

Pharmacy & Therapeutics Committee Meeting

Private Dining Room

October 8, 2020 7:00 a.m.

Agenda Items

Individual

Responsible

- 1. Call to Order Nathan Chamberlain, MD
- 2. Conflict of Interest Disclosure Rachel Kile, PharmD
- 3. Approval of Aug 2020 Minutes Nathan Chamberlain, MD

- 4. CSH System P&T Committee – September 2020 Decision Brief Page
5

- 5. Old Business
 - A. Workgroup: Care for patients experiencing opioid withdrawaln/a

- 6. Formulary Decisions & Therapeutic Interchanges
 - A. Sodium zirconium cyclosilicate (Lokelma) 12
 - B. Oritavancin (Orbactiv) 13
 - C. Biosimilar formulary additions- *information only*..... n/a

Next Meeting Date: December 10, 2020 at 7:00 AM in the Private Dining Room

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: August 27, 2020
 LOCATION: Private Dining Room

CALLED TO ORDER: 7:05 A.M.
 ADJOURNED: 7:50 A.M.

Members Present:		Members Absent:	Guests:	
Nathan Chamberlain, MD Mark Anderson, MD David Dodson, MD F. Lee Hamilton MD William Haren, MD Matthew Kodsi, MD Richard Yap, MD Allen Atchley, MD	Rhonda Hatfield, RN-CNO Karen Frank, RN-Quality Patrick Ellis, PharmD Rachel Kile, PharmD Daniel Marsh, PharmD Carey Smith, RPh Susan Fuchs, RD Lori Hammon, RN-Quality	Manuela Bresee, RN Chris Chastain	Chad Paxson, MD Vimal Ramjee, MD Karen Babb, PharmD Shannon Harris, RN Rodney Elliott Chris Chastain	Andrea Wilkinson, PharmD Kristen Liveris, PharmD La'Travia Howard, PharmD Sierra Detwiler, PharmD Courtney Troglin, Student

This meeting will be convened under the protection of the Tennessee Statute 63-6-219 and the Health Care Quality Improvement Act of 1986, Public Law 99-660. All information, case reviews, meeting minutes, statistics and correspondence are confidential and protected. Included in that protection are those that are involved in the review of the information. Any discussion of this information outside the realm of Peer Review constitutes a breach and violates the protection of the persons involved in the breach.

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Minutes	The June 2020 minutes were approved as submitted.	Approved	Complete
CSH System P&T Committee	July 2020 Decision Brief: The medications that were reviewed at the CommonSpirit Health (CSH) System P&T committee meeting were reviewed. All new system formulary medications or changes were either consistent with existing Memorial formulary decisions or are described in the "Therapeutic Interchanges and Formulary Changes" section of the minutes below, or will be reviewed at an upcoming P&T meeting.	Information	Complete
Old Business	1. Workgroup: Guidelines for treatment of the acutely agitated or violent patient: Progress will be shared at the next committee meeting.	Information	Pending
	2. Workgroup: Care for patients experiencing opioid withdrawal: A multidisciplinary group has formed to ensure adequate resources are dedicated to caring for inpatients with or at risk for opioid withdrawal. Representatives from nursing, quality, case management, hospitalists, and pharmacy are engaged. The next action item is a panel discussion with the CHI Franciscan team to learn best practices, as they have an established program.	Information	Complete
	3. ProcalAmine Medication Use Update/Evidence-based guidelines for enteral nutrition: Rachel shared the results of an updated ProcalAmine MUE which confirmed similar results to the previous MUE: failure to provide sufficient protein and kcals. Discussions from a workgroup with pharmacy, nutrition, and nursing, regarding enteral feeding was shared. The committee asked that the results of this MUE as well as education on guideline-directed enteral feeding be provided at the next hospitalist meeting.	Information	Complete
Formulary Decisions & Therapeutic Interchanges	1. Argatroban formulary removal: The committee approved removal of argatroban from formulary. Argatroban is significantly more costly than bivalirudin and is more difficult to titrate to therapeutic aPTT. Prior to this meeting, this was approved by cardiothoracic surgery, hematology/oncology, and cardiology. Bivalirudin will remain the IV direct thrombin inhibitor formulary agent. Argatroban will not be stocked.	Approved	Complete
	2. Biosimilar formulary additions: Per the Biosimilar policy approved at the last P&T committee meeting, new biosimilars that have been FDA approved for the same indications as the RP will be	Approved	Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	<p>automatically added to hospital formulary if the RP is currently approved as a formulary agent. Any formulary restrictions currently in place for the RP will be applied to the biosimilar medication. Biosimilars approved for addition to formulary: Nivestym (filgrastim-aafi), Renflexis (infliximab-abda), and Zirabev (bevacizumab-bvzr).</p> <p>3. Levalbuterol (Xopenex): Levalbuterol utilization was reviewed. The committee approved the addition of levalbuterol 0.63 mg/3 ml nebulized solution to formulary with restrictions as follows: use as a home medication due to albuterol intolerance, or documented tachydysrhythmia with albuterol. The restrictions will be built into the EHR. The 1.25 mg dose will not be stocked.</p> <p>4. Levothyroxine IV: The committee approved updated restriction/utilization criteria. The following will be built into the EHR: One of the following criteria must be met:</p> <ul style="list-style-type: none"> a. IV levothyroxine may be initiated after 5 days without PO therapy (due to long half-life) <ul style="list-style-type: none"> i. Once therapy is started, adjust dosing interval for IV route to 48 hours b. Presence of clinical hypothyroidism (TSH \geq 10 mIU/mL, decreased T4 or signs and symptoms of hypothyroidism) who are strict NPO c. Myxedema coma d. Patients on hypothermia protocol e. Potential organ donor status <p>5. Lurasidone (Latuda): Lurasidone was reviewed and added to formulary only for use as continuation of home medication therapy in order to allow for continuity of care for patients who cannot provide their own supply. This restriction will be built into the EHR.</p> <p>6. Vabomere & Avycaz: Updated restriction criteria for meropenem/vaborbactam (Vabomere) and ceftazidime/avibactam (Avycaz) were reviewed and approved, in alignment with updated CSH criteria. This restriction criteria will be updated in the EHR. Vabomere and Avycaz were already reviewed for assignment of formulary status at prior P&T committee meetings.</p>	<p>Approved</p> <p>Approved</p> <p>Approved</p> <p>Approved</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p> <p>Complete</p>
Policies	<p>1. Hypertonic Saline (3% NS) For Adults: Policy updated to reflect EHR workflows, but no clinical updates were necessary per pharmacy and nephrology reviews. The committee approved the policy updates.</p> <p>2. Vancomycin Dosing: Policy updated to consolidate vancomycin dosing management by pharmacists in preparation for pharmacy implementation of AUC-based monitoring later this year, in alignment with new IDSA/ASHP/SIDP vancomycin dosing guidelines. The committee recommended education on the new dosing process be shared with providers and nursing.</p>	<p>Approved</p> <p>Approved</p>	<p>Complete</p> <p>Complete</p>
Medication Safety	<p>1. ADR Summary: Rachel reviewed the adverse drug reaction summaries for May-September 2019 and no new trends were observed. Steroid induced hyperglycemia and leukocytosis remain the most common inpatient ADRs reported. There were zero category 3 ADRs.</p> <p>2. Sodium ferric gluconate: Dr. Dodson reported a recent infusion reaction attributed to sodium ferric gluconate (hypotension, nausea). There were similar reports several months ago from the CHI Franciscan market. Patrick will investigate to understand if this is related to a specific lot or manufacturer of medication.</p> <p>3. Expediting anaphylaxis treatment (medication protocols): Dr. Dodson reported a recent delay in treatment of anaphylaxis to ceftriaxone with epinephrine by nursing staff due to inability to access medication. Patrick reminded the committee of the P&T committee approved medication protocol (Anaphylaxis & Drug Hypersensitivity Treatment) that can be ordered and initiated by a nurse without an initial order from a physician. It was identified that nursing reeducation is needed on the</p>	<p>Information</p> <p>Information</p> <p>Information</p>	<p>Complete</p> <p>Complete</p> <p>Complete</p>

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
	approved medication protocols. Rachel will work with nursing leadership to ensure education is coordinated.		
Protocols & Orders	1. Medication Protocols & Standing Orders – TJC Annual Review: Per annual protocol and standing order review requirements, Rachel reviewed with the committee the medication related protocols and standing orders. See Attachment A of the minutes for the list of protocols and standing orders with committee-approved actions required. These were reviewed to ensure consistency with the latest standards of practice per evidenced-based guidelines, as well as if there have been any preventable adverse patient events resulting from use. Nursing reeducation is needed on the approved medication protocols. Rachel will work with nursing leadership to ensure education is coordinated.	Approved	Complete

There being no further business, the meeting was adjourned at 7:50 A.M. The next P&T meeting is **October 8, 2020 at 7:00 a.m.**

Respectfully submitted,
Patrick N. Ellis, PharmD, Director of Pharmacy

Approved by,
Nathan Chamberlain, MD, Chairman

CSH SYSTEM PHARMACY AND THERAPEUTICS (P&T) COMMITTEE DECISION BRIEF

September 2020 Decisions

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

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Timeline to Implementation
		Formulary Unrestricted	NonFormulary	Formulary Restricted		
HYALURONATE SODIUM	symptoms of knee osteoarthritis		HYALGAN			Within 90 days CSH System P&T approval
			DUROLANE			
			GEL ONE			
			GELSYN-3			
			GENERIC VISC 850			
			HYMOVIS			
			MONOVISC			
			ORTHOVISC			
			TRILURON			
			TRIVISC			
			VISCO-3			
					SUPARTZ FX	
			SYNVISC	Outpatient setting for FDA-approved or payer-approved off-label indications subsequent to insurance approval or prior authorization.		
			SYNVISC-ONE			
			EUFLEXXA			
FERRIC CARBOXYMALTOSE	Treatment of iron deficiency			INJECTAFER	1. Outpatient setting for FDA-approved or payer-approved off-label indications subsequent to insurance approval or prior authorization. 2. Patients with a known hypersensitivity to Fera heme 3. If third party coverage does not pay for Fera heme but does reimburse Injectafer	Within 90 days CSH System P&T approval
FERUMOXYTOL				FERAHEME	Outpatient Use Only for 1. FDA approved indication 2. Payer-approved off-label indications subsequent to insurance approval or prior authorization	

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Timeline to Implementation
		Formulary Unrestricted	NonFormulary	Formulary Restricted		
IRON DEXTRAN COMPLEX				INFED	1. Inpatient use (must utilize test dose) 2. If one-time doses are needed 3. Outpatient use (must utilize test dose) 4. FDA-approved or payer-approved off-label indications subsequent to insurance approval or prior authorization 5. If one-time doses are needed	
IRON SUCROSE COMPLEX				VENOFER	1. Patients with known hypersensitivity to sodium ferric gluconate 2. If unable to utilize sodium ferric gluconate immediately after dilution 3. Pregnant patients 4. Patients younger than 6 years of age	
SODIUM FERRIC GLUCONATE		SODIUM FERRIC GLUCONATE AND FERRLECIT				
LUSPATERCEPT-AAMT	Treatment of anemia associated with beta thalassemia.			REBLOZYL	1. Outpatient setting for FDA-approved indications or payer-approved off-label subsequent to insurance approval or prior authorization. 2. Patient has failed erythropoiesis-stimulating agents (ESA) if used for MDS	Within 90 days of System P&T Committee approval
TRASTUZUMAB-HYALURONIDASE-OYSK	HER2+ breast cancer in the adjuvant setting		HERCEPTIN HYLECTA			Within 90 days of System P&T Committee approval
RITUXIMAB/HYALURONIDASE	Untreated or relapsed/refractory follicular lymphoma.			RITUXAN HYCELA	1. Use of intravenous rituximab biosimilar is preferred 2. Outpatient setting for FDA-approved indications or payer-approved off-label subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
MELOXICAM INJECTION	NSAID analgesic for pain		ANJESO			Within 60 days of System P&T Committee approval
SUBLINGUAL SUFENTANIL CITRATE	Opioid analgesic for pain		DSUVIA			Within 60 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Timeline to Implementation
		Formulary Unrestricted	NonFormulary	Formulary Restricted		
DICLOFENAC SODIUM	Topical NSAID analgesic for pain	DICLOFENAC SODIUM / VOLTAREN 1% GEL				Within 90 days of System P&T Committee approval
			DICLOFENAC SODIUM / SOLARAZE 3%			
DALBAVANCIN HCL	Long acting glycopeptide antibiotic for gram positive infections.			DALVANCE 500 MG VL	ED setting / discharge facilitation: <ul style="list-style-type: none"> • ABSSSIs where inpatient hospitalization would otherwise be required for IV antibiotic therapy and MRSA, MSSA, or strep is identified or strongly suspected (i.e. low risk for gram negative or anaerobic infection) and no other antibiotic can be used, either oral or intravenous Infusion center setting: <ul style="list-style-type: none"> • Prior authorization must be obtained prior to ordering or dispensing the medication. The pharmacy should be notified at least 24-48 hours prior to the date of infusion 	Within 90 days of System P&T Committee approval
ORITAVANCIN DIPHOSPHATE	Long acting glycopeptide antibiotic for gram positive infections.			ORBACTIV 400 MG VL	Inpatient setting: oritavancin <ul style="list-style-type: none"> • ID consult when available • To facilitate discharge of patients with ABSSSIs where inpatient hospitalization would otherwise be required for IV antibiotic therapy and MRSA, MSSA, or strep is identified or strongly suspected (i.e. low risk for gram negative or anaerobic infection) and no other antibiotic can be used, either oral or intravenous • Administration will expedite hospital discharge and no other antibiotic can be used, either oral or intravenous ED setting / discharge facilitation: <ul style="list-style-type: none"> • ABSSSIs where inpatient hospitalization would otherwise be required for IV antibiotic therapy and MRSA, MSSA, or strep is identified or strongly suspected (i.e. low risk for gram negative or anaerobic infection) and no other antibiotic can be used, either oral or intravenous Infusion center setting: <ul style="list-style-type: none"> • Prior authorization must be obtained prior to ordering or dispensing the medication. The pharmacy should be notified at least 24 - 48 hours prior to the date of infusion 	Within 90 days of System P&T Committee approval
PATIROMER	Hyperkalemia		VELTASSA PWD			Within 90 days

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Timeline to Implementation
		Formulary Unrestricted	NonFormulary	Formulary Restricted		
CALCIUM SORBITE	in non-emergent, non-life threatening settings.					of System P&T Committee approval.
SODIUM POLYSTYRENE SULFONATE		SODIUM POLYSTYRENE / KIONEX				
SODIUM ZIRCONIUM CYCLOSILICATE		LOKELMAPKT				
BRIMONIDINE TARTRATE	Reduce intraocular pressure		BRIMONIDINE / ALPHAGAN P TART 0.15% OPH SOL		See Alpha₂ agonist interchange	Within 90 days of System P&T Committee approval.
			ALPHAGAN P 0.1 % O/S		See Alpha₂ agonist interchange	
		BRIMONIDINE TARTRATE 0.2% O/S				

FORMULARY ALIGNMENT

Critical Care	
Dexmedetomidine	<p>Formulary, Restricted:</p> <p>Recommend not to bolus in adults in the critical care setting: Inclusion in order comments</p> <p>Procedural sedation and pediatrics are out of scope</p> <p>Infusion: Inclusion in order comments</p> <ul style="list-style-type: none"> • Hold infusion if HR \leq 50 and call MD • Notify MD if SBP \leq 90 <p>Use by Intensivists, Anesthesiologists, Emergency Medicine and Trauma Surgery only [for facilities with Intensivist coverage]</p> <p>Alcohol withdrawal: Step up use only for moderate to severe cases (e.g. standard ETOH treatment failure)</p> <p>Not indicated in certain conditions where goal RASS is -3 or deeper (e.g. Paralyzed patients, Post Cardiac Arrest patients receiving hypothermia, Severe ARDS and Status Epilepticus)</p>
Phenoxybenzamine	<p>Formulary, Restricted</p> <ul style="list-style-type: none"> • Restricted to pheochromocytoma
Bivalirudin	<p>Formulary, Restricted</p> <p>Utilize the NCDR CathPCI Bleeding Risk Score Estimator in all patients undergoing PCI. Risk Score must be reviewed prior to PCI.</p> <ul style="list-style-type: none"> • Low bleeding risk: Heparin use is preferred; bivalirudin is not recommended. • Intermediate bleeding risk: Radial artery access and use of heparin is encouraged; an alternate approach is femoral artery access and bivalirudin use. • High bleeding risk: Bivalirudin use is preferred; radial artery access should be strongly considered. Minimize routine use of GP IIb/IIIa inhibitors. <p>Unrestricted use for: HIT, LVAD, ECMO patients.</p>
Edoxaban	Non-Formulary
Fondaparinux	<p>Formulary, Restricted</p> <ul style="list-style-type: none"> • Restricted to suspected and confirmed HIT patients
Dalteparin	Non-Formulary
Antithrombin III (Plasma der)	<p>Formulary, Restricted</p> <ul style="list-style-type: none"> • ECMO or Open Heart patients with ATIII $<$ 50% • Hematologist, anesthesiologist or pathologist • in surgery for heparin 'resistance'
Ferric subsulfate (Monsels)	Formulary, Unrestricted
Nimodipine	<p>Formulary, Restricted</p> <ul style="list-style-type: none"> • Restricted to Neurology, Neurosurgery, Trauma or Emergency Medicine • Continue home medication

Oncology	
Note: Retail and retail specialty are out of scope	
Abiraterone (Zytiga, Yonsa)	Non-Formulary
ADO-TRASTUZUMAB EMTANSINE (Kadcyla)	Formulary Restricted Outpatient Use Only for: 1. FDA approved indication 2. Payer-approved off-label indications subsequent to insurance approval or prior authorization
CARMUSTINE IN POLIFEPROSAN 20 Implant (Gliadel)	Formulary Restricted <ul style="list-style-type: none"> Use restricted to inpatient for second line treatment of GBM at time of surgery Payer-approved off-label indications subsequent to insurance approval or prior authorization
CHLORAMBUCIL (Leukeran)	Non-Formulary
IMATINIB (Gleevec)	Formulary Restricted <ul style="list-style-type: none"> Inpatient Use <ul style="list-style-type: none"> ALL Philadelphia chromosome positive CML, new diagnoses Bridge until home medication supply can be attained Restricted to Oncology Outpatient Use

Infectious Disease	
Rifaximin	Formulary Unrestricted
Fosfomycin	Formulary restricted: <ul style="list-style-type: none"> For Cystitis AND <ul style="list-style-type: none"> Documented ESBL or VRE, OR Failed other outpatient therapy with unknown culture or susceptibility, OR Drug allergy or intolerance to Bactrim® AND nitrofurantoin
Caspofungin	Non-Formulary
Clotrimazole 1 & 2% solutions	Non-Formulary (topical 1% cream and 10mg lozenge formulations remain on formulary)
Clotrimazole/betamethasone dip	Non-Formulary
Ketoconazole (shampoo)	Non-Formulary

Miconazole nitrate	Non-Formulary
Teroconazole	Non-Formulary

General Medicine	
Denosumab	Formulary Restricted Outpatient Use Only for: <ol style="list-style-type: none"> 1. FDA approved indications 2. Payer-approved off-label indications subsequent to insurance approval or prior authorization
Ibandronate (injection)	Formulary Restricted <ul style="list-style-type: none"> • Outpatient setting for FDA-approved indications or payer-approved off-label subsequent to insurance approval or prior authorization
Ibandronate (oral)	Nonformulary <ul style="list-style-type: none"> • Interchange to alendronate if ordered for use in long term acute care facilities
Risedronate sodium	Nonformulary <ul style="list-style-type: none"> • Interchange to alendronate if ordered for use in long term acute care facilities
Alendronate	Formulary, Restricted <ul style="list-style-type: none"> • Use in long term acute care facilities (see Oral Bisphosphonate Interchange (ordered for osteoporosis prevention or treatment in the long-term acute care facilities)) • Weekly dosage forms (35mg and 70mg only)

Therapeutic Substitutions

[Oral Bisphosphonate Interchange \(ordered for osteoporosis prevention or treatment in the long-term acute care facilities\)](#)

Ordered	Provided
Alendronate 5mg daily	Alendronate 35mg weekly
Alendronate 10mg daily Risedronate 5mg daily	Alendronate 70mg weekly

[Ophthalmic Alpha2 agonist interchange](#)

Ordered	Provided
<i>Brimonidine 0.1% ophth sol 1 drop TID</i>	<i>Brimonidine 0.2% ophthalmic sol 1 drop each eye TID</i>
<i>Brimonidine 0.15% ophth sol 1 drop TID</i>	<i>Brimonidine 0.2% ophthalmic sol 1 drop each eye TID</i>

FORMULARY UPDATE

GENERIC NAME: Sodium zirconium cyclosilicate

PROPRIETARY NAME: Lokelma®

BACKGROUND/RATIONALE:

Potassium binders are used to decrease potassium levels in non-emergent, non-life threatening settings. Current FDA approved potassium binders include sodium polystyrene sulfonate (SPS), patiromer (Veltassa), and sodium zirconium cyclosilicate (Lokelma). Sodium zirconium cyclosilicate was approved to our local formulary in August 2019, with restrictions for use.

Due to contract opportunity, the September 2020 CommonSpirit Health (CSH) National P&T committee re-evaluated potassium binder formulary preferences across CommonSpirit Health. All restrictions for sodium zirconium cyclosilicate were removed since it is now closer in cost compared to SPS.

As per the CSH system formulary process, local P&T committees may approve with no changes or approve with more restrictions. Additionally, sites may request an exception or appeal to any formulary decision with accompanying clinical documentation supporting the appeal.

PHARMACOECONOMICS/COST:

Product	Cost/Day	
	Initial Dose/\$	Maintenance Dose/\$
SPS (Kayexalate) 10gm (\$0.85)	30gm / \$2.58	30gm / \$2.58
Patiromer (Veltassa) 8.4gm (\$37.25)	8.4gm / \$37.25	8.4 – 25.2gm / \$37.25
Sodium zirconium cyclosilicate (Lokelma) 5gm (\$3.80)	10g TID / \$22.80	5-15gm/day / \$3.80 – \$11.40

CURRENT CHI MEMORIAL FORMULARY USE CRITERIA:

- 1) Management of severe hyperkalemia ($K \geq 6.0\text{mEq/L}$). Not be used as monotherapy for emergent treatment of life-threatening hyperkalemia because of its delayed onset of action.
- 2) If patient intolerant to or failed therapy with SPS (Kayexalate)
- 3) Continuation of home therapy

RECOMMENDATION/DISCUSSION:

Sodium zirconium cyclosilicate has been reported to be more palatable than SPS. Recently, contract negotiations for CSH have decreased the gap of cost of care between sodium zirconium cyclosilicate and SPS. It is recommended to remove our current use restrictions.

The restriction criteria for use will be removed from the medication record of the EHR.

FORMULARY UPDATE

GENERIC NAME: Oritavancin diphosphate

PROPRIETARY NAME: Orbactiv®

BACKGROUND/RATIONALE:

Oritavancin was reviewed by our local P&T committee in 2015 and designated non-formulary. Non-formulary utilization has remained very low since that decision, on a case-by-case basis, need as determined by infectious disease.

The September 2020 CommonSpirit Health (CSH) National P&T committee re-evaluated restriction criteria for long-acting glycopeptide antibiotics across CommonSpirit Health and approved updated restriction criteria for formulary use. As per the CSH system formulary process, local P&T committees may approve with no changes or approve with more restrictions. Additionally, sites may request an exception or appeal to any formulary decision with accompanying clinical documentation supporting the appeal.

INDICATIONS: Oritavancin is approved for the treatment of adult patients with acute bacterial skin and skin structure infections (SSSIs) caused by or suspected to be caused by susceptible isolates of designated gram-positive microorganisms, including *Staphylococcus aureus* (methicillin susceptible and methicillin resistant), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates).

DRUG INTERACTIONS: Coadministration with warfarin may result in increased warfarin levels and increased risk of bleeding due to inhibition of CYP2C9 metabolism. Patients can be treated with the combination but should be monitored for signs of bleeding. Coagulation tests (eg, prothrombin time, international normalized ratio) may be unreliable for up to 24 hours after oritavancin administration. Oritavancin has been shown to artificially prolong aPTT for up to 120 hours, may prolong PT and INR for up to 12 hours and ACT for up to 24 hours.

CONTRAINDICATIONS: Use of intravenous unfractionated heparin for 120 hours (5 days) after oritavancin administration

DOSING: 1,200 mg administered as a single IV infusion over 3 hours.

PHARMACOECONOMICS/COST:

Product	Cost
Orbactiv (oritavancin) 1,200 mg	\$2,774.98

CURRENT CHI MEMORIAL FORMULARY STATUS:

- Non-formulary; non-formulary use may be considered on a case by case basis for special circumstances for the treatment of off label indications per ID and antimicrobial stewardship approval

UPDATED CSH FORMULARY RESTRICTIONS:

Inpatient setting:

1. ID consult when available
2. To facilitate discharge of patients with ABSSSIs where inpatient hospitalization would otherwise be required for IV antibiotic therapy and MRSA, MSSA, or strep is identified or strongly suspected (i.e. low risk for gram negative or anaerobic infection) and no other antibiotic can be used, either oral or intravenous
3. Administration will expedite hospital discharge and no other antibiotic can be used, either oral or intravenous

ED setting:

1. ABSSSIs where inpatient hospitalization would otherwise be required for IV antibiotic therapy and MRSA, MSSA, or strep is identified or strongly suspected (i.e. low risk for gram negative or anaerobic infection) and no other antibiotic can be used, either oral or intravenous

Infusion center setting:

1. Prior authorization must be obtained prior to ordering or dispensing the medication. The pharmacy should be notified at least 24 - 48 hours prior to the date of infusion

RECOMMENDATION/DISCUSSION:

Based on our historical utilization needs, it is recommended to adopt a more restrictive approach to oritavancin use than the above criteria and locally designate oritavancin as a formulary product, with inpatient use restricted to infectious disease physicians only. Only 1 dose will be stocked. Oritavancin will not be used in the emergency department setting.