

Pharmacy & Therapeutics Committee Meeting

SCN Boardroom

March 30, 2023 7:00 a.m.

<u>Agenda Items</u>	<u>Individual Responsible</u>	
1. Call to Order	Nathan Chamberlain, MD	
2. Conflict of Interest Disclosure	Rachel Kile, PharmD	
3. Approval of February 2023 Minutes	Nathan Chamberlain, MD	
4. CSH System P&T Committee – March 2023 Decision Brief		Page n/a
5. Old Business		
A. Hydralazine IV orders		n/a
6. Formulary Decisions & Therapeutic Interchanges		
A. Spesolimab-sbzo (Spevigo)		6
B. Aminolevulinic acid (Gleolan)- <i>formulary update</i>		11
C. Sulfadiazine- <i>formulary removal</i>		12
D. Acetaminophen with codeine- <i>formulary removal</i>		13
E. Drug shortages update		14
7. Policies		
A. MRSA Nasal PCR		15
8. Miscellaneous		
A. Report: Pharmacist Clinical Interventions, Serious Significance Level		16

Next Meeting Date: June 15, 2023 at 7:00 a.m. via Zoom

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: February 9, 2023
 LOCATION: SCN Boardroom

CALLED TO ORDER: 7:01 a.m.
 ADJOURNED: 8:09 a.m.

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

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 December minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	January 2023 Decision Brief: The medication decisions that were approved at the CommonSpirit Health System P&T committee meeting were reviewed. All new system formulary medications or changes were either consistent with existing CHI Memorial formulary decisions or are described in the "Formulary Decisions & Therapeutic Interchanges" section of the minutes below, or will be reviewed at an upcoming P&T committee meeting.	Approved	Complete
Old Business	A. 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. An email 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. Order sets including hydralazine with current administration instructions were excluded. Rachel will continue to update the committee as the EHR build progresses.	Approved	Complete

	<p>steps before administration, has reduced infection rates, and comparable nutrition efficacy. Several local and regional hospitals have successfully incorporated use of Clinimix products into their parenteral nutrition protocols. There are considerations for patients with fluid restrictions due to volume delivered, and these cases should be discussed on a per patient basis with Nephrology. Adoption of Clinimix products to formulary would allow for substantial annual cost savings for the hospital as it was estimated that approximately 40 percent of current TPN volume would transition to Clinimix E. It was recommended to:</p> <ul style="list-style-type: none"> ● Approve Clinimix products to formulary ● Approve the Consult to Pharmacist for TPN management to allow the pharmacist to use guidelines, existing TPN policy, and clinical judgment to determine if the patient shall be initiated on a Clinimix product or a custom TPN ● Do not allow blanket requests by prescribers such as “No Clinimix for any of my patients” ● Update the TPN order set to add Clinimix as an option <p>E. Pantoprazole infusions: Pantoprazole is a proton pump inhibitor (PPI) that is used as adjunct therapy to endoscopy and is effective pharmacotherapy in high-risk patients with peptic ulcer bleeding. Current treatment of GI bleeds after endoscopy is pantoprazole 80 mg bolus followed by 8 mg/hour continuous infusion for 72 hours. However, studies demonstrate that pantoprazole 40 mg IV given every 12 hours was as effective as a high dose regimen in reducing risk of recurrent bleeding. Pantoprazole infusions are also incompatible with many IV medications and are laborious to compound. Implementing an IV push regimen would allow for easier administration for nurses and does not tie up an IV site. By initiating patients on a 40 mg pantoprazole IV bolus every 12 hours, the hospital would also have a modest cost savings. The following recommendations were made:</p> <ul style="list-style-type: none"> ● Eliminate the high dose pantoprazole regimen (80 mg IV x 1, followed by 8 mg/hour for up to 72 hours) in lieu of the intermittent low dose bolus regimen (40 mg IV every 12 hours for up to 72 hours) ● For GI bleeds, a one-time bolus dose of pantoprazole 40 mg IV may be administered in the emergency department (ED), followed by an immediate GI consult <ul style="list-style-type: none"> ○ Pantoprazole 40 mg IV bolus dose may be administered a second time if endoscopy will not occur within 12 hours after initial dose ● Pantoprazole 40 mg IV Q 12 hours should be administered for up to 72 hours after endoscopy ● Patients should be continued on oral PPI therapy (pantoprazole 40 mg PO Q 24 hours) <ul style="list-style-type: none"> ○ Patients can be transitioned to oral therapy <u>before</u> 72 hours, if applicable ○ No more than <u>3 days</u> of an IV PPI should be used after endoscopy unless extenuating circumstances (NPO, etc.) <p>F. Drug shortages update: The injectable lorazepam supply has recovered and lorazepam IV push at 0.5 mg x 1 dose has been requested to be added back to the MCT IP CAR CORONARY CTA PRE MEDICATION ORDERS order set. Dr. Mandawat researched this request and determined that the use of IV lorazepam during this testing is a standard protocol across the country for acute management of anxiety due to bradycardia caused by beta blocker administration 60-90 minutes prior to the study. It is recommended to update the order set and replace the oral tablet with the IV push formulation.</p> <p>G. Medications for COVID-19: It was recommended to make the Pfizer-BioNTech COVID-19 Vaccine (monovalent) and Bivalent booster vaccines non-formulary due to a lack of usage, high waste with use, and lack of need for administration for patients discharging to SNF/facilities. Paxlovid use inclusion criteria for inpatients was updated to read “diagnosis of COVID-19 with mild to moderate symptoms” in lieu of having a positive Covid test, as per the EUA update.</p>	<p>Approved</p> <p>Approved</p> <p>Approved</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p>
<p>Medication Use</p>	<p>A. “Once” Medication Orders: This was a proposal from a cross-market pharmacy group including Texas and Kentucky (shared EPIC EHR). “Once” medication orders that are documented as “Not Given” remain active on</p>	<p>Approved</p>	<p>Complete</p>

	<p>the MAR and Pyxis. This has led to medication errors including the Once medication being given days later without a new order being obtained from the provider. The question posed to the committee was: “How long should medication orders with the frequency of “once” remain active/available for administration on the MAR if not documented as “not given”?</p> <ul style="list-style-type: none"> ● Discussion surrounding the purpose of a Once order along with timing the medication should be given <ul style="list-style-type: none"> ○ Once orders by providers intended to be given within a timely manner (vs days later) ○ Account for possible patient transfers and time off the floor for diagnostic testing ● Solution: change Once orders to auto-discontinue after 12 hours <p>The proposed solution will be shared back to the cross-market committee. Rachel will update the committee once a decision is finalized.</p>		
Policies	<p>A. Medication Administration: Timeliness of Scheduled Medications: Updated to align with current EPIC workflows. Changes to the “Standard Scheduled Administration Times” include:</p> <ul style="list-style-type: none"> ● 3 times daily changed to 0900, 1500, 2100 ● Multiple respiratory therapy (RT) timing changes 	Approved	Complete

There being no further business, the meeting was adjourned at 8:09 a.m. The next P&T meeting is **March 30, 2023**.

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

Approved by,
Nathan Chamberlain, MD, Chairman

FORMULARY REVIEW

GENERIC NAME: Spesolimab-sbzo

PROPRIETARY NAME: *Spevigo*®

INDICATIONS:

FDA Approved
Generalized pustular psoriasis (GPP) in adults

THERAPEUTIC CATEGORY: Interleukin-36 receptor (IL-36R) antagonist monoclonal antibody

PHARMACOKINETICS:

	Spesolimab-sbzo
Absorption	After a single IV dose of spesolimab-sbzo, the population PK model-estimated AUC _{0-∞} (95% CI) and C _{max} (95% CI) in a patient with GPP were 4750 (4510, 4970) mcg*day/mL and 238 (218, 256) mcg/mL, respectively. The AUC increased dose-proportionally from 0.3 to 20 mg/kg.
Distribution	Based on the population pharmacokinetic analysis, the typical total volume of distribution at steady state was 6.4 L.
Metabolism	The metabolic pathway has not been identified. As a humanized IgG1 monoclonal antibody, it is expected to be degraded into small peptides and amino acids via catabolic pathways similar to endogenous IgG.
Elimination	Excretion for a GPP patient without adenosine deaminase weighing 70 kg was 0.184 [95% CI (0.175, 0.194)] L/day. The terminal half-life was 25.5 (24.4, 26.3) days.

SPECIAL POPULATIONS:

	Spesolimab-sbzo
Pregnancy	Human IgG crosses the placental barrier; thus, spesolimab-sbzo may act in the same manner. Data is limited on the use of this medication in pregnant women and insufficient to determine safety in pregnancy. IV administration in mice during the organogenesis period did not elicit any reproductive toxicity.
Lactation	There is no data on the presence in human milk, the effects on the breastfed infant, or the effects on milk production. Because the medication is a monoclonal antibody, it is expected to be present in human milk.
Pediatrics	Safety and efficacy have not been established in pediatric patients.
Geriatrics	In the Effisayil-1 study, two patients were 65-74 years of age, and no patients were 75 years of age or older. Unable to determine differences within the geriatric population due to insufficient numbers.
Hepatic Impairment	Not expected to undergo hepatic elimination.
Renal Impairment	Not expected to undergo renal elimination.
Other	Age, gender, and race did not have an effect on the pharmacokinetics of spesolimab-sbzo based on population pharmacokinetic analyses.

CLINICAL STUDIES:

Effisayil-1 Study
METHODS

Study Design	Randomized, double-blind, placebo-controlled, phase 2 trial
Patient Enrollment Inclusion	<p>Patients aged 18 to 75 years of age with a GPPGA (Generalized Pustular Psoriasis Physician Global Assessment) score of 0 or 1 and a documented history of GPP</p> <p>First GPP flare of moderate-to-severe intensity</p> <p>Evidence of fever, and/or asthenia, and/or myalgia, and/or elevated C-reactive protein, and/or leukocytosis with peripheral blood neutrophilia</p>
Patient Enrollment Exclusion	<p>Plaque psoriasis without pustules or with pustules restricted to psoriatic plaques</p> <p>Drug-triggered acute generalized exanthematous pustulosis</p> <p>Immediate, life-threatening flare of GPP warranting intensive care treatment</p> <p>Current treatment with restricted medications including, but not limited to, methotrexate, cyclosporine, retinoids, and specified biologics</p>
Baseline Characteristics	The study population consisted primarily of women (68%) with a mean age of 43 years (range: 21 to 69 years). 55% of patients were Asian and 45% were White. Majority of patients had a GPPGA pustulation subscore of 3 (43%) or 4 (36%) and a GPPGA total score of 3 (81%) or 4 (19%). One-fourth of the patients enrolled had previously been treated with a biologic agent for GPP. Patients were required to discontinue other systemic and topical therapies for GPP prior to the study period.
Treatment Plan	Single IV dose of spesolimab 900 mg (N=35) vs placebo (N=18). Subjects in either group with continued flare symptoms at week 1 could receive a single open-label dose of spesolimab 900 mg IV. After week 1 to week 12, subjects with GPP flare reoccurrence could receive a single open-label rescue dose of spesolimab 900 mg IV. The maximum number of doses allowed in the study was 3.
RESULTS	
Outcomes Summary	At the end of week 1, 54% of patients in the treatment group have a GPPGA pustulation subscore of 0 (no visible pustules) vs 6% of patients in the placebo group. 43% of patients in the treatment group vs 11% in the placebo group had a GPPGA total score of 0 or 1 (clear or almost clear skin) at the end of week 1. Due to 15 of 18 patients in the placebo group receiving open-label spesolimab at the end of week 1, planned hierarchical testing of secondary endpoints at week 4 was noninformative, and the remaining secondary endpoints were reported descriptively.
Primary Endpoint	GPPGA pustulation subscore of 0 (no visible pustules): 54% in treatment group vs 6% in placebo group (95% CI, 21 to 67; p<0.001).
Secondary Endpoint	GPPGA total score of 0 or 1 (clear or almost clear skin): 43% in treatment group vs 11% in placebo group (95% CI, 2 to 53; p=0.02).
Adverse Events	<p>Week 1:</p> <p>66% of patients in treatment group (N=35) experienced at least one AE</p> <p>56% of patients in the placebo group (N=18) experienced at least one AE</p> <p>Week 12: spesolimab (N=51)</p> <p>82% of patients who received at least one dose of spesolimab experienced at least one AE</p> <p>12% of patients experienced a serious AE</p> <p>47% of patients experienced an infection</p> <p>No patients experienced an AE leading to discontinuation of the drug or death throughout the treatment period</p>

Limitations	Small sample size; Short period of randomized treatment; Limited follow-up time; Baseline imbalances of the trial groups
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COMPARATIVE EFFICACY:

This product is currently the only FDA approved medication for GPP flares.

According to the Medical Board of the National Psoriasis Foundation, first-line medications for GPP are methotrexate, systemic retinoids, cyclosporine, and infliximab. Treatment recommendations are largely based on data from small, single-arm trials, retrospective reviews, and case studies. Despite limited data, infliximab is considered by many experts to be first-line therapy in patients with extensive disease. Infliximab and cyclosporine have a faster onset of action than other treatments, so many physicians consider these drugs as first-line treatment in patients with severe, acute disease. Anti-interleukin 17 or 23 biologic agents have also been used in recent years. Data on these therapies for GPP is limited and insufficient to determine relative efficacy. Rapid initiation is needed for patients with a GPP flare; thus, treatment availability of medications often impacts the choice of therapy.

WARNING AND PRECAUTIONS:

- Increased risk of infections; do not initiate during any clinically important active infection
- Evaluate patients for TB prior to treatment initiation
- Hypersensitivity (including DRESS) and infusion-related reactions may occur; discontinue immediately and initiate appropriate treatment if a serious hypersensitivity reaction occurs
- Do not concurrently administer live vaccines with spesolimab-sbzo

BLACK BOX WARNINGS: None

CONTRAINDICATIONS: Severe or life-threatening hypersensitivity to the drug or excipients

ADVERSE REACTIONS:

Adverse Reactions	Intervention Group (N=35) (%)	Placebo or Standard of Care Group (N=18) (%)
Cardiovascular	N/A	N/A
Central Nervous System	Asthenia and Fatigue (9%), Headache (9%)	Headache (6%)
Gastrointestinal	Nausea and Vomiting (9%)	Nausea and Vomiting (6%)
Hematologic and Oncologic	N/A	N/A
Hepatic	N/A	N/A
Infection	Urinary Tract Infection (6%), Bacteremia (3%), Bacteriuria (3%), Cellulitis (3%), Herpes Dermatitis and Oral Herpes (3%), Upper Respiratory Tract Infection (3%)	N/A
Metabolic	N/A	N/A
Neuromuscular & Skeletal	N/A	N/A
Renal	N/A	N/A
Respiratory	Dyspnea (3%)	N/A
Skin	Pruritus and Prurigo (6%), Infusion Site Hematoma and Bruising (6%), Urticaria (3%)	N/A
Ophthalmic	Periorbital Edema (3%)	N/A

CLINICALLY SIGNIFICANT DRUG INTERACTIONS: No formal drug interaction studies have been conducted

DOSING AND ADMINISTRATION:

Administer as a single 900 mg dose by intravenous infusion over 90 minutes. If flare symptoms persist, may administer an additional intravenous 900 mg dose one week after the initial dose.

RECOMMENDED MONITORING: Signs and symptoms of active TB during and after treatment

PHARMACOECONOMICS/COST:

Medication specific billing codes:

J1747 – effective April 1, 2023

Product (Drug, Strength, Form)	Cost/Day	Cost/Defined Course of Therapy	Cost/Year
SPEVIGO 450mg/7.5ml IV solution – packaged as 2 vials per carton	\$51,133	Up to \$102,266 per disease flare	N/A

CONCLUSION & RECOMMENDATION:

Generalized pustular psoriasis (GPP) is a rare (estimated prevalence of <5,000 individuals in the U.S.), inflammatory skin condition characterized by widespread, sterile pustules and recurrent, acute flares. Systemic symptoms may or may not be present and include pain, fever, malaise, fatigue, loss of appetite, muscle weakness, and edema. The disease course varies from a benign, chronic process to an acute life-threatening episode, and optimal treatment depends on severity. Without treatment, flares generally last 2-5 weeks, but can persist longer than 3 months and lead to complications. Complications may include mucosal symptoms, arthritis, neutrophilic cholangitis, and secondary amyloidosis. Life-threatening complications include sepsis and renal, hepatic, respiratory, and heart failure. Approximately 50% of GPP flares require hospitalization, and mortality ranges from 5 to 32%. Current treatment recommendations are largely based on data from small, single-arm trials, retrospective reviews, and case studies. Oral retinoids, methotrexate, cyclosporine, infliximab, and other biologic agents have been used as off-label treatments in these patients.

Spesolimab-sbzo is a humanized monoclonal antibody that inhibits IL-36 signaling by specifically binding to the interleukin-36 receptor (IL-36R). Binding of spesolimab-sbzo to IL-36R prevents the subsequent activation of IL-36R by ligands and downstream activation of pro-inflammatory and pro-fibrotic pathways. Spesolimab-sbzo was granted breakthrough therapy designation and underwent fast-track approval to gain FDA approval in September 2022.

The Effisayil-1 study demonstrated that the percent of patients that had no visible pustules at week 1 after treatment was 54% in the treatment group vs 6% in the placebo group. The percent of patients that had clear or almost clear skin at week 1 after treatment was 43% in the treatment group vs 11% in the placebo group.

Several notable warnings and precautions exist including the risk for infections and hypersensitivity reactions (including drug reaction with eosinophilia and systemic symptoms (DRESS)).

It is recommended that due to the significant cost and the rarity of GPP in the United States, spesolimab-sbzo should be added to formulary, but with restrictions to outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.

FAILURE, MODE AND EFFECTS ANALYSIS (FMEA)

Medication Management Step	Identified Risk	Steps for Prevention
Selection		
Therapeutic interchange?	N/A	
Special Ordering Requirements?	N/A	
Storage		
LASA* separation of stock?	N/A	
Special storage (e.g. refrigeration, protect from light, controlled substance)?	Yes	Store refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze.
Pharmacist/Technician Education?	Yes	Educate on storage
Ordering & Prescribing		
Restriction to particular specialty, indication, or particular patient population?	Yes	Preferably restrict to rheumatology or dermatology. Restrict to diagnosis of moderate-to-severe GPP flare.
Dosing Issues (e.g. renal, hepatic dosage adjustment, max dose warnings)?	N/A	
Drug Interactions?	N/A	
Pregnancy?	N/A	
Absolute Contraindications?	Yes	Severe or life-threatening hypersensitivity to spesolimab-sbzo or any of the excipients in Spevigo
Requires Order Set, Protocol, concomitant therapy with another drug?	N/A	
LASA* nomenclature issues?	N/A	

Medication Management Step	Identified Risk	Steps for Prevention
Prescriber education?	N/A	
Processing, Preparing, & Dispensing		
High-risk drug double check?	N/A	
Drug Interaction check in place?	N/A	
LASA* computer warnings?	N/A	
Administration Notes for MAR (e.g. handling precautions, surrounding food or other drugs)?	Yes	Administer within 4 hours of reconstitution
Packaging/Labeling (e.g. prepacking)?	N/A	
Dispensing (e.g. auxiliary labeling, light protection, refrigeration)?	Yes	Refrigerate, protect from light
Documentation required (e.g. double check, worksheet)?	N/A	
Pharmacist/Technician Education?	Yes	Dilution procedure: remove 15 mL from 100 mL of 0.9% NaCl injection solution and slowly replace with 15 mL of Spreviso (two vials of 450 mg/7.5 mL)
Administration		
Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, or other administration information?	Yes	Do not mix or administer with other medicinal products. If the infusion is slowed or temporarily stopped, the total infusion time (including stop time) should not exceed 180 minutes. Flush pre-existing IV line with 0.9% NaCl prior to and at the end of infusion. Administer within 4 hours of reconstitution.
Special delivery system (e.g. pump)?	Yes	Use pump to administer over 90 minutes
Documentation required? (e. g. double check)	N/A	
Nurse education?	Yes	Educate on total infusion time (not to exceed 180 minutes) and to administer alone within 4 hours of dilution
Monitoring		
Interactions, adverse effects, efficacy, changes in renal function, or similar?	Yes	Infections, TB, hypersensitivity and infusion-related reactions including DRESS
Follow-up laboratory tests?	Yes	CBC
Education?	Yes	Discontinue infusion immediately if a serious hypersensitivity reaction occurs
Operational Impact		
Unique procurement process? (e.g. orphan medication)	Yes	Available from McKesson Specialty
Unique equipment required?	N/A	
Complex preparation process required	N/A	

FORMULARY UPDATE

THERAPEUTIC CLASS: Optical imaging agent/photosensitizing agent

GENERIC NAME: Aminolevulinic acid

PROPRIETARY NAME: Gleolan®

BACKGROUND/RATIONALE:

In Oct 2021, the CHI Memorial P&T Committee voted to approve Gleolan to formulary. Gleolan is an oral optical imaging agent indicated in patients with glioma as an adjunct for the visualization of malignant tissue during surgery. Dosing is weight-based at 20 mg/kg. Dr. Babu utilizes Gleolan.

Currently, patients are being charged for the full amount of the Gleolan vial (1 vial = 1500 mg) even though based on the weight-based dose, they may not receive 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.

Recently, other CommonSpirit facilities using Gleolan have adopted a fixed-dose strategy to resolve this issue.

- Patient weight ≤ 120 kg = 1500 mg (1 vial)
- Patient weight > 120 kg = 3000 mg (2 vials)

PHARMACOECONOMICS/COST:

Product	Cost per vial
Aminolevulinic acid (Gleolan) 1500 mg	\$2,998

DISCUSSION:

A review of patients who have received Gleolan since we started using it in early 2022 was performed. There were 4 patients total. All weighed less than 120 kg so would have received one 1500 mg vial. One of the 4 patients would have had a substantial dose change- the fixed dose of 1500 mg is ~32% less than the administered dose.

Dr. Ranjith Babu has reviewed the data and has approved the fixed-dose strategy.

RECOMMENDATION:

It is recommended to adopt a fixed-dose strategy for Gleolan as follows:

- Patient weight ≤ 120 kg = 1500 mg (1 vial)
- Patient weight > 120 kg = 3000 mg (2 vials)
- Pharmacist to round to the nearest vial size

FORMULARY UPDATE

THERAPEUTIC CLASS: Antibiotic

GENERIC NAME: Sulfadiazine

BACKGROUND/RATIONALE:

Sulfadiazine is an oral antibiotic tablet. Its mechanism of action interferes with bacterial growth by inhibiting bacterial folic acid synthesis through competitive antagonism of PABA. Sulfadiazine is FDA approved for treatment of toxoplasmosis encephalitis in combination with pyrimethamine and prophylaxis of rheumatic fever in patients with penicillin allergy.

In the past 6 months, there have been no inpatient orders for sulfadiazine tablets.

The cost for sixty 500 mg tablets is \$884.

RECOMMENDATION/DISCUSSION:

It is recommended to remove sulfadiazine tablets from formulary. Patients will be allowed to continue their own home supply.

This recommendation was approved by Dr. Anderson.

FORMULARY UPDATE

THERAPEUTIC CLASS: Analgesic; opioid

GENERIC NAME: Acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL

BACKGROUND/RATIONALE:

Acetaminophen with codeine is indicated for pain management of mild to moderate pain where treatment with an opioid is appropriate and for which alternative treatments are inadequate. Use should be reserved for patients for whom alternative treatment options (eg, nonopioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate.

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 (it was available in a 40 count unit dose package). The only option for purchase currently is a 100 count package at a higher price, so most of it will be wasted based on utilization.

A utilization report for 12 months showed only 3 doses were administered during that time frame. All were in the EDs; 1 at Glenwood (adult) and 2 at Georgia (pediatric patients).

DISCUSSION/RECOMMENDATION:

Alternative oral liquid options for mild to moderate pain on formulary include: acetaminophen, ibuprofen, hydrocodone with acetaminophen.

Dr. Champion approved of formulary removal of acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL due to low use and availability of oral liquid alternatives for mild to moderate pain.

It is recommended to approve removal of acetaminophen 120 mg and codeine phosphate 12 mg per 5 mL from formulary.

DRUG SHORTAGE MANAGEMENT

BACKGROUND/RATIONALE:

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

MEDICATION #1: Duoneb (ipratropium 0.5 mg/albuterol 2.5 mg per 3 ml)

Summary: Duoneb is currently a critical shortage item. On March 7, 2023, the P&T Committee chairman emergently approved the automatic interchange by pharmacists of Duoneb to the separate components, ipratropium and albuterol, as individual medications. Nebulizing the separate medications takes double the nebulization time by the RRT due to essentially double the nebulized volume.

Discussion/Recommendation: While we have received some backorders, Duoneb remains a critical shortage item with little new supply. Pharmacists are still required to manually perform this substitution for most orders for Duoneb. In collaboration with respiratory therapy leadership, orders for Duoneb are being slowly integrated back into patient care on 5N, 6N, and 7N only due to RRT staffing.

It is recommended to formally approve the pharmacist emergent automatic interchange for orders of Duoneb to individual orders of ipratropium and albuterol nebulizers during times of Duoneb shortage.

POLICY

Title: METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) NASAL PCR – PHARMACY ORDERING			
Page 1 of 1			
Policy Number: MM-05471		Date Last reviewed/Revised: 8/20	Valid Until: 8/23
Campus: <input checked="" type="checkbox"/> CHI Memorial Glenwood <input checked="" type="checkbox"/> CHI Memorial Hixson <input checked="" type="checkbox"/> CHI Memorial Georgia <i>Check all that apply</i>			
Department(s) Affected: Pharmacy, Clinical Staff		Review Period: every 3 years	

PURPOSE:

Intravenous (IV) vancomycin is frequently utilized for the empiric treatment of pneumonia in patients with suspected methicillin-resistant *Staphylococcus Aureus* (MRSA). The Infectious Diseases Society of America (IDSA) guidelines for pneumonia recommend empiric anti-MRSA therapy in patients with specific risk factors. When anti-MRSA coverage is initiated, it is recommended to obtain cultures and a rapid nasal PCR for de-escalation.

The MRSA rapid nasal PCR has been shown to have a high negative predictive value (95-99%) for MRSA pneumonia and has been safely used to de-escalate vancomycin therapy in studies. Several studies have also demonstrated that pharmacy managed MRSA nasal swab programs can reduce the duration of unnecessary empiric IV vancomycin therapy.

POLICY:

The policy is intended to improve the utilization of IV vancomycin for patients with pneumonia.

PROCEDURE:

1. Pharmacist performing daily IV vancomycin dosing will review patient chart for indication.
2. If IV vancomycin was ordered for the treatment of pneumonia and no MRSA nasal swab ordered, pharmacist will place order for the test. See [MEDICATION ORDERS – PHARMACIST REVIEW](#) policy.
3. Upon result finalization, pharmacist will discuss IV vancomycin de-escalation with the provider.

Key Contact: Pharmacy Clinical Manager, Pharmacy Review Team

Approved/Reviewed by: Pharmacy & Therapeutics committee, Director of Pharmacy, Nursing Professional Practice Council, Chief Nursing Officer

Reference(s):

1. [Kalil AC, Metersky ML, Klompas M, et al.](#): Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Infect Dis*. 2016, 63:61.
2. [Metlay JP, Waterer GW, Long AC, et al.](#): Diagnosis and treatment of adults with community-acquired pneumonia. *Am J Respir Crit Care Med*. 2019, 7:e45-e67.
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Pharmacist Clinical Interventions
“Serious’ Significance Level

Background:

Pharmacists are expected to routinely document their clinical activities and interventions. Documentation includes a default significance level of low, moderate, or serious. The pharmacist may choose to modify the significance level to a higher level from the default if the activity/intervention meets the standard definition for the corresponding significance level. The pharmacy clinical manager routinely reviews the documented clinical interventions in order to provide retrospective feedback.

When time allows, the P&T Committee will begin a periodic review of the "serious" significance level interventions made by pharmacists, including those rejected by providers.

Data Summary:

<i>Pharmacist Clinical Intervention Documentation</i>				
<i>Dec 2022-Feb 2023</i>				
<i>LOC NAME</i>	<i>INTERVENTION TYPE</i>	<i>INTERVENTION SUBTYPE</i>	<i>RESPONSE</i>	Grand Total
CHI Memorial Hospital	Anticoagulation	Discontinue Therapy	Accepted	1
		Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted	1
		Drug Optimization		1
			Accepted	4
	ED Pharmacy Service	Discontinue Therapy	Accepted	1
	Med Rec/Transition of Care	Added Drug Therapy		1
	Medication Related Problems	Clarify Drug Order		1
		Discontinue Therapy	Accepted	2
		Dose Optimization (renal, hepatic, age, weight, etc.)		2
			Accepted	2
		Drug Interaction Problem Resolved	Accepted	1
		Drug Optimization		4
			Accepted	2
		Opioid Stewardship	Drug Optimization	Accepted
CHI Memorial Hospital Hixson	Anticoagulation	Added Drug Therapy	Accepted	1
		Drug Information	Provider Drug Information Provided	Accepted
	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)		1
		Drug Optimization	Accepted	1
Grand Total				28

Clinical Intervention Detail:

LOC NAME	INTERVENTION TYPE	INTERVENTION SUBTYPE	RESPONSE	ORDER NAME	DOCUMENTATION
CHI Memorial Hospital Hixson	Anticoagulation	Added Drug Therapy	Accepted	phytonadione (vitamin K1) (AQUA-MEPHYTON) 10 mg in sodium chloride 0.9% (NS) 50 mL IVPB	<p>"Patient admitted to ED with life threatening bleed of unknown origin. Patient bleeding copiously from rectum and mouth. It was known that patient was taking an oral anticoagulant at the time, but no records could confirm which agent patient was taking nor could her spouse. MD in ED empirically treated with Kcentra. After patient was stabilized and transferred to ICU, our pharmacy medrec tech did confirm that patient was taking Jantoven per her outpatient doctor's office. Knowing this, I contacted Dr. Patton-Evans to notify her of the fact that patient was taking Warfarin and that typically it's recommended to give Vitamin K IV 5-10 mg in addition to PCC in order to sustain anticoagulation reversal. MD thanked me and stated to please give Vit K 10 mg IV due to seriousness of bleed."</p>
CHI Memorial Hospital	Anticoagulation	Discontinue Therapy	Accepted	apixaban (ELIQUIS) tablet 2.5 mg	<p>"Eliquis/phenytoin - drug interaction - heparin d/cd and Eliquis ordered but phenytoin on MAR -pt is high risk for clotting. I called Dr. Andresscu. He is seeing if can use warfarin but he asked if warfarin is not an option then can he use a higher dose of Eliquis -&gt; 5 mg bid - pt borderline technically qualifies for this dose, but I told him that I was a little nervous because pt came in a VERY low dose of Eliquis 2.5 mg po daily** (low dose why?? - bleed complication?? Unknown). We discussed this. I told him I still recommended the warfarin use because their would still be interaction with Eliquis at the higher dose, But if warfarin was ABSOLUTELY not a possibility. He opted to leave on the heparin gtt gtt for now and hold on the Eliquis and converse with patient and providers since pt is high risk for clot. He also mentioned pt on dilantin for 28 years due to brain tumor surgery but pt has never had one seizure.swelling of the ankles he is evaluating if pt needs the phenytoin at all. She took warfarin before and CHI d/cd due to leg swelling? Update:12/4 Andresscu - called back and said Neuro said to remove/stop the phenytoin and when they rule out GIB with Melena from EGD so they can now use Eliquis. Pt high risk for clot so heparin gtt is to remain on until the EGD Per Cardiology: Given that GI has been consulted, we will hold on transitioning to apixaban and continue heparin gtt for now. Perhaps the Hb drop is spurious but her Hb downtrend, dark stools, and abdominal pain give me concern that she may have a UGIB</p>

					<p>Still on heparin drip.</p> <p>Per Cardiology: When okay with GI and primary service Eliquis 2.5 mg twice daily can be restarted.</p> <p>GI has not cleared patient for Eliquis yet. Patient remains on heparin drip.</p> <p>Eliquis restarted, phenytoin stopped "</p>
CHI Memorial Hospital	Anticoagulation	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted	apixaban (ELIQUIS) tablet 5 mg	"Eliquis reordered from home medication list as daily, since patient reported taking daily. Noticed patient was recently here for a PE and was discharged on 10 mg po bid then 5 mg po bid. Contacted MD about this and asked to go back to 5 mg po bid given this information. MD agreed. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization	Accepted	cyanocobalamin (VITAMIN B-12) injection 1,000 mcg	"Vit B12 IM on anticoag w/ cirrhosis - changed to SC to avoid hematomas "
CHI Memorial Hospital	Anticoagulation	Drug Optimization	Accepted	clopidogreL (PLAVIX) tablet 75 mg	"Clopidogrel - pt is POD #0- just out of CAB surgery - Dr. Richey accidentally ordered Plavix now - I texted to make sure he did not want this for POD #2 (instead of POD 0). He said POD #2 and thanked us for catching that. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization	Accepted	heparin injection 5,000 Units	"Spoke to Dr. Michealis because she had ordered 5000 units to be the drip adjustment bolus for PTT <57. This was a mistake and she told me she meant to do it as the protocol ordered. I fixed the order. She also clarified this patient did not receive TNK. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization	Accepted	heparin infusion 50 units/mL in 0.45% NaCl	"Dr. Ledford ordered Eliquis 2.5 mg BID along with a heparin drip for possible LAA thrombus. The RN called to clarify starting rate of heparin drip since the PTT > 150. I explained that per protocol, she does not need to start a heparin drip until the PTT < 108 and that she needs to call the MD back to clarify orders. She called Penny Milligan, NP who re-ordered a PTT. In the meantime, the patient's INR increased from 1.6 to 2.4 even though the patient held Coumadin x 3 days prior to procedure. I told the RN to add a stat INR, which came back at 1.8 allowing us to start Eliquis. The PTT was still elevated > 150, so the heparin drip was not started. Dr. Ledford called the pharmacy to address the situation explaining why he wants Eliquis to be bridged with heparin x 8 hours. I explained to him that per protocol, the PTT is too elevated and the heparin drip can't be started. Also explained that the most recent INR was 2.4, so Eliquis shouldn't be started until INR < 2. He was ok with this plan and appreciated pharmacy's input. I decided to discuss further with Rachel Kile, who agreed that the heparin drip should not be continued along with Eliquis as the Eliquis peak time is only 3-4 hours. Also, the patient should be on 10 mg BID x 7 days, then 5 mg BID thereafter for DVT treatment. I called Dr. Ledford back to discuss these changes. He was ok with changing Eliquis to treatment dosing and reducing the heparin bridge to 4 hours. I reiterated that the PTT is too high and the heparin drip

					can't be started yet. He was ok with this as long as the patient is anticoagulated. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization		apixaban (ELIQUIS) tablet 10 mg	"Dr. Ledford ordered Eliquis 5 mg BID to be bridged with a heparin drip for 8 hours for mitral valve thrombus. Messaged Dr. Ledford to change Eliquis to 10 mg BID x 7 days, then 5 mg BID thereafter treatment dosing. He was ok with this change and reduced the heparin bridge to 4 hours. "
CHI Memorial Hospital Hixson	Drug Information	Provider Drug Information Provided	Accepted	prothrombin complex (human) (KCENTRA) injection 2,000 Units	"Patient started on Protonix drip and Octreotide drip empirically for suspected GI bleed. Dr. Dowlen called down and stated that pt's Hgb was down to 4.1 on admission. Patient tachycardic with severe tachypnea as well appears white as a sheet. MD stated that patient takes Eliquis. Based on this and obvious urgent need for Eliquis reversal due to severe GI bleed, I recommended PCC 2000 units x 1 STAT. Entered order for MD, made the infusion which actually did make exactly 2000 units (never had that happen before) and Stacy, Pharm.D. checked PCC and delivered to nurse. "
CHI Memorial Hospital	ED Pharmacy Service	Discontinue Therapy	Accepted	prothrombin complex concentrate (KCENTRA) injection placeholder	"Spoke with Dr. Joels about reversing Eliquis with PCC. After she found out last dose was at 6:30 AM yesterday, we both decided benefit dose not outweigh risk of administration. Also, BP is stable after fluids and Hgb is relatively stable. "
CHI Memorial Hospital	Med Rec/Transition of Care	Added Drug Therapy			"Pt is post Stemi , leaving mic, the prasugrel was prescribed but asa 81 mg was not continued. Contacted Penny Mulligan NP and she added to discharge list. "
CHI Memorial Hospital	Medication Related Problems	Clarify Drug Order		milrinone (PRIMACOR) infusion 20 mg in dextrose 5% (D5W) 100 mL (200 mcg/mL)	"Pre-op CAB orders - I called CVTS and spoke to Greg Evans - orders would have made me d/c milrinone, revatio, and Lasix, and made sure that I was not supposed to take all of these off, and he said we definitely needed to leave all of that on despite the pre-op standard orders. I left them all on the MAR for surgery planned on 12/12. "
CHI Memorial Hospital	Medication Related Problems	Discontinue Therapy	Accepted	digoxin (LANOXIN) injection 250 mcg	"Digoxin load doses were already given and re-ordered by new physician next day- called Dr. Bruce and he had not seen prior day load doses - he opted to cancel the 500 mcg now and in 6 hrs, another 250 mcg x1 IV, and he decided to then give digoxin 250 mcg x 1 now and start oral on 12/13. "
CHI Memorial Hospital	Medication Related Problems	Discontinue Therapy	Accepted	divalproex (DEPAKOTE SPRINKLE) capsule 500 mg	"Patient on depakote sprinkles and valproic acid soln. Sprinkles started last night, other started this am. Called Dr. Lewis. He had intended to stop the depakote sprinkles and asked that I do so. "
CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted		"Cyclophosphamide - critical care wanted doses after EACH dialysis. - I thought most Ive ever used for ANCA vasculitis was once every 2 weeks. I talked to nephrology and they said to order when I say to give it next time - no more cyclophosphamide at this time - Dr. McCarley will look at again in 2 weeks. "

CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)		flecainide (TAMBOCOR) tablet 75 mg	"AKI/flecainide - told Dr. Gross about and she agreed to a decrease in the Flecainide dose with AKI and to clearance estimates of ~ 28 ml/min - I decreased as recommended in AKI by 50% of the previous dose of flecainide 150 mg po bid - talked about cardiology is not seeing as of now and she said to decrease the dose and that ICU staff would keep an eye on vitals. "
CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)		pyridostigmine (MESTINON) injection 20 mg	"Pt was on pyridostigmine 60 mg po and provider ordered 20 mg iv , I contacted provider and notified that the iv/im dose is 1/13 of the po dose. NP changed dose to 2mg iv q6 instead of 20 mg iv "
CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted	lithium capsule 300 mg	"Lithium level - 1.8 - high and pt was having progressive weakness (main issue for admission). Alerted provider to reduce dose to see if would help - pt also on baclofen, zanaflex, oxybutinin, and clonazepam. I alerted the staff. "
CHI Memorial Hospital Hixson	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)			"This patient came in for reblast and scr had risen to 1.25 on 11-30, crcl <35ml/min, I asked the RN to repeat the scr and today is 1.6, saved pt receiving reblast with declining renal function "
CHI Memorial Hospital	Medication Related Problems	Drug Interaction Problem Resolved	Accepted		"Pt can only take nexium 40 mg po bid for GERD, called Melinda helton NP because this med has an interaction with sprycel - can lower the serum conc and with MTX can increase serum conc. Dr Donnellan ordered pt only take once daily due to the interaction "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization			"Patient on sotalol, NP Jamie Taylor wrote for diflucan and zithromax. I contacted her and notified her of the potential of prolonged QTC interval of these 3 meds. She discontinued the diflucan. I explained if going to keep pt on zithromax will need to monitor QTC interval while receiving the zithromax "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization		latanoprost (XALATAN) 0.005 % ophthalmic solution 1 drop	"Clarified emergent eye drops with family - corneal transplant -Clarified 4 different eye drops - including Oflaxin for the left eye. Family said the restasis "was not important" as the other 4 drops and not to include at this time this per the family regarding written ophthalmology/corneal transplant instructions (family was very attentive with written pt instructions) - this will get clarified with home med reconciliation but when restasis placed in we would normally just substitute to Refresh saline gtts per hospital policy anyway. All other emergent eye drops placed on MAR as I was instructed to ask them regarding placing these on the MAR for administration by Dr. Gross "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization		insulin regular (HumuLIN R,NovoLIN R) 250 Units in sodium chloride 0.9% (NS) 250 mL infusion	"Insulin drip question stated to change drip to 2 units/kg/hr which would have resulted in 300 units of insulin per hr but Dr. Holguin meant for it to be 2 units/hr. So I changed it to 0.01 units/kg/hr to result in 1.5 units/hr. "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization	Accepted	ondansetron PF (ZOFTRAN) injection 4 mg	"Rejected zofran. Patient with prolonged QT interval - Sotalol (home med) also currently held until addressed. "

CHI Memorial Hospital	Medication Related Problems	Drug Optimization		metoprolol succinate (TOPROL-XL) 24 hr tablet 50 mg	"Metoprolol - bradycardia - Pt just returned from cath lab - I verified amlodipine for BP to give but metoprolol was ordered by Dr. Wiggins and HR - 58. I called and got hold of SSU RN who just received pt from cath lab. I asked if pt was on a pacer. She said "no". Pt would get the pacer tomorrow on 1/13. I told her I would hold the metoprolol for now with the HR. She agreed and she said she was NOT going to be able to get a hold of EP at 5:30 PM. I told her that I would not give the metoprolol right now, but we both compromised to time out to about 2100 so the sedation may wear off and her HR may come up. She said she was aware and I told her to also pass it off in report to the following RN also. She said yes..and will watch the HR before giving the metoprolol at 2100 too. - MCU - 1/12 @ 17:41 Intervention closed automatically "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization	Accepted	Adult Central TPN continuous infusion	"TPN/DVT -PICC pulled - alerted staff for heparin/Lovenox use - no anticoag on the MAR with DVT - Rx Called -Staff said they are now presently waiting on the provider orders to use anticoagulation/approval and instructions regarding a new PICC. I told them that they could run D10W in place of TPN peripherally @55 ml/hr along with the NS@60. "
CHI Memorial Hospital Hixson	Medication Related Problems	Drug Optimization	Accepted	modafinil (PROVIGIL) tablet 200 mg	"Patient now experiencing wide-complex tachycardia and requiring Amiodarone infusion. Patient still on Provigil 200 mg BID. Notified Dr. Virani of this and got TORB to hold stimulant while patient is experiencing wide-complex tachycardia. "
CHI Memorial Hospital	Opioid Stewardship	Drug Optimization	Accepted		"Patient admitted with seizures + hx of seizure do. On high dose oral morphine. HD. Suspect part of cause was due to opiate withdrawal as son shares morphine with patient. We have patient on MS Contin 60 BID but patient is only prescribe 30 tabs each of 60 mg and 30 mg. Would be out early even if she wasn't abusing. Patient lives in Sweetwater TN but doc and pharmacy are in Columbus, GA. Only one doc - looked him up and he recently settled \$1 million to resolve violations of CSA and False Claims Act at end of October. Morphine metabolite buildup in dialysis patients can lower seizure threshold. Patient did have HTN causing PRES. 1 case report of opiate withdrawal also causing PRES. Spoke with Neuro NP and relayed all this info."