED:
HR Policy Committee – (1/27/2023)
Pharmacy Enterprise Executive Council (PEEC) - (04/19/2023)
Nursing Executive Council (NEC) - (04/27/2023)
System Pharmacy Procurement and Operations Team (SPPOT) - (05/04/2023)
System Pharmacy and Therapeutics (P&T) Committee - (05/18/2023)

EFFECTIVE DATE: 07/01/2023

TEMPLATE
COMMONSPIRIT POLICY TEMPLATE FOR LOCAL USE/ADOPTION

Guideline: retail pharmacy own use

COMMONSPIRIT HEALTH
ADMINISTRATIVE GUIDELINE

SUBJECT: Pharmaceutical Own Use Guidance	
GUIDELINE NUMBER: (To be assigned by Policy System Admin)	**EFFECTIVE DATE:** (Date Approved)

X National/System Offices X Acute Care Facilities X Non-Acute Care Facilities

AFFECTED AREAS OR DEPARTMENTS
Any hospital pharmacy that will be purchasing pharmaceuticals for an associated retail pharmacy for patients that qualify as 'Own Use' as defined by the Nonprofit Institutions Act ("NPIA") exemption to the Robinson-Patman Act and the associated court cases.

KEY WORDS
"Own Use"

OBJECTIVE
Non-profit healthcare organizations that purchase pharmaceuticals and other medical supplies receive preferential pricing based on their non-profit status and are generally precluded from reselling those items with certain exceptions. The NPIA permits nonprofit entities that obtain pharmaceuticals or other supplies at preferential prices to dispense and resell the drugs or supplies only for their "Own Use".

This guidance will assist pharmacists in determining whether a pharmaceutical may be considered "Own Use" when dispensed and resold to patients and third parties.

GUIDELINE:
1) If a pharmacy purchases pharmaceuticals at both preferential pricing and commercial pricing, the pharmacy must maintain documentation that pharmaceuticals purchased at the preferential pricing are only dispensed and sold to qualifying purchasers.
2) Before a pharmaceutical is dispensed or sold, the pharmacist must determine whether the sale qualifies as Own Use. A reconciliation may be completed at the end of each month and sales that do not qualify as Own Use must be purchased on the retail class of trade account.
3) Controlled substances do not qualify for Own Use and are excluded from being purchased for Own Use purposes.
4) Pharmaceuticals that are classified as Limited Distribution Drugs (LDDs) are excluded from being purchased for Own Use purposes.
5) The use of the term "dependent" in the following chart means (1) a dependent for IRS income tax purposes, or (2) an eligible dependent under the enrollee's health plan. A person is not a dependent if the person does not satisfy one of these two definitions, even if the person is a family member and living in the household.
6) The pharmacy is permitted to dispense and resell a pharmaceutical to non-Own Use entities on an emergency basis for humanitarian purposes.
7) Retail pharmacies that are part of the 340B program (i.e. registered with HRSA as a shipping address under the Covered Entity that is subject to the GPO prohibition and must purchase on the WAC and 340 B purchasing accounts) are excluded from purchasing under Own

Use. Retail pharmacies that are 340B contract pharmacies to one or more 340B Covered Entities may purchase under Own Use provided there are separate wholesaler accounts for the pharmacy's Own Use purposes and processes are in place to prevent a prescription from qualifying for Own Use if that same prescription qualifies under 340B.
8) The pharmacy is required to comply with any state law restrictions governing dispensation and resale of a pharmaceutical that is more stringent than the federal laws and regulations. Sites should consult with local legal counsel for analysis of state law restrictions specific to their practice situation.
9) The pharmacy may also be limited in the resale of a pharmaceutical if a group purchase organization's contract expressly limits the pharmaceutical resale for Own Use as defined in the *Abbott Laboratories* case.
10) The following chart provides general guidelines for permitted and prohibited resale of pharmaceuticals. If a particular sale is not listed as permissible, it should not be considered Own Use.

Drugs To Be Dispensed/Sold To:	Permitted	Not Permitted (Except for a Medical Emergency)
Inpatients, outpatients, and ER patients for personal use by such individuals as part of the individual's treatment while on the hospital's premises.	X	
Inpatients, outpatients, and ER patients for personal use by such individuals off of the premises, when administered upon discharge provided that the take-home dispensation is for a limited and reasonable time and is a continuation of or supplement to the individual's treatment in the hospital.	X	
Family members of inpatients, outpatients, or ER patients, for the family member's personal use (and not the patient).		X
Former or discharged patients NOT in a continuing physician/patient relationship with the hospital, (except if administered upon discharge for a limited and reasonable time and as a continuation of or supplement to the individual's treatment in the network entity. See above.)		X
Former or discharged inpatients, outpatients and ER patients requesting refills or renewal of a prescription which was originally given when the individual was a patient at the hospital.		X
Employees, solely for personal use by such employees or their dependents. (This includes an employee who is on a leave of absence, but excludes all former employees See below.)	X	
Non-Employee Professionals, including a special duty nurse and pastoral care chaplain, working at the hospital, solely for personal use by such non-employee professionals or their dependents.	X	
Students and residents assigned to the hospital, solely for personal use by such students or their dependents.	X	

Drugs To Be Dispensed/Sold To:	Permitted	Not Permitted (Except for a Medical Emergency)
Volunteers working at the hospital, solely for personal use by such volunteers or their dependents.	X	
Contract workers assigned to work at the hospital, solely for personal use by such contract workers or their dependents, provided the contract worker's job activities are intimately involved with the charitable purposes and activities of the hospital (e.g., tradespersons are not included).	X	
Physicians on the medical staff of the hospital, solely for personal use by such physicians or their dependents.	X	
Physicians on the medical staff at the hospital (or any other physicians or licensed professionals, including, e.g., D.P.M.s, D.D.S.s and D.V.M.s) for their office use.		X
Any employee, volunteer, student, medical staff physician or contract worker, for use with animals (e.g., by such individuals' pets).		X
Former employees, volunteers, students, contract workers, physician staff of the hospital, or any individual no longer in a direct relationship with the hospital. This includes terminated or retired employees *(even if they are still covered by COBRA or the hospitals' health plans)*, volunteers, students, contract workers and hospital medical staff physicians who are no longer on staff.		X
Nonprofit health care entities affiliated with the hospital for the buying entity's own use (the buying entity must only dispense the drugs to allowable individuals or entities as set forth in this chart).	X	
Nonprofit health care entities not affiliated with the hospital		X
Indigent individuals who do not otherwise qualify under any other criteria on this chart.		X
Members of the general public without an ongoing patient relationship with the hospital		X
Members of the general public in an emergency situation where a drug is temporarily unavailable in the community; e.g., earthquake, hurricane or tornado, civil unrest.	X	
Non-owned entity for an emergency basis and for humanitarian purposes	X	
Enrollees of managed care plans that contract with the hospital but are not otherwise directly associated with the hospital as an employee, ongoing patient, etc.		X
Nonprofit clinics affiliated with the hospital for on-site use at such clinics	X	

Drugs To Be Dispensed/Sold To:	Permitted	Not Permitted (Except for a Medical Emergency)
Employees and their dependents of professional practices owned by the hospital as divisions of the hospital or as nonprofit affiliates of the hospital.	X	
Nonprofit professional practices owned by the health system and are within the health system's market area of the retail pharmacy for its patients with an ongoing patient relationship.	X	
Prescriptions mailed to the health system's employees and their dependents.	X	
Out of state prescriptions mailed to patients of professional practices owned by the hospital.		X

DEFINITIONS:
"Own Use" means what reasonably may be regarded as use by the hospital in the sense that such use is a part of and promotes the hospital's intended institutional operation in the care of persons who are its patients. Nonprofit institutions receive preferential pricing for their pharmaceutical purchases but use of those pharmaceuticals is restricted to use by the nonprofit for its own purposes, and such nonprofits are prohibited from reselling or dispensing pharmaceuticals at the preferential pricing unless the nonprofit institution fits into an exception.

STATUTORY/REGULATORY AUTHORITIES:
The Prescription Drug Marketing Act of 1987 (21 U.S.C. ch. 9 §§ 331, 353, 381) (PDMA), amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301, *et seq.*), to make it unlawful (absent certain exceptions) to sell, purchase or trade any drug that was purchased by a hospital or other health care entity (whether or not at preferential prices), or was donated or supplied at a reduced price to a charitable 501(c)(3) organization. The PDMA imposes a straightforward prohibition on the resale of a prescription drug even when such resale may otherwise be permissible under the Robinson-Patman Act, unless an exception applies. The PDMA excludes the following from its prohibition:
(a) The purchase of drugs for its own use by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of the organization. (ii) a hospital's resale to a nonprofit affiliate "to the extent otherwise permitted by law";" (iv) resale among hospitals or other health care entities under common control; or (v) for emergency medical reasons.
(b) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

1 A "nonprofit affiliate" is another nonprofit corporation that is either controlled by the hospital selling the drugs (i.e., a subsidiary), or controls the hospital (i.e., a parent) or is under common control with the hospital (e.g., a "sister" corporation that has a common parent with the hospital).

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control.
(d) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.
(e) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a valid prescription.
(f) The sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug by hospitals or health care entities owned or operated by Federal, State, or local governmental units to other hospitals or health care entities owned or operated by Federal, State, or local governmental units.
(g) The sale, purchase, or trade of, or the offer to sell, purchase, or trade blood or blood components intended for transfusion.
(h) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a registered blood establishment that qualifies as a health care entity any:
(1) Drug indicated for a bleeding or clotting disorder, or anemia;
(2) Blood collection container approved under section 505 of the act; or
(3) Drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative);
as long as all of the health care services that the establishment provides are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem/progenitor cells or performing diagnostic testing of specimens provided that these specimens are tested together with specimens undergoing routine donor testing. Blood establishments relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy.
(i) The sale, purchase, or trade of, or the offer to sell, purchase, or trade, by a comprehensive hemophilia diagnostic treatment center that is receiving a grant under section 501(a)(2) of the Social Security Act and that qualifies as a health care entity, any drug indicated for a bleeding or clotting disorder, or anemia, or any drug that is a blood derivative (or a recombinant or synthetic form of a blood derivative). Comprehensive hemophilia diagnostic treatment centers relying on the exclusion in this paragraph must satisfy all other requirements of the act and this part applicable to a wholesale distributor or retail pharmacy. (21 C.F.R. Part 203).

The FDA defines "emergency medical reasons" to permit transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same State or same marketing or service area, or nearby licensed practitioners, of drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage; but do not include regular and systematic sales to licensed practitioners of prescription drugs that will be used for routine office procedures. (21 C.F.R. §203.3 (m).

The Robinson-Patman Antidiscrimination Act of 1936 (15 U.S.C. § 13) prohibits anticompetitive practices by suppliers, wholesalers, or manufacturers from knowingly inducing preferential or otherwise unjustified prices from a seller where the effect of such action may be to "substantially lessen competition." Thus, where nonprofit entity pays a lower price for pharmaceuticals or other supplies than the price paid by other purchasers, the nonprofit entity is at risk for a claim of unlawful inducement of price discrimination absent some exception to the law.

The Nonprofit Institutions Act (15 U.S.C. § 13c) (NPIA), enacted in 1938, amended the Robinson-Patman Act to exempt "purchases of their supplies for their own use by . . . hospitals, and charitable institutions not operated for profit." Under the NPIA, nonprofit entities that obtain prescription drugs or other supplies at preferential prices may dispense and resell the drugs or supplies only for their "own use".

Cases Discussing "Own Use" by Hospitals

In *Abbott Laboratories v. Portland Retail Druggists Assn's.*,425 U.S.1 (1976), the U.S. Supreme Court interpreted the term "own use" and articulated specific circumstances that would be deemed to constitute "own use" and thus exempt such purchases from Robinson-Patman Act liability. The Supreme Court interpreted the "own use" requirement to protect only purchases that "reasonably may be regarded as use by the hospital in the sense that such use is a part of and promotes the hospital's intended institutional operation in the care of persons who are its patients."

In *St. Peter's Hospital of the City of Albany*, 89 F.T.C. 689 (1977), modified at 92 F.T.C. 1037 (1978), the Federal Trade Commission ("FTC") expanded upon *Abbott Laboratories* and opined that the restrictive "own use" standards articulated by the Supreme Court should not prohibit resales at cost, by one charitable institution to another, that are limited, in turn, to the purchaser's own use. *Id.* at Under the standard of this opinion, a nonprofit institution's resale of prescription drugs or other supplies at its cost to another nonprofit institution for the purchaser's "own use" would not violate the Robinson-Patman Act.

BJC Health System (BJC) is a nonprofit charitable organization that owns hospitals and other health care health care providers. In BJC Health System (November 9, 1999) (FTC Staff opinion letter), the FTC acknowledged that BJC itself is entitled to the protection of the NPIA as well as its nonprofit hospitals and affiliated entities when it purchased supplies for its own use, and that BJC's employees as a group, like the hospital employees in *Abbott Labs*, are directly related to their employer's core function in the delivery of patient care. The FTC concludes that the NPIA protects the purchases by the hospital for transfer to affiliated nonprofit institutions and their employees.

In Yakima Valley Memorial Hospital (August 16, 2010) (FTC staff opinion letter), the FTC concluded that the non-profit hospital, through its on-site pharmacy, may sell discounted pharmaceuticals to employees of (1) its affiliated medical group, for which the hospital was its sole member and it was operated in a manner consistent with the hospital's 501(c)(3) tax exempt status, and (2) its affiliated non-profit outpatient diagnostic imaging center. The FTC determined that the hospital's central institutional function was to deliver comprehensive health care services to its patients and the medical group and outpatient diagnostic center were operated in furtherance of the hospital's mission. In addition, the FTC noted that the employees of the medical group and outpatient diagnostic imaging center provide critical services to the hospital's patients. As a result, the FTC opined that the hospital's sale of discounted pharmaceuticals to employees of the two affiliated entities fall within the NPIA exemption.

In Crouse Health Hospital (October 20, 2017) (FTC staff opinion letter), the FTC stated that a non-profit hospital may sell discounted prescription drugs to the employees and dependents of an affiliated for-profit medical practice corporation structured as a "Captive PC" (such that it was eligible for and obtained IRC Section 501(c)(3) tax exemption) without violating antitrust restrictions on different pricing for the same products under the Robinson-Patman Act. The FTC's analysis focused on whether the provision of discounted drugs to Crouse Medical Group's employees was for Crouse Hospital's "own use" and therefore qualified for the Nonprofit Institution

Act's ("NPIA") exemption. The FTC noted that the hospital's mission included promoting community health and providing physician services designed to improve access to health care and the hospital formed Crouse Medical Group to further its mission. Crouse Hospital had ultimate decision-making authority and control over Crouse Medical Group, and any financial benefits from the extended discount plan would accrue to Crouse Hospital pursuant to the relationship between the two entities and Crouse Medical Group was an integral part of the hospital's mission. The FTC found it was reasonable to treat the two organizations as "one unit" in analyzing the applicability of the NPIA exemption.

In the Doylestown Health (September 2, 2021) (FTC staff opinion letter), the FTC evaluated whether the Doylestown Health Physicians, a subsidiary of Doylestown Health, could provide discounted pharmaceuticals to Doylestown Health's affiliated hospital, Doylestown Hospital, for use for its outpatients under the NPIA. In determining that the arrangement would fall within the NPIA's exemption, the FTC stated that each nonprofit institution qualifies as an eligible entity under the NPIA. Doylestown Hospital and Doylestown Health Physicians are not-for-profit 501(c)(3) corporations. Additionally, the FTC stated that both organizations shared the institutional mission and were managed by the same executive team.[2]

Ambulance Restocking. Healthcare entities that participate in ambulance restocking and structure their arrangements according to the Safe Harbor for Ambulance Restocking Arrangements under the Anti-kickback Law would be exempt from liability or prosecution under federal anti-kickback laws. The healthcare entity conducting the restocking and the ambulance provider must comply with federal health care program billing requirements for restocked drugs and supplies and compliance with other applicable laws. The requirements of the regulation are sufficiently complex that legal counsel should be engaged whenever ambulance restocking arrangements are contemplated.

2 The FTC Commissioner is not bound by the FTC staff opinion letters and reserves its right to rescind the opinions it at a later time.

Guideline: Oncology Clinical Institute (OCI) extended interval zoledronic acid

CommonSpirit

Oncology Clinical Institute
Extended Interval Zoledronic Acid
February 2023

Guidance:
The CommonSpirit Oncology Clinical Institute supports extended interval dosing of zoledronic acid when used for the prevention of skeletal-related events (SREs) in patients with bone metastasis from breast cancer.

Background
The NCCN recommends treatment with a bone modifying agent if bone metastasis is present and expected survival is ≥ 3 months. Treatment with these agents is associated with fewer SREs, pathologic fractures, and reduced need for radiation and surgery for bone pain. The first SRE often occurs early in the course of metastatic disease. In a trial conducted by Stopeck, 37% of patients had already experienced an SRE at a median time of 2 months from evidence of bone metastases. There are currently 3 bone-modifying agents approved by the FDA for the prevention of SREs in patients with multiple myeloma, breast cancer, prostate cancer, and other solid tumors. Bisphosphonates, including pamidronate (PAM) and zoledronic acid (ZA) inhibit bone resorption and disrupt osteoclast activity while denosumab (DEN) is a monoclonal antibody that inhibits receptor activator of nuclear factor-κB ligand (RANKL). Each of these agents is dosed primarily every 4 weeks however data published in recent years suggest that dosing in breast cancer, prostate cancer and multiple myeloma may be extended to every 12 weeks without compromising efficacy. Data on alternative dosing intervals of pamidronate or denosumab are less robust and therefore are not recommended by ASCO or the NCCN outside of a clinical trial. There are currently 2 clinical trials evaluating extended dosing intervals of denosumab.

Bone-Modifying Agents Dosing Regimens: FDA Approved for Bone Metastases from Solid Tumors

Agent	Route	Dose	Interval
Pamidronate	Intravenous	90 mg	Every 3 - 4 weeks
Zoledronic acid	Intravenous	4 mg	Every 3 - 4 weeks
Denosumab	Subcutaneous	120 mg	Every 4 weeks

Extended Interval Data in Breast Cancer

Reference	Study Design	Results
Prior bisphosphonate therapy		
ZOOM study, Amadori et al. phase III, open-label, randomized	• 425 patients • Breast cancer ≥ 1 bone metastases • Previously completed 12-15 months of zoledronic acid • Randomly assigned to ZA 4mg every 4 or 12 weeks. • 1 year follow-up • Primary outcome was skeletal morbidity rate (SMR), SRE/patient/year	• 68% completion rate • SMR was 0.22 in 4w group and 0.26 in 12w group • ONJ occurred in 4 patients in the 12w group and 3 patients in the 4w group.
OPTIMIZE-2, Hortobagyi, prospective, randomized, double-blind, multicenter	• 403 patients • Bone metastases from breast cancer • Previously received ≥ 9 doses of ZA or PAM. • Randomized to ZA 4mg every 4 or 12 weeks. • Primary endpoint was rate of SRE	• 53% -63% completion rate. • 22% of patients in 4w and 23.2% in 12w group experienced ≥ 1 SREs (P=0.79) • Time to first SRE, SMR and SRE-free survival not significantly different between the groups. • Renal adverse events occurred at similar rates • ONJ occurred in 2 patients in the 4w arm and no patients in 12w arm.
Bisphosphonate naive		

CALGB 70604, Himelstein, Open-label, non-inferiority study	• 855 patients with breast cancer, prostate cancer, or myeloma ≥ 1 site of bone involvement
	• No prior IV bisphosphonate.
	• Randomly assigned to ZA 4mg every 4 or 12 weeks x 2y.
	• Primary endpoint = proportion of patients with ≥1 SRE at 2 years.
		• 45% (390) of breast cancer patients completed 2 years of follow-up.
		• Median follow-up = 1.2 years
		• SRE rate 29.5% in 4w arm and 28.6% in 12w arm. (P=0.50) demonstrating noninferiority
		• Across all 3 disease states:
		  ○ ONJ 2% (4w arm) and 1% (12w arm)
		  ○ Grade 3/4 renal dysfunction 1.2% (4w arm) and 0.5% (12w arm).

CommonSpirit

CSH System Pharmacy and Therapeutics (P&T) Committee
Meeting Date: May 18, 2023
DECISION BRIEF

Summary:

In each of three clinical trials, there was no difference in skeletal-related events when zoledronic acid was administered every 4 weeks or every 12 weeks. In addition, there were fewer cases of ONJ and renal dysfunction in the every 12 week treatment arm.

Additional Considerations

1. In FY22, CommonSpirit Health drug spend on bone-modifying agents used for the prevention of skeletal related events was as follows:
   - Zoledronic acid: $80, 400
   - Denosumab 120 mg: $10.1 million
2. FY22 purchase history reflects the following breakdown based on vials purchased:
   a. Zoledronic acid = 44%
   b. Denosumab = 56%
3. Consideration should be given to the difference in route of administration between denosumab and zoledronic acid. Denosumab is administered subcutaneously while zoledronic acid is a 15 minute IV infusion.
4. Patient visits for the administration of bone-modifying agents would be reduced by 66% per year with a change to extended interval dosing which may improve infusion center capacity.
5. There is a significant drug cost savings opportunity for the use of zoledronic acid in lieu of denosumab. The availability of generic zoledronic acid in addition to clinical data supporting the ability to give less frequent dosing contributes to the lower cost of care compared to denosumab. A cost effectiveness study demonstrated that when compared to zoledronic acid dosed every 3 months, the mean incremental cost per mean SRE avoided for denosumab ranged from $162,918 to $347,655 (based on a range of SRE probability with denosumab).

National Guideline Recommendations

ASCO Bone-Modifying Agents in Metastatic Breast Cancer: Guideline Update 2017
- One bone-modifying agent is not recommended over another for patients with breast cancer who have evidence of bone metastases.
- Dosing options for zoledronic acid 4mg may include either every 12 weeks or every 3 to 4 weeks.

NCCN Breast Cancer Guidelines v4.2002
- In a non-inferiority trial, monthly denosumab has shown to delay time to first SRE by 18% compared to monthly zoledronic acid.
- The NCCN panel recommends an optimal dosing of every 12 weeks for zoledronic acid.
- Dosing of denosumab outside of every 3-6 weeks has not been studied

ESMO Clinical Practice Guideline Bone Health 2020
- Most patients selected for treatment with zoledronate can de-escalate this agent safely to administration every 12 weeks, preferably after monthly treatment for 3–6 months

Oncology Clinical Institute Recommendations

1. Patients with *newly diagnosed metastatic bone disease from breast cancer* should be considered for treatment with zoledronic acid 4 mg IV every 12 weeks. The NCCN Panel acknowledges every 12 weeks as the optimal dosing interval.
2. De-escalation of zoledronic acid is a reasonable alternative to monthly dosing in a patient who is not at imminent risk for significant SREs. Patients with stable bone disease *currently receiving treatment with monthly zoledronic acid* should be converted to every 12 week dosing after 12 months of therapy.
3. Zoledronic acid is not recommended for patients with a creatinine clearance < 30ml/min. In this setting, monthly denosumab is the preferred agent.

Implementation
1. OCI Executive Council dyads to communicate recommendation to division medical oncologists. 2. Document to be included in System P&T meeting consent agenda 3. Document to be distributed to SCrPT Onc members for distribution to facility oncology clinical staff for review and implementation 4. Recommendation to be presented at facility leaders meeting and office hours meeting 5. National ticket to be entered for construction of EHR order sets for zoledronic acid 4mg IV Q12 weeks (breast) 6. Patient education document to be published on OCI website

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Reviewers:
Dr. Peter Emanuel - 3/14/23
Dr. Jessica Croley- 3/14/23
OCI Breast Council - 3/14/23

Approved By: OCI Executive Council
Date:

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CommonSpirit

CSH System Pharmacy and Therapeutics (P&T) Committee
Meeting Date: May 18, 2023
DECISION BRIEF

Guideline: Oncology Clinical Institute (OCI) daratumumab infusion

Daratumumab Infusion Guidelines

S

- Daratumumab received FDA approval for the treatment of multiple myeloma in 2016. The original approval required a lengthy infusion time of approximately 7 hours in an effort to decrease infusion-related reactions (IRRs). In clinical trials, 37% of patients had an IRR during the first infusion. This rate decreases to 2-6% with subsequent infusions.
- There is additional data supporting the safety of an accelerated infusion rate and therefore represents an opportunity to standardize practice as well as optimize chair time.

B

- In 2019 the FDA updated the label to include an option for split-dosing which splits the first infusion over 2 consecutive days thereby reducing the daily infusion time to 3-4 hrs.
- Beginning in 2018, multiple studies have shown the safety of infusing daratumumab over 90 minutes starting after 2 doses at the standard infusion rate. These studies have proven the safety of a shorter infusion time with no increase in IRRs, minimizing patient inconvenience and shortening patient chair time.
- Daratumumab infusion recommendations are based on guidance provided in the medication package insert as well as clinical literature.

A

	Week 1 (Dose 1)	Week 2 (Dose 2)	Week 3 (Dose 3) and beyond (Accelerated rate***)
Dosing	Single dose infusion (day1): 16 mg/kg in 1000 ml OR Split-dose infusion: 8 mg/kg in 500 ml on days 1 and 8 mg/kg in 500 ml on day 2	16 mg/kg in 500ml (if no prior infusion reactions)	16 mg/kg in 500ml
Rate	50 ml/hr x 1 hour, if no reactions, increase the rate by 50 ml/hr every hour (max rate: 200 ml/hr)	50 ml/hr x 1 hour, if no reactions, increase the rate by 50 ml/hr every hour (max rate: 200 ml/hr)	Infuse 20% of the dose over 30 minutes (200 mL/hour) and the remaining 80% of the dose over 60 minutes (450 mL/hour). ***Patients should demonstrate tolerability to a 500ml infusion before converting to accelerated infusion.
Approximate infusion time	7 hours (includes day1 and day 2)	4 hours	90 min
Monitoring	Baseline vital signs, then every 15 minutes for 1 hour then at the end of infusion. No additional post-infusion monitoring required.	Baseline vital signs, then every 15 minutes for 1 hour then at the end of infusion. No additional post-infusion monitoring required.	Baseline vital signs, then every 15 minutes for 1 hour then at the end of infusion. First accelerated infusion. Observe for 30 minutes after the first accelerated infusion (Lexi-comp)

*Premedications should include acetaminophen, diphenhydramine, dexamethasone, +/- famotidine and montelukast.
**See full document for complete literature review and references

	***Barr H, Dempsey J, Waller A, et al. Ninety-minute daratumumab infusion is safe in multiple myeloma. *Leukemia*. 2018;32(11):2495-2518. doi: 10.1038/s41375-018-0120-2.
R	• Based on a review of available literature, patients who have successfully completed at least two or more doses infused at manufacturer recommended rates *should receive daratumumab at an accelerated infusion rate.* • Implementation of the accelerated rate will decrease chair time by 2.5 hours per dose for an annualized savings of approximately 53 hours and $38,690 (based on NCCN estimate of $730 direct margin per hour of infusion) per patient.

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3/14/23

Reviewed By: SCrPT Oncology 3/16/23
Approved By:

FORMULARY REVIEW

GENERIC NAME: Vibegron

PROPRIETARY NAME: *Gemtesa®*

INDICATIONS:

FDA Approved
Overactive bladder with symptoms of urge urinary incontinence, urinary urgency, and urinary frequency in adults

THERAPEUTIC CATEGORY: β3 agonist

PHARMACOKINETICS:

Absorption	● Mean T_{max} (hr): ~1 to 3 ● Absorption is clinically unchanged: o If tablet is crushed and taken with applesauce when compared to oral administration of intact tablet o Following administration of a high-fat meal
Distribution	● Mean apparent Vd: 6304 L ● Protein binding: ~50% ● Blood to Plasma ratio: 0.9
Metabolism	● Minor hepatic metabolism via CYP3A4 ● Half-life (hr): 30.8
Elimination	● Half-life of 30.8 hours across all populations ● Fecal excretion 59% (54% unchanged) ● Urine excretion 20% (19% unchanged)

SPECIAL POPULATIONS:

Pregnancy	Has not been studied
Lactation	Has not been studied
Pediatrics	Has not been studied in populations <18 years of age
Geriatrics	No clinically significant differences in the pharmacokinetics based on age (range 18-93 years)
Hepatic Impairment	Child-Pugh B (moderate hepatic impairment) ● No clinically significant differences in the pharmacokinetics of vibegron Child-Pugh C (severe hepatic impairment) ● Not clinically studied ● Not recommended for use
Renal Impairment	No clinically significant differences in the pharmacokinetics in patients with: ● eGFR 60 to <90 mL/min/1.73m^2 ● eGFR 30 to < 60 mL/min/1.73m^2 ● eGFR <30 mL/min/1.73m^2 The effects of more severe renal impairment (eGFR <15 mL/min/1.73m2) with or without hemodialysis has not been studied.

CLINICAL STUDIES:

International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: EMPOWUR	
METHODS	
Study Design	Randomized, double-blind, placebo-controlled
Patient Enrollment Inclusion	● ≥18 years of age ● History of overactive bladder (OAB), diagnosed >3 months prior to screening

<table>
<tr><td></td><td>

Diary based criteria for wet (urinary urgency with urge incontinence) or dry (urinary urgency without urge incontinence)

≤25% of patients could have dry OAB

Up to 15% of patients could be male

</td></tr>
<tr><td>Patient Enrollment Exclusion</td><td>

Urine volume output >3000 mL

</td></tr>
<tr><td>Baseline Characteristics</td><td>
<table>
<tr><td>Median Age</td><td>61
42.9% were ≥65 years of age</td></tr>
<tr><td>Female Sex</td><td>85.2%</td></tr>
<tr><td>Wet OAB</td><td>77%</td></tr>
<tr><td>Mean UUI Episodes/Day</td><td>FAS: 8.1
FAS-I: 3.5</td></tr>
<tr><td>Mean Micturitions/Day</td><td>11.5 (SD 3.6)</td></tr>
<tr><td>Mean mL Voided/Micturition</td><td>150.5 mL (SD 61.7 mL)</td></tr>
</table>
</td></tr>
<tr><td>Treatment Plan</td><td>
Prior to randomization

One to five week screening period
28-day washout period
2-week, single-blind placebo run-in period
12-week, double-blind randomized period

540 participants randomized to placebo (486 completed)
547 participants randomized to vibegron (502 completed)
431 participants randomized to tolterodine (385 completed)

Following randomized treatment period

4-week follow-up safety evaluation

</td></tr>
<tr><td colspan="2">RESULTS</td></tr>
<tr><td>Outcomes Summary</td><td>Of 1518 patients randomized, 1373 (90.4%) completed the 12-week trial and 1463 (96.4%) contributed data for changes in number of micturitions, composing the FAS. Among patients with wet OAB, 1127 contributed data for changes in the number of UUI episodes, composing the FAS-I.</td></tr>
<tr><td>Primary Endpoints</td><td>
<table>
<tr><th></th><th>Vibegron vs. Placebo</th><th>Mean difference</th></tr>
<tr><td>CFB in micturition frequency</td><td>-1.8 vs. -1.3</td><td>-0.5 (95% CI -0.8 to -0.2)
p <0.001</td></tr>
<tr><td>CFB in frequency of UUI in patients with wet OAB</td><td>-2.0 vs. -1.4</td><td>-0.6 (95% CI -0.9 to -0.3)
p < 0.0001</td></tr>
</table>
<table>
<tr><th></th><th>Tolterodine vs. Placebo</th><th>Mean Difference</th></tr>
<tr><td>CFB in micturition frequency</td><td>-1.6 vs. -1.3</td><td>-0.3 (95% CI -0.6 to 0.1)
p = 0.0988</td></tr>
<tr><td>CFB in frequency of UUI in patients with wet OAB</td><td>-1.8 vs. -1.4</td><td>-0.4 (95% CI -0.7 to -0.1)
p = 0.0123</td></tr>
</table>
</td></tr>
<tr><td>Secondary Endpoints</td><td>
<table>
<tr><th></th><th>Vibegron vs. Placebo</th><th>Mean Difference</th></tr>
<tr><td>CFB in frequency of urgency episodes</td><td>-2.7 vs. -2.0</td><td>-0.7 (95% CI -1.1 to -0.2)
p = 0.0020</td></tr>
<tr><td>Change in volume voided per micturition</td><td>23.5 mL vs. 2.2 mL</td><td>21.2 (95% CI 14.3 to 28.1)
p <0.0001</td></tr>
<tr><td>Proportion of wet OAB cases with ≥75% reduction from baseline in UUI episodes</td><td>52.4% vs. 36.8%</td><td></td></tr>
</table>
<table>
<tr><th></th><th>Tolterodine vs. Placebo</th><th>Mean Difference</th></tr>
<tr><td>CFB in frequency of urgency episodes</td><td>-2.5 vs. -2.0</td><td>-0.4 (95% CI -0.9 to 0.0)
p = 0.0648</td></tr>
</table>
</td></tr>
</table>

	Change in volume voided per micturition	15.5 vs. 2.2 mL	13.3 (95% CI 5.9 to 20.7) $p < 0.001$
	Proportion of wet OAB cases with ≥75% reduction from baseline in UUI episodes	47.6% vs. 36.8%	
Adverse Events	Adverse events were reported in 38.7% of patients in the vibegron group and 33.3% in the placebo group. Of the adverse events reported, 1.5% in the vibegron group and 1.1% in the placebo group were considered serious by the clinical investigator. Two patients of both the vibegron and placebo groups developed serious adverse events including pneumonia and noncardiac chest pain which were classified by the investigator but not the sponsor as possibly or probably treatment related. Nine patients of the vibegron group and 6 patients of the placebo group discontinued the study drug due to adverse events.		

COMPARATIVE EFFICACY:
Clinical guidelines for the treatment of overactive bladder recommend behavioral therapies which include bladder training, bladder control strategies, pelvic floor muscle training and fluid management as first-line treatment. If behavioral strategies alone are ineffective, clinicians may initiate either antimuscarinic therapy or β3 adrenergic receptor agonist therapy in combination with behavioral therapy. Mirabegron was approved in 2012 and remained the sole β3 agonist for several years, however mirabegron is associated with drug interactions via inhibition of cytochrome-p450 (CYP) 2D6, warnings including hypertension, and must be administered as a whole tablet to maintain adequate absorption.

Vibegron, a β3 agonist, was approved in 2020. While the trial did not statistically assess the comparison of vibegron and tolterodine, the results of the EMPOWUR trial and its extension trial highlight that vibegron may be as effective as or more effective than tolterodine without clinically meaningful differences in safety profiles between the two.

No head-to-head comparison trials have been conducted to evaluate the differences in safety and efficacy of vibegron and mirabegron. Nevertheless, the pharmacological properties of vibegron in combination with the results of the EMPOWUR trial indicate that vibegron may be a safer and more convenient therapy option than mirabegron. In terms of efficacy, the trial revealed vibegron efficacy to begin by week two, while mirabegron is effective within eight weeks. In terms of safety, vibegron does not undergo major metabolism via CYP pathways and therefore is associated with a lesser risk of drug interactions. Additionally, the results of the EMPOWUR trial revealed that vibegron is associated with hypertension incidence rates comparable to placebo. The 52-week extension study comparing vibegron to tolterodine yielded hypertension incidence rates of vibegron consistent with the initial 12-week trial. In contrast, mirabegron is associated with dose-related increases in supine blood pressure. In two randomized, placebo-controlled, healthy volunteer studies, 50 mg of mirabegron daily was associated with a mean maximum increase in systolic/diastolic blood pressure approximately 3.5/1.5 mmHg greater than placebo. An additional advantage of vibegron in comparison to mirabegron is the ability to crush the tablet without a clinically significant loss of pharmacokinetic properties within the body.

WARNING AND PRECAUTIONS: Urinary retention

BLACK BOX WARNINGS: None

CONTRAINDICATIONS: Prior hypersensitivity reaction to vibegron or any components of the product

ADVERSE REACTIONS:

Adverse Reactions	Vibegron (N=545) (%)	Placebo (N=540)
UTI	5	6.1
Headache	**4**	**2.4**
Nasopharyngitis	**2.8**	**1.7**
Diarrhea	**2.2**	**1.1**
Nausea	**2.2**	**1.1**
Upper Respiratory Tract Infection	**2**	**0.7**
Dry Mouth	1.7	0.9
Hypertension	1.7	1.7
Dizziness	0.9	1.1

CLINICALLY SIGNIFICANT DRUG INTERACTIONS:
Digoxin- Vibegron increases digoxin maximal concentrations and systemic exposure

DOSING AND ADMINISTRATION:
Overactive bladder: 75 mg orally once daily
Tablet may be crushed and mixed with one tablespoon (15 mL) of applesauce and taken immediately with a glass of water
Hepatic Impairment

- Mild to moderate (Child Pugh A and B): No dosage adjustments recommended
- Severe (Child Pugh C): Use not recommended

Renal Impairment

- Mild, moderate, or severe (eGFR 15 to <90 mL/min/1.73 m^2): No dosage adjustments recommended
- More severe (eGFR <15 mL/min/1.73 m^2) with or without hemodialysis: Use not recommended

RECOMMENDED MONITORING:
Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction and patients taking muscarinic antagonist medications for the treatment of OAB.

PHARMACOECONOMICS/COST:
Product and Comparator Purchase Prices

Product (Drug, Strength, Form)	Cost/Day
Vibegron (Gemtesa) 75 mg tablet	$13.98
Formulary products:	
Mirabegron (Myrbetriq) 25 or 50 mg extended release tablet	$12.72
Oxybutynin 15 mg XL tablet	$0.26-$0.52
Oxybutynin 5 mg tablet	$0.22-$0.44
Trospium 20 mg tablet	$0.28

CONCLUSION & RECOMMENDATION:
Vibegron (Gemtesa) selectively activates the β3 adrenergic receptor within the bladder to relax the detrusor smooth muscle and increase bladder capacity. Vibegron is the second β3 agonist to be approved for the indication of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults. Approval was based on the results from the EMPOWUR trial which revealed statistically significant and clinically meaningful improvements in overactive bladder symptoms as compared to placebo.

No head-to-head trials have been conducted to assess the differences of safety and efficacy of vibegron and mirabegron. However, study results demonstrate a lower risk of drug interactions, lower incidence rates of increased blood pressure, and a quicker onset of efficacy with vibegron. At the time of system review, the tablet formulation of vibegron is more expensive than the tablet formulation of mirabegron, which is the current formulary product for CHI Memorial and CommonSpirit Health.

CommonSpirit Health system P&T committee approved the following:

Formulary, restricted: Mirabegron

- Patients who are unable to take antimuscarinic agents
- Continuation from home

Non-formulary: Vibegron

- Orders should be therapeutically interchanged as follows:
  Vibegron 75 mg po daily to Mirabegron 25 mg po daily

It is recommended to adopt the CommonSpirit Health system P&T decisions stated above, including an automatic pharmacist or EHR therapeutic interchange of vibegron 75 mg po daily to mirabegron 25 mg po daily.

FAILURE, MODE AND EFFECTS ANALYSIS (FMEA)

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
Therapeutic interchange?	Yes	Interchange to mirabegron 25 mg po daily
Special Ordering Requirements?	No	
Storage		
LASA* separation of stock?	No	
Special storage (e.g. refrigeration, protect from light, controlled substance)?	No	
Pharmacist/Technician Education?	No	
Ordering & Prescribing		
Restriction to particular specialty, indication, or particular patient population?	No	
Dosing Issues (e.g. renal, hepatic dosage adjustment, max dose warnings)?	Yes	Do not use in severe renal impairment (eGFR <15 mL/min/1.73 m^2) Do not use if patient on hemodialysis Do not use in severe hepatic impairment (Child Pugh C)
Drug Interactions?	Yes	Recommend digoxin level
Pregnancy?	Yes	Avoid
Absolute Contraindications?	Yes	Hypersensitivity Urinary Retention Bladder Outlet Obstruction
Requires Order Set, Protocol, concomitant therapy with another drug?	No	
LASA* nomenclature issues?	No	
Prescriber education?	Yes	Not indicated if patient has bladder outlet obstruction or urinary retention
Processing, Preparing, & Dispensing		
High-risk drug double check?	No	
Drug Interaction check in place?	Yes	Digoxin
LASA* computer warnings?	No	
Administration Notes for MAR (e.g. handling precautions, surrounding food or other drugs)?	No	
Packaging/Labeling (e.g. prepacking)?	No	
Dispensing (e.g. auxiliary labeling, light protection, refrigeration)?	No	
Documentation required (e.g. double check, worksheet)?	No	
Pharmacist/Technician Education?	No	
Administration		
Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, or other administration information?	Yes	Administer with or without food Monitor for signs and symptoms of digoxin toxicity
Special delivery system (e.g. pump)?	N/A	
Documentation required? (e. g. double check)	No	
Nurse education?	No	
Monitoring		
Interactions, adverse effects, efficacy, changes in renal function, or similar?	Yes	Digoxin toxicity Blood pressure Urinary retention
Follow-up laboratory tests?	No	
Education?	Yes	Take this medication with or without food

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.

<u>MEDICATION #1</u>: IV Solu-cortef (hydrocortisone)

Summary: Solu-cortef is currently a critical shortage item due to manufacturing delays. Pfizer has Solu-cortef available only in limited supply and only via direct orders. We receive a very small allocation each month. Unfortunately a potential alternative, Solu-medrol, is also in shortage for most formulations.

Discussion/Recommendation: While we have received some backorders, Solu-cortef remains a critical shortage item with little supply. 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. When a provider attempts to order Solu-cortef, they will see the following LMA with alternative recommendations:

Hydrocortisone (Solu-Cortef) injection supply is critically low.

Please choose an alternative option below or enter a different order.

- If able to take meds by mouth/per tube (preferred): hydrocortisone PO/PT at 1:1 IV to PO conversion.
- If unable to take oral/per tube meds or IV route preferred: methylPREDNISolone IV + *fludrocortisone PO/PT (if able) per dosing recommendations below.

hydrocortisone 100 mg (IV/PO) = methylPREDNISolone 20 mg + fludrocortisone 0.2 mg

Hydrocortisone Dose	Approximately Equivalent Alternatives
100 mg q8 IV	hydrocortisone 100 mg q8 PO OR methylPREDNISolone 20 mg q8 + *fludrocortisone 0.3 mg PO/PT q12
50 mg q6 IV	hydrocortisone 50 mg q6 PO OR methylPREDNISolone 20 mg q12 + *fludrocortisone 0.2 mg PO/PT q12

*Note: methylPREDNISolone lacks mineralocorticoid activity (i.e. it does not provide benefits for blood pressure support in adrenal insufficiency and septic shock patients). Fludrocortisone can be added to methylPREDNISolone to provide mineralocorticoid activity.

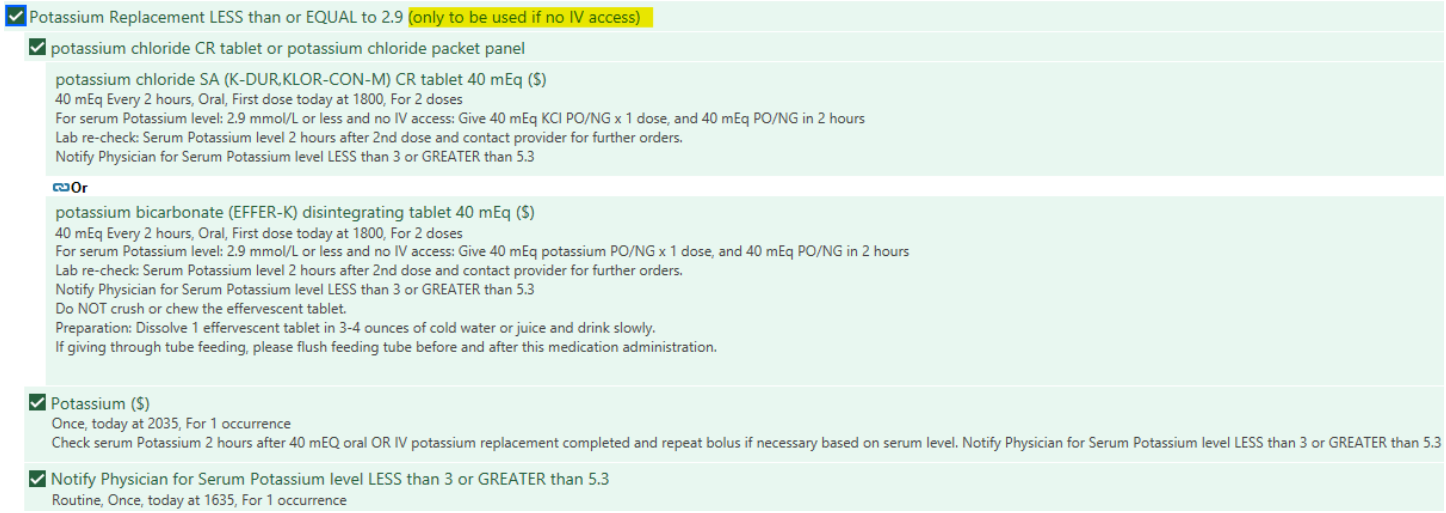
Solu-medrol is available as 40 mg, 125 mg, 500 mg, or 1000 mg vials.

It is recommended to formally 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 shortage of the 125 mg Solu-medrol vials..

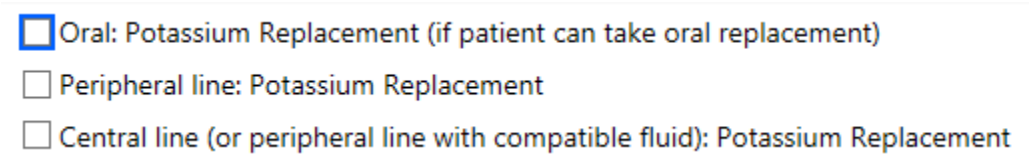
Electrolyte Replacement Guidelines - Proposed Update

The current electrolyte replacement protocol states that if the potassium level is less than or equal to 2.9, replacement can only be accomplished using IV replacement, unless IV access is not available. Each 10 Meq of IV potassium replacement requires a 1 hour infusion time and 50-100 ml fluid. To replace 80 mEq of potassium, as indicated per protocol for potassium of 2.9 or less, 8 hrs and 400-800 ml fluid would be needed. To minimize fluid overload and reduce the time to achieve normalized potassium level, 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.

Current protocol if selecting oral replacement:



In situations when a patient can take oral medication and has IV access it is proposed to allow for a mixture of oral and IV replacement. Current protocol in Epic first requires selection of route of replacement. This proposal may require remodeling of protocol to first select potassium level and then options for route.



Recommendation:

- For potassium level of 2.9 or less:
    - 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 replacement

Evaluation of weight-based versus fixed dosing of four-factor prothrombin complex concentrate in the management of direct oral anticoagulant associated bleeding

BACKGROUND:

Four-factor prothrombin complex concentrate (Kcentra®) is a concentrate of coagulation factors II, VII, IX, and X currently FDA approved for reversal of vitamin K antagonist therapy in patients with acute major bleeding or a need for an urgent surgery or invasive procedure. Kcentra is used off-label for treatment of life-threatening bleeding associated with direct oral anticoagulants (DOAC). In February 2021, the CHI Memorial Antithrombotic Reversal & Surgical Management Guidelines were reviewed and updated to reflect data that suggested lower doses of Kcentra were safe and effective in the management of DOAC-related bleeding.

RECOMMENDATION:
After discussion with all service lines utilizing Kcentra for DOAC reversal, the following lower dosing strategy is recommended for the indication of DOAC reversal:

- 2000 units
- If ICH (spontaneous or traumatic) use 2500 units
- May repeat the same dose once within 6 hours of the initial dose if hemostasis is not achieved and/or maintained

OBJECTIVE:

To evaluate the efficacy, safety, and cost savings associated with using fixed dosing of Kcentra for the management of DOAC-related bleeding compared to weight-based dosing at our institution.

METHODS:

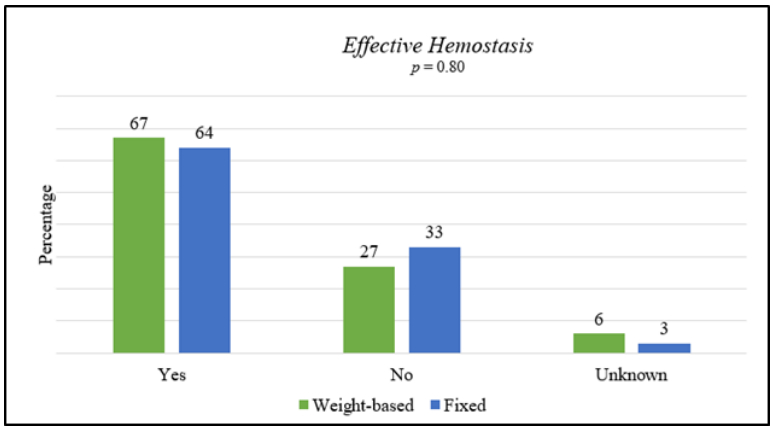
A retrospective chart review was performed to identify patients who received Kcentra for DOAC reversal between March 1, 2021 through December 31, 2021 compared to March 1, 2022 through December 31, 2022. Patients were eligible for inclusion if they received Kcentra for DOAC reversal and were at least 18 years of age. Exclusion criteria included cardiovascular surgery patients receiving Kcentra for intraoperative or postoperative hemostasis and patients who received Kcentra for DOAC reversal due to an urgent or emergent surgery without an active bleed. The primary endpoints in this study were effective hemostasis and cost savings. Secondary endpoints were adherence to hospital approved dosing protocol, death during admission, thromboembolic events post-Kcentra during admission, blood product use, and average length of stay.

RESULTS:

	Weight-based (n = 33)	Fixed (n = 39)	*p*-value
Female, n (%)	10 (30)	18 (46)	0.23
Age, avg ± SD	75 ± 8.7	78 ± 10.2	0.19
Race, n (%) White Black	 31 (94) 2 (6)	 37 (95) 2 (5)	1.00
Weight, avg ± SD	89.6 ± 23.2	80 ± 21.0	0.07
DOAC, n (%) Apixaban Rivaroxaban Edoxaban	 24 (73) 9 (27) 0 (0)	 32 (82) 7 (18) 0 (0)	0.40

Figure 1. Baseline Characteristics

Figure 2. Effective Hemostasis



Effective Hemostasis by Bleed Type		
Type of Bleed	**Weight-based (n = 33)**	**Fixed (n = 39)**
Gastrointestinal, n (%)	13 (39)	11 (28)
ICH, n (%)	4 (12)	9 (23)
Internal, n (%)	3 (9)	3 (8)
Other, n (%)	2 (6)	2 (5)

Figure 3. Cost Savings

	Dose (units), avg ± SD	Repeat Dose Required (n)	Total Cost
Weight-based	3733 ± 1107	0	$247,592
Fixed	2271 ± 389	2	$186,984

DISCUSSION:

In this retrospective chart review, no statistically significant difference was found in achieving hemostasis between using weight-based versus fixed dosing of Kcentra for DOAC-associated bleeding. This outcome suggests that in our patient population, fixed dosing is just as effective at achieving hemostasis which allowed for a decreased average dose per patient by nearly 1500 units. The majority of patients included in this study had a gastrointestinal bleed (53%), which may make these results more applicable to those patients. The results of this evaluation demonstrated that utilizing fixed-dosing of Kcentra is a more cost effective alternative, allowing for a cost saving of over $60,000 when comparing the study periods. The true cost savings is likely even greater, as there were 7 more patients included in the fixed group versus the weight-based group. Furthermore, the switch to fixed dosing improved the adherence to our hospital's approved dosing protocol as evidenced by the significant decrease in inappropriate dosing (p=0.04). The remaining secondary outcomes were similar between groups, including average length of stay, death during admission, or thromboembolic events post Kcentra during admission.

CONCLUSION:

This study demonstrated that modifying Kcentra dosing from weight-based to fixed is a cost effective alternative for the management of DOAC-related bleeding. There are currently no modifications to the CHI Memorial Antithrombotic Reversal & Surgical Management Guidelines recommended.

Implementation and Impact of Pharmacy-led Beta-lactam Allergy Clarification and Delabeling at a Community Hospital

BACKGROUND:
Approximately 10% of all US patients report having an allergic reaction to a penicillin antibiotic in their past. However, less than 1% of the population experiences a true IgE-mediated reaction, and approximately 80% of those patients with a previous IgE mediated reaction lose sensitivity after 10 years. The presence of an unnecessary beta-lactam allergy label may result in providers using second-line agents which may lead to: resistance and treatment failure, higher hospital readmission rates, and longer hospital length of stay. The IDSA recommends that antimicrobial stewardship programs promote allergy assessments and penicillin skin testing.

BETA-LACTAM ALLERGY GUIDELINE:
https://formweb.com/files/memorial/documents/Beta_Lactam_Allergy_Guide.pdf
A guideline was developed to guide clinicians in prescribing antibiotics for inpatients with reported allergic reactions to penicillin or cephalosporin antibiotics by allowing these patients to receive more narrow-spectrum, more effective, less toxic, and/or less costly antibiotics. The guideline was approved by the antimicrobial stewardship team and includes a patient allergy assessment tool, allergic reaction risk category chart (low, moderate, high risk reactions), cross-reactivity matrix, and test dosing procedure (PO and IV).

PHARMACY WORKFLOW:
Medication history technicians (MHTs) collect allergy histories using the patient allergy assessment tool in addition to utilizing outpatient EHR to collect any beta-lactam prescriptions within the last year. Patient's allergy is updated with the information collected. Antimicrobial stewardship pharmacists review inpatients with beta-lactam allergies utilizing an EPIC generated list. The clarified information allows the pharmacist to more quickly evaluate the patient for potential interventions (low risk: delabeling or PO challenge; moderate: beta-lactam IV challenge with dissimilar side chain or penicillin skin test).

OBJECTIVE:
To evaluate the impact of our pharmacy-led program on beta-lactam allergy clarification and delabeling on inpatients.

METHODS:

A retrospective chart review was conducted of inpatients with penicillin or cephalosporin allergy who were admitted through the emergency department from January 1, 2023 through January 31, 2023. Primary endpoints include the number of patients with their allergies clarified and total number of pharmacy interventions made. The secondary endpoints include breaking down the interventions made by type (clarification, delabeling, challenge, etc) in addition to capturing details of patients' allergies which were collected from the patient allergy assessment tool questionnaire.

RESULTS:

Figure 1. Pharmacy Interventions by Type

	Post-Protocol Interventions (n = 167) n (%)
Allergy clarifications	143 (85.6)
Delabelings of allergy	13 (7.8)
PO challenges conducted	6 (3.6)
Direct De-escalation of therapy	3 (1.8)
Beta-lactam IV challenges conducted	1 (0.6)
Skin test performed	1 (0.6)

Figure 2. Patient Assessment Questionnaire

Secondary Endpoints	Patients with Allergies Clarified (n = 143) n (%)
Time since allergy occurred	
> 10 years ago	104 (72.2)
< 10 years ago	11 (7.7)
Unknown time frame	28 (19.6)
When reaction occurred	
Immediate	48 (33.6)
Delayed	17 (11.9)
Unknown	78 (54.4)
Previous outpatient beta-lactam prescription in the last year	
None	81 (56.7)
Previous penicillin class antibiotic	22 (15.4)
Previous cephalosporin antibiotic	40 (27.9)

A total of 394 patients qualified for inclusion criteria and were ultimately analyzed out of a total of 1397 patients who presented to the hospital with a beta-lactam allergy. There were 143 patients who had their allergies clarified with a total of 167 pharmacy interventions made in January 2023. Patient's reactions were categorized with their associated risk level: minimal (4.9%), low (36.7%), moderate (35.7%), and high (16.2%). Figure 2 displays the secondary endpoints related to questions asked by the MHTs in addition to the number of patients with previous outpatient beta-lactam prescriptions found in outpatient EHR within the past year.

DISCUSSION:

The implementation of this pharmacy-led beta-lactam allergy clarification program led to 167 pharmacy interventions with the most common intervention being allergy clarifications by the emergency department pharmacy medication history technicians. 24 of those interventions were conducted by pharmacists which resulted in allergy delabeling, de-escalation of therapy, and allergy challenges.

This study also shows there are substantial opportunities for delabeling with approximately 40% of patients' allergies being categorized as either minimal or low-risk reactions. It is important to remember the majority of IgE-mediated reactions are desensitized if the reaction occurred over 10 years ago, and we see in our study 72% of patients had their reaction occur in this timeframe. Lastly, 43% of patients had previously received a beta-lactam outpatient prescription in the past year, further reinforcing the ability for these patients to be capable of utilizing a beta-lactam or penicillin in their therapy.

The sheer volume of patients being admitted to the hospital with beta-lactam allergies confirms the need for guidance on actively addressing these patients' allergies. There remains a large percent of the population with beta-lactam allergy labels who were not included in this study such as patients directly admitted to the hospital for surgery or patients who visit the emergency department without being admitted. One limitation in the clarification process we found includes patients who may be incapable of providing an accurate history, such as those with dementia, acutely altered mental status, or rapidly intubated upon arrival.

CONCLUSION:

The beta-lactam allergy delabeling and clarification program at CHI Memorial has led to multiple interventions in an effort to optimize patient care. The beta-lactam allergy guideline is an accessible tool all healthcare providers and staff here have access to.

Impact of Pharmacist Intervention on Discharge Antibiotic Therapy for Community-Acquired Pneumonia

BACKGROUND:
Patients are commonly discharged from the hospital on prolonged courses of antibiotics. Excessive antibiotic exposure may lead to adverse events and increased antimicrobial resistance. It has been shown that increasing total antibiotic duration beyond five days in clinically stable patients with community-acquired pneumonia (CAP) has no benefit. Most patients complete their antibiotic course after being discharged from the hospital, therefore, it is imperative for antimicrobial stewardship initiatives to target patients at the point of discharge. A pharmacist driven initiative was implemented at CHI Memorial to target patients with the diagnosis of CA

OBJECTIVE:
To measure the effectiveness of this pharmacist-driven intervention on discharge CAP antibiotic therapy

METHODS:

A quasi-experimental study was performed on adult inpatients with a diagnosis of CAP. Patients were included if they were admitted for at least 48 hours and met criteria for five days of treatment for CAP per hospital guidelines. Patients were excluded if they completed their antibiotic course more than 24 hours before discharge, had concomitant infections, bacteremia, expired during admission, or had a cavitary pneumonia or lung abscess. Patients were also excluded if they had pneumonia caused by or suspected to be caused by MRSA, Pseudomonas, or a multi-drug resistant gram negative rod. The primary endpoint was total median antibiotic duration of therapy pre-and post-intervention. Secondary endpoints included appropriateness of discharge antibiotics, length of stay, 30-day readmission for pneumonia, antibiotic resistance seen in subsequent cultures, and antibiotic side-effects.

RESULTS:

Figure 1. Baseline Characteristics

	Pre-Intervention (n=36)	Post-intervention (n=37)	p-value
Male, n (%)	17 (47.2)	17 (45.9)	1.000
Median age (IQR)	69 (58.3-79.5)	74 (60.5-80.5)	0.106
Comorbidities, n (%)			
CKD	11 (30.6)	12 (32.4)	1.000
Lung Cancer	3 (8.3)	3 (8.1)	1.000
COPD	22 (61.1)	15 (40.5)	0.103

Figure 2. Outcomes

	Pre-Intervention (n=36)	Post-Intervention (n=37)	p-value
Total median duration of therapy in days, n	6.1	5.3	0.142
Median duration of discharge antibiotics in days, n	3	2	0.039
Median length of stay in days (IQR)	3 (2.3-4.0)	3 (3.0-4.5)	0.525
Antibiotic side effects, n (%)	1 (2.8)	0	0.493
Antibiotic resistance seen in subsequent cultures, n (%)	0	0	N/A
Appropriateness of discharge antibiotics, n (%)	33 (91.7)	36 (97.3)	0.358
30-day readmission for PNA, n (%)	1 (2.8)	3 (8.1)	0.615

DISCUSSION:

This quasi- experimental study found that the pharmacist-interventions directed at antibiotic duration for CAP in clinically stable patients shortened both total duration of therapy and discharge duration of antibiotic therapy by 1 day in the post-intervention group. This was a statistically significant outcome for the total discharge duration of therapy, but not for total antibiotic duration. Because patients are often discharged on prolonged courses of antibiotics, it was important to target these antimicrobial stewardship interventions at the point of discharge. Therefore, the significant difference in discharge antibiotic duration is a promising find. Though not statistically significant, there was a higher percent of appropriate antibiotics in the post-intervention group. Additionally, all pharmacist interventions were accepted by providers and all were related to duration of therapy.

The information gathered in this study can help guide further directions in how to ensure 5 days total duration of therapy for CAP in clinically stable patients. It also demonstrated that most antibiotics prescribed for CAP at CHI Memorial are appropriate in regards to adjustment based on the final culture, susceptibility report, renal function, and/or per guideline recommendations. The main issue faced is duration of therapy. Further education on hospital policy and guideline recommendations is planned for pharmacists and providers, and a further analysis of the impact of this pharmacist-driven intervention will be warranted.

CONCLUSION:

The implementation of a pharmacist- driven intervention on duration of CAP therapy, particularly at the point of discharge, decreased both total duration of antibiotics and discharge duration of antibiotics by one day. All interventions were related to duration of therapy and 100% were accepted by providers.

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
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