Pharmacy & Therapeutics Committee Meeting

Private Dining Room

December 15, 2022

Agenda Items	Individual Responsible
1. Call to Order	Nathan Chamberlain, MD
2. Conflict of Interest Disclosure	Rachel Kile, PharmD
3. Approval of November 2022 Minutes	Nathan Chamberlain, MD

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

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: November 3, 2022 CALLED TO ORDER: 7:02 a.m.
LOCATION: Private Dining Room + Zoom ADJOURNED: 7:46 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**	**Rachel Anderson, PharmD**
	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**		Kenneth Dyer, PharmD- Operations Manager	**Jordan Tynes, Pharmacy Resident**
X	**David Dodson, MD- Hospitalist**		Chad Paxson, MD- Intensivist		Rodney Elliott- Purchasing	**Chris D'Amico, Pharmacy Resident**
	Karen Frank, RN- Quality		James Wahl, MD- Hospitalist, GA	X	**Lori Hammon, RN- Quality**	**Morgan Knight, Pharmacy Student**
X	**Sherry Fusco, RN- CNO**		Richard Yap, MD- Hospitalist	X	**Shannon Harris, RN- Infection Prevention**	
X	**F. Lee Hamilton, MD- Hospitalist**			X	**Kevin Hopkins, RT- Director of Resp Therapy**	
	William Haren, MD- Psychiatry			X	**Rachel Kile, PharmD- Clinical Manager**	
				X	**Carey Smith, RPh- Manager, GA**	

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

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Minutes	The August minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	**September 2022 Decision Brief:** The medication decisions that were approved at the CommonSpirit Health System P&T committee meeting were reviewed. All new system formulary medications or changes were either consistent with existing CHI Memorial formulary decisions or are described in the "Formulary Decisions & Therapeutic Interchanges" section of the minutes below, or will be reviewed at an upcoming P&T committee meeting.	Approved	Complete
Formulary Decisions & Therapeutic Interchanges	**A. Posaconazole (Noxafil)**: Posaconazole is an antifungal azole derivative approved to the CommonSpirit Health formulary. CHI Memorial approved isavuconazole (Cresemba®) to formulary in 2015 and substituted any potential patients in need of posaconazole to isavuconazole. Since this decision, the cost of oral posaconazole tablets have significantly decreased. It was recommended to add posaconazole oral tablets to formulary, with restrictions to Infectious Diseases providers for new initiation or continuation of patient home medication.	Approved	Complete
	B. Vabomere to Avycaz: Ceftazidime/avibactam (Avycaz) was approved to CHI Memorial formulary in 2015. Meropenem/vaborbactam (Vabomere), a similar agent, replaced ceftazidime/avibactam in 2019 due to cost and availability of a CMS New Technology Add-on Payment (NTAP) program which provided additional payments for the drug for qualifying cases. The NTAP program for meropenem/vaborbactam has since expired and the cost of ceftazidime/avibactam is now lower than that of meropenem/vaborbactam. It was recommended to replace meropenem/vaborbactam with ceftazidime/avibactam as the formulary product for treatment of infections due to susceptible MDR gram-negative rod for which other preferred treatment options are unavailable, with restrictions to Infectious Diseases providers and cases meeting qualifying criteria. Ceftazidime/avibactam will be dose adjusted for renal function per existing pharmacist dose-adjustment policy.	Approved	Complete
	C. Beta-lactam allergy guidance:The purpose of this guideline is to guide clinicians in prescribing antibiotics for inpatients with reported allergic reactions to penicillin or cephalosporin antibiotics by allowing these patients to	Approved	Complete

		receive more narrow-spectrum, more effective, less toxic, and/or less costly antibiotics. It was recommended to adopt the decision of the Antimicrobial Stewardship Subcommittee and approve these guidelines and associated policy. Education will be provided to hospitalists.		
	D.	**Ammonia smelling salts**: Ammonia inhalant capsules (smelling salts) are considered a medication. In March, ammonia inhalants were removed from the CHI Memorial outpatient lab due to lack of medication orders for use and lack of secure storage. The lab's venipuncture policy was also updated to remove references to its use. Rachel reported ~60% of dispensed doses at CHI Memorial are not documented as administered which leads to inaccurate medical record keeping and lost charges. It was recommended to remove ammonia inhalant capsules from formulary and utilize alternative methods to avoid syncope.	Approved	Complete
	E.	**Banana bags**: "Banana bag" therapy, which usually includes thiamine 100 mg, folic acid 1 mg, multivitamin, ± magnesium 2 gm in a 1 liter 0.9% sodium chloride bag, is a common treatment used in alcohol withdrawal patients. There is no literature to support administering a banana bag in the treatment of alcohol withdrawal. The CSH System P&T Committee recently approved removal of banana bags from formulary. As an alternative, individual components were approved for the treatment of alcohol withdrawal including options for thiamine, folic acid, magnesium, and IV fluid replacement. IV multivitamin was approved for use only in TPN. Rachel reported an estimated annual savings of $12,087. It was recommended to adopt the decision of the CSH system P&T committee mentioned above, which will align with the newly approved alcohol withdrawal management protocol utilizing phenobarbital. An ordering panel with the above options will be developed in the EHR to assist with ease of ordering the components in place of a banana bag. Use of the "custom IV infusion" entry by providers to design their own banana bag will not be verified by pharmacists and it was approved to adopt an automatic therapeutic interchange by the pharmacist to the individual components above using the ordering panel.	Approved	Complete
	F.	**Dexmedetomidine taper**: Dexmedetomidine is an alpha-2 adrenergic receptor agonist approved for the sedation of intubated and non-intubated patients for up to 24 hours. Due to its favorable pharmacodynamic properties, it has become a widely used agent for sedation in the intensive care setting. However, abrupt discontinuation of dexmedetomidine has been associated with symptoms such as tachycardia, reflex hypertension, agitation, and other hypersympathetic conditions. Joseph proposed a weaning protocol utilizing a percentile reduction of dexmedetomidine paired with concomitant guanfacine. The implementation of a weaning protocol was recommended to standardize infusion durations of dexmedetomidine. The proposed changes will update the current "Intubation and as Ventilator Weaning MCT" order set in addition to developing a new standalone medication entry for the dexmedetomidine infusion weaning protocol plus guanfacine taper. The non-weaning dexmedetomidine infusion will remain available as an ordering option. Concerns were voiced in regards to the ease of accessibility of the nursing reference guide for weaning which will be followed-up by Joseph.	Approved	Complete
	G.	**Tecovirimat (Tpoxx)**: Monkeypox is an orthopoxvirus that is related to the smallpox virus. Since May 2022, an outbreak of monkeypox has been ongoing in several countries, including the United States. Tecovirimat (Tpoxx) is an antiviral agent FDA indicated for smallpox. Based on the CDC interim clinical guidance for the treatment of monkeypox, tecovirimat may be considered for treatment of monkeypox in certain patients. Tecovirimat (Tpoxx) was recently approved to the CSH system formulary. CHI Memorial has obtained oral Tpoxx from the state of TN and is now a "pre-positioned" site in order to ensure expedited treatment of patients, especially those that may present through the ED. CHI Memorial hospital may distribute Tpoxx to the Hixson campus and our ID physicians' office if needed. Tpoxx distributed from TN cannot be shared with GA per state guidelines. It was recommended to add Tecovirimat (Tpoxx) to formulary. Education will be provided to pharmacy and ED staff.	Approved	Complete

	H. Medications for COVID-19: The Pfizer-BioNTech COVID-19 bivalent booster vaccine was recommended to add to formulary for inpatient use. The current monovalent vaccine on formulary can no longer be used as a booster vaccine; only as part of the initial series.	Approved	Complete
Protocol & Orders	**A. Annual Review of Medication Protocols:** Per regulatory requirements, the current medication related protocols were reviewed. See Attachment A of the minutes for the list of protocols 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.	Approved	Complete
	B. Meditech order sets approved during EHR downtime: The former Meditech order sets that were emergently reviewed and approved by the P&T Committee during the October 2022 extended EHR downtime were reviewed. These order sets were only approved for use during that downtime and any requested use in the future would require re-approval by the committee.	Approved	Complete
Policies	**A. 24 Hour Stop On Routine Perioperative Antibiotic Prophylaxis**: No changes to this policy were required at this time. Approved per routine review.	Approved	Complete
	B. Renal Dosing Adjustments: Updates were made to the automatic dose adjustment per pharmacist for ampicillin, cefepime, and meropenem. The changes were previously approved by the Antimicrobial Stewardship Subcommittee.	Approved	Complete
	C. Beta Lactam Allergy: This is a new policy accompanying "C" under Formulary Decisions & Therapeutic Interchanges.	Approved	Complete
	D. Pharmacy & Therapeutics Committee: No changes to this policy were required at this time. Approved per routine review.	Approved	Complete
Appendices	**A. Subcommittee Meeting Minutes: Antimicrobial Stewardship (ASP)**: The June and September 2022 ASP meeting minutes were reviewed and approved.	Approved	Complete

There being no further business, the meeting was adjourned at 7:46 a.m. The next P&T meeting is **December 15, 2022.**

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

November 2022 Decisions

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

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
tirzepatide	Type 2 diabetes mellitus treatment			MOUNJARO		Within 60 days of System P&T Committee approval
levonorgestrel	Heavy menstrual bleeding and pregnancy prevention	LILETTA			Liletta is the preferred CommonSpirit Health product Restriction Criteria: Non-Catholic facilities and clinics Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Catholic facilities and clinics Outpatient setting for FDA-approved or payer-approved off-label non-contraceptive indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
		MIRENA			Restriction Criteria: Liletta is not available or payer-approved Non-Catholic facilities and clinics Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Catholic facilities and clinics Outpatient setting for FDA-approved or payer-approved off-label non-contraceptive indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
epoetin alfa	Anemia of cancer and chronic kidney disease	EPOGEN			Restriction Criteria: If Retacrit is not payer approved • 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
		PROCRIT			Restriction Criteria: If Retacrit is not payer approved • 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
			RETACRIT epoetin alfa-epbx			Within 60 days of System P&T Committee approval
botulinum toxin A	Injectable neurotoxin agent used for multiple indications including but not limited to blepharospasm, cervical dystonia, sialorrhea, spasticity, etc.	DYSPORT abobotulinumtoxinA			IncobotulinumtoxinA (Xeomin) is the preferred botulinum toxin when payer-approved Restriction Criteria: FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization* * if prior authorization or payer approval required	Within 90 days of System P&T Committee approval
		BOTOX onabotulinumtoxinA			IncobotulinumtoxinA (Xeomin) is the preferred botulinum toxin when payer-approved Restriction Criteria: FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization* * if prior authorization or payer approval required	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
	Injectable neurotoxin agent used for multiple indications including but not limited to blepharospasm, cervical dystonia, sialorrhea, spasticity, etc.	XEOMIN incobotulinumtoxinA			Preferred botulinum toxin (outpatient and inpatient) Restriction Criteria: FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization* * if prior authorization or payer approval required Link to evidence summary by indication	Within 90 days of System P&T Committee approval
tafasitamab-cxix	Diffuse large B-cell lymphoma	MONJUVI			Restriction Criteria: Outpatient settings 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
pegloticase	Gout	KRYSTEXXA			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
sutimlimab-jome	Cold agglutinin disease	ENJAYMO			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
daridorexant HCl	Insomnia in adults			QUVIVIQ		Within 60 days of System P&T Committee approval
sublingual dexmedetomidine	Acute agitation associated with select psychiatric conditions			IGALMI		Within 60 days of System P&T Committee approval
injectable ibuprofen	Pain and patent ductus arteriosus (PDA) closure	IBUPROFEN LYSINE			Restriction Criteria: PDA closure in premature neonates < 32 weeks gestational age	Within 90 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
azelastine 0.05% ophthalmic drops	Allergic eye symptoms			AZELASTINE HCL	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
olopatadine ophthalmic drops	Allergic eye symptoms			OLOPATADINE HCL 0.1% and 0.2%	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
fluorometholone ophthalmic products	Eye inflammation			FML S.O.P.	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				FML Liquifilm	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				FML FORTE	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
			FLUOROMETHOLONE Suspension 0.1%			Within 60 days of System P&T Committee approval
Carboxymethyl-cellulose sodium	Dry eyes		REFRESH TEARS			Within 60 days of System P&T Committee approval
			REFRESH CELLUVISC			Within 60 days of System P&T Committee approval
			REFRESH LIQUIGEL			Within 60 days of System P&T Committee approval
			THERA TEARS			Within 60 days of System P&T Committee approval
Carboxymethyl-cellulose sodium/glycerin	Dry eyes		REFRESH OPTIVE			Within 60 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
			REFRESH OPTIVE SENSITIVE			Within 60 days of System P&T Committee approval
lodoxamide tromethamine	Allergic eye symptoms			ALOMIDE	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
apraclonidine ophthalmic drops	Elevated intraocular pressure			IOPIDINE	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				APRACLONIDINE HCL	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
ketotifen fumarate	Allergic eye symptoms		GENERIC KETOTIFEN			Within 60 days of System P&T Committee approval
				ZADITOR	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				ALAWAY	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
difluprednate 0.5% ophthalmic drops	Eye inflammation			DUREZOL	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
loteprednol ophthalmic drops and ointment	Eye inflammation			LOTEMAX drops, suspension, gel and ointment	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				LOTEPREDNOL ETABONATE	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
travoprost	Elevated intraocular pressure			LZBA	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval

Medication Name	Medication Used For	Formulary Decision			Restrictions and Therapeutic Interchanges	Timeline to Implementation
		Formulary Restricted	Formulary Unrestricted	NonFormulary		
				TRAVATAN Z		Within 60 days of System P&T Committee approval
tafluprost	Elevated intraocular pressure			ZIOPTAN	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
bimatoprost	Elevated intraocular pressure			LATISSE	Link to Therapeutic Interchange	Within 60 days of System P&T Committee approval
				LUMIGAN		Within 60 days of System P&T Committee approval
deucravacitinib	Moderate-to-severe plaque psoriasis			SOTYKTU		Within 60 days of System P&T Committee approval
sodium phenylbutyrate/taurursodiol	Amyotrophic lateral sclerosis (ALS)			RELYVRIO		Within 60 days of System P&T Committee approval

THERAPEUTIC INTERCHANGES

OPHTHALMIC ANTIALLERGIC AGENTS	
Ordered	**Provided**
olopatadine 0.1 %	Generic ketotifen 1 drop twice a day
azelastine 0.05 %	
Alomide 0.1 %	
olopatadine 0.2 %	
Zaditor 0.025 % (0.035 %) eye drops	
Alaway 0.025 % (0.035 %) eye drops	
OPHTHALMIC CORTICOSTEROIDS	
Ordered	**Provided**
Durezol 0.05 %	

FML Forte 0.25 %	Generic dexamethasone 0.1% suspension 2 drops at frequency ordered up to four times a day
FML Liquifilm 0.1 %	
FML S.O.P. 0.1 % eye ointment	
Lotemax 0.5 % eye drops, suspension	
Lotemax 0.5 % eye gel drops	
Lotemax 0.5 % eye ointment	
loteprednol etabonate 0.5 % eye drops, suspension	
Maxidex 0.1 % eye drops, suspension	
OPHTHALMIC DRUGS, MISCELLANEOUS	
Ordered	**Provided**
Iopidine 1 % eye drops in a dropperette	Generic brimonidine 0.2% eye drops 1 drop each eye three times a day
apraclonidine 0.5 % eye drops	
OPHTHALMIC PROSTAGLANDIN ANALOGS	
Ordered	**Provided**
Travoprost (Izba®, Travatan Z®) 1 drop daily to affected eye	Latanoprost (Xalatan®) 1 drop daily to affected eye
Zioptan (Tafluprost®) 1 drop daily to affected eye	
Bimatoprost (Lumigan®, Latisse®) 1 drop daily to affected eye	

FORMULARY REVIEW

GENERIC NAME: Dexmedetomidine (Bioxcel)

PROPRIETARY NAME: *Igalmi®*

INDICATIONS:

FDA Approved
Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder

THERAPEUTIC CATEGORY: Alpha-2 adrenergic receptor agonist

PHARMACOKINETICS:

Absorption	72% & 82% Bioavailability sublingual versus buccal administration respectively
Distribution	118 L (Vss)
Metabolism	CYP2A6, CYP 2D6, CYP2C19
Excretion	Clearance estimated to be 39 L/h following IV dexmedetomidine administration
Cmax (ng/L)	143 & 144 sublingual and buccal respectively
t ½ (hr)	2.8 following sublingual/buccal administration
AUC (ng*h/L)	851 & 584 sublingual versus buccal respectively
Protein binding (%)	94
Fraction excreted unchanged in urine (%)	None

SPECIAL POPULATIONS:

Pregnancy	No data
Lactation	Present in breast milk
Pediatrics	Not studied
Geriatrics	No differences in pharmacokinetic profile of IV dexmedetomidine based on age
Hepatic Impairment	IV dexmedetomidine clearance varies depending upon hepatic function
Renal Impairment	Dexmedetomidine pharmacokinetics were not significantly different in patients with normal renal function versus those with creatinine clearance < 30 mL/minute

CLINICAL STUDIES:

Sublingual Dexmedetomidine for the Treatment of Acute Agitation in Adults With Schizophrenia or Schizoaffective Disorder: A Randomized Placebo-Controlled Trial (SERENITY I)	
METHODS	
Study Design	Randomized, double-blind, placebo-controlled trial
Study Funding	BioXcel Therapeutics Inc.
Patient Enrollment Inclusion	● Adults aged 18 – 75 ● Patients with a diagnosis of schizophrenia or schizoaffective disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM 5) ● Patients who provide written informed consent ● Patients who are clinically agitated at screening and baseline with a total score of >= 14 on the 5 items of PANSS Excited Component (poor impulse control, tension, hostility, uncooperativeness, and excitement) ● Patients who have a score of >= 4 on at least 1 of the 5 items on the PEC at baseline

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- Female participants of child-bearing potential, and male participants with a partner of child-bearing potential who agree to use a medically accepted method of contraception

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

- Patients with agitation caused by acute intoxications e.g. positive identification of alcohol by breathalyzer or drugs of abuse (except THC) during urine screening
- Use of benzodiazepines, hypnotics, or antipsychotic drugs in the 4 hours before study treatment
- Use of alpha-1 noradrenergic blockers
- Patients at serious risk of suicide
- Pregnant or breastfeeding patients
- Patients with certain neurological conditions (hydrocephalus, seizure disorder, history of head trauma, stroke, transient ischemic attack, Parkinson's, etc…)
- History of syncope, current evidence of hypovolemia, orthostatic hypotension
- Patients with laboratory or ECG abnormalities considered clinically significant by the investigator (ex. advanced heart block, diagnosis of sick sinus syndrome)
- Patients with serious or unstable medical illnesses (ex. Moderate-severe hepatic impairment, renal, gastroenterologic, respiratory, cardiovascular, endocrinologic, or hematologic)
- Patients who have received an investigational drug within 30 days prior to the current agitation episode
- Patients who are considered by the investigator, for any reason, to be an unsuitable candidate for receiving dexmedetomidine (DEX) (ex. Patients with a history of allergic reactions to DEX)

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<tr><td>Intervention</td><td>Patients were randomized 1:1:1 to receive Igalmi 180 mcg, 120 mcg, or matching placebo film. Participants were instructed on the appropriate method of self-administration, and study drug was self-administered under supervision. A second dose of sublingual dexmedetomidine of 90 or 60 mcg (half of the initial 180 or 120 mcg dose respectively) could be given 2 hours after the first dose if the change in Positive and Negative Syndrome Scale - Excited Component (PEC) scale was less than 40% with no safety concerns.
The study included a screening visit, treatment visit (day 1), follow-up visit (day 2), discharge (day 3), and end of study visit (day 7). Patients were confined to a clinical research setting or hospitalized under medical supervision while undergoing screening procedures</td></tr>
<tr><td>Baseline Characteristics</td><td>

	Igalmi 180 mcg (n=126)	Igalmi 120 mcg (n=129)	Placebo (n=126)
Mean Age (years)	46.0	45.7	45.1
Sex (male)	82 (65.1%)	77 (59.7%)	82 (65.1%)
Race (black or African American)	103 (81.7%)	92 (71.3%)	102 (81.0%)
Diagnosis Schizophrenia Schizoaffective disorder	 101 (80.2%) 25 (19.8%)	 113 (87.6%) 16 (12.4%)	 108 (85.7%) 18 (14.3%)
Mean CGI-S	4.1	4.2	4.1
Mean PEC score	17.6	17.5	17.6

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<tr><td colspan="2">RESULTS</td></tr>
<tr><td>Primary Endpoint</td><td>The mean changes from baseline in total PEC total score 2 hours following treatment doses were -10.3 for sublingual dexmedetomidine 180 mcg, -8.5 for sublingual dexmedetomidine 120 mcg, and -4.8 for placebo. Least squares mean confidence interval differences from placebo at 2 hours post dose were (97.5% Confidence interval [CI] -5.5 (-6.7 to -4.3, P < 0.001) in the 180 mcg group and (97.5% CI -3.7, -4.9 to -2.5, P < 0.001)</td></tr>
<tr><td>Adverse Events</td><td>

	Igalmi		Placebo (n=126)
	180 mcg (n=126)	120 mcg (n=129)	
Serious adverse event	0	0	0
Any treatment-emergent adverse event	47 (37.3%)	51 (39.5%)	19 (15.1%)
Any drug-related adverse event	44 (34.9%)	46 (35.7%)	15 (11.9%)

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	Somnolence	29 (23.0%)	28 (21.7%)	10 (7.9%)
	Hypotension	5 (4.0%)	8 (6.2%)	0
	Dizziness	8 (6.3%)	3 (2.3%)	1 (0.8%)
	Dry mouth	5 (4.0%)	10 (7.8%)	2 (1.6%)

Limitations	● Assessed efficacy of sublingual dexmedetomidine after a single incidence of agitation ● Study participants had the capacity to provide informed consent which may limit the use of Igalmi who present with more severe cases of acute agitation ● Patients with acute alcohol intoxication were excluded, but it was not possible to determine whether any drug or alcohol withdrawal contributed to agitation ● No comparison with other treatments indicated for agitation such as antipsychotics ● The Richmond Agitation-Sedation Scale (RASS), a commonly used assessment scale for agitation, was not measured

Effect of Sublingual Dexmedetomidine vs Placebo on Acute Agitation Associated With Bipolar Disease (SERENITY II)	
METHODS	
Study Design	Randomized, double-blind, placebo-controlled trial
Study Funding	BioXcel Therapeutics Inc.
Patient Enrollment Inclusion	● Adults aged 18 – 75 ● Patients who have met DSM-5 criteria for bipolar I or II disorder ● Patients who provide written informed consent ● Patients who are clinically agitated at screening and baseline with a total score of >= 14 on the 5 items of PANSS Excited Component (poor impulse control, tension, hostility, uncooperativeness, and excitement) ● Patients who have a score of >= 4 on at least 1 of the 5 items on the PEC at baseline ● Female participants of child-bearing potential, and male participants with a partner of child-bearing potential who agree to use a medically accepted method of contraception
Patient Enrollment Exclusion	● Patients with agitation caused by acute intoxications e.g. positive identification of alcohol by breathalyzer or drugs of abuse (except THC) during urine screening ● Use of benzodiazepines, hypnotics, or antipsychotic drugs in the 4 hours before study treatment ● Use of alpha-1 noradrenergic blockers ● Patients at serious risk of suicide ● Pregnant or breastfeeding patients ● Patients with certain neurological conditions (hydrocephalus, seizure disorder, history of head trauma, stroke, transient ischemic attack, Parkinson's, etc…) ● History of syncope, current evidence of hypovolemia, orthostatic hypotension ● Patients with laboratory or ECG abnormalities considered clinically significant by the investigator (ex. advanced heart block, diagnosis of sick sinus syndrome) ● Patients with serious or unstable medical illnesses (ex. Moderate-severe hepatic impairment, renal, gastroenterologic, respiratory, cardiovascular, endocrinologic, or hematologic) ● Patients who have received an investigational drug within 30 days prior to the current agitation episode ● Patients who are considered by the investigator, for any reason, to be an unsuitable candidate for receiving DEX (ex. Patients with a history of allergic reactions to DEX)
Intervention	Patients were randomized 1:1:1 to receive Igalmi 180 mcg, 120 mcg, or matching placebo film. Participants were instructed on the appropriate method of self-administration, and the study drug was self-administered under supervision. A second dose of sublingual dexmedetomidine of 90 or 60 mcg (half of the initial 180 or 120 mcg dose respectively) could be given 2 hours after the first dose if the change in Positive and Negative Syndrome Scale - Excited Component (PEC) scale was less than 40% with no safety concerns. The study included a screening visit, treatment visit (day 1), follow-up visit (day 2), discharge

(day 3), and end of study visit (day 7). Patients were confined to a clinical research setting or hospitalized under medical supervision while undergoing screening procedures

Baseline Characteristics

	Igalmi 180 mcg (n=126)	Igalmi 120 mcg (n=126)	Placebo (n=126)
Mean Age (years)	45.9	46.1	44.8
Sex (male)	59 (46.8%)	59 (46.8%)	53 (42.1%)
Race (black or African American)	72 (57.1%)	68 (54.0%)	72 (57.1%)
Diagnosis			
Mania	59 (46.8%)	58 (46.0%)	63 (50.0%)
Depressed	28 (22.2%)	20 (15.9%)	26 (20.6%)
Mixed episodes	30 (23.8%)	27 (21.4%)	22 (17.5%)
Hypomania	5 (4.0%)	14 (11.1%)	10 (7.9%)
Unspecified	4 (3.2%)	7 (5.6%)	5 (4.0%)
Mean CGI-S	4.1	4.1	4.1
Mean PEC score	18.0	18.0	17.9

RESULTS

Primary Endpoint

The mean change from baseline in PEC total score 2 hours after taking the medication were -10.4 for sublingual dexmedetomidine 180 mcg, -9.0 for sublingual dexmedetomidine 120 mcg, and -4.9 for placebo. The least-squares mean differences from placebo were -5.4 (97.5% Confidence Interval (CI), -6.6 to -4.2; $P < 0.001$) for sublingual dexmedetomidine 180 mcg and -4.1 (97.5% CI, -5.3 to -2.9; $P < 0.001$) for sublingual dexmedetomidine 120 mcg.

Adverse Events

	Igalmi		Placebo (n=126)
	180 mcg (n=126)	120 mcg (n=126)	
Serious adverse event	0	1 (0.8%)	0
Any treatment-emergent adverse event	45 (35.7%)	44 (34.9%)	22 (17.5%)
Any treatment-related adverse event	39 (31.0%)	41 (32.5%)	15 (11.9%)
Somnolence	27 (21.4%)	26 (20.6%)	6 (4.8%)
Hypotension	8 (6.3%)	6 (4.8%)	0

Limitations

- Assessed efficacy of sublingual dexmedetomidine after a single incidence of agitation
- This study only assessed efficacy in mild/moderate cases of agitation based on baseline PEC score. The level of cooperation required to administer a medication sublingually limits the generalizability of these results to patients who are able or willing to self-administer this treatment.
- Patients with acute alcohol intoxication were excluded, but it was not possible to determine whether any drug or alcohol withdrawal contributed to agitation
- No comparison with other treatments indicated for agitation
- The Richmond Agitation-Sedation Scale (RASS), a commonly used assessment scale for agitation, was not measured

COMPARATIVE EFFICACY:
The American Association for Emergency Psychiatry recommends the use of benzodiazepines, first-generation antipsychotics, second-generation antipsychotics, or a combination of these for the acute management of agitation but selection should depend upon the etiology of a patient's agitation. Antipsychotics are generally recommended first line in patients with agitation due to a psychiatric condition. There are currently no head-to-head comparisons between sublingual dexmedetomidine and other treatment options in the management of acute agitation.

WARNING AND PRECAUTIONS:
- Hypotension, orthostatic hypotension, and bradycardia
- QT interval prolongation
- Somnolence
- Risk of withdrawal reaction
- Tolerance and tachyphylaxis

- Look-alike / Sound-alike (LASA) Error Risk Potential: Dexmedetomidine may be confused with dexamethasone

BLACK BOX WARNINGS: None

CONTRAINDICATIONS: None

ADVERSE REACTIONS:

Adverse Reactions (%)	Igalmi 180 mcg (n=252)	Igalmi 120 mcg (n=255)	Placebo (n=252)
Somnolence	23	22	6
Paresthesia oral or hyperesthesia oral	7	6	1
Dizziness	6	4	1
Hypotension	5	5	0
Orthostatic hypotension	5	3	<1
Dry mouth	4	7	1
Nausea	3	2	2
Bradycardia	2	2	0
Abdominal discomfort	2	0	1

Mean Blood Pressure and Heart Rate Decrease at 2 Hours Post-Dose

	IGALMI 180 mcg (n=252)	IGALMI 120 mcg (n=255)	Placebo (n=252)
Mean systolic decrease (mmHg)	15	13	1
Mean diastolic decrease (mmHg)	8	7	< 1
Mean heart rate decrease (bpm)	9	7	3

CLINICALLY SIGNIFICANT DRUG INTERACTIONS:

Interacting Drug	Effect
Drugs that Prolong the QT Interval	Concomitant use of drugs that prolong the QT interval may add to the effects of IGALMI and increase risk for cardiac arrhythmia
Anesthetics, Sedatives, Hypnotics, and Opioids	Concomitant use of anesthetics, sedatives, hypnotics, or opioids is likely to lead to enhanced CNS depressant effects.

DOSING AND ADMINISTRATION:
Agitation Associated with Schizophrenia or Bipolar I or II Disorder

Patient Population	Agitation Severity	Initial dose	Optional 2nd or 3rd dose[1]	Maximum Recommended Total Daily Dosage
Adults	Mild or Moderate	120 mcg	60 mcg	240 mcg
	Severe	180 mcg	90 mcg	360 mcg
Patients with Mild or Moderate Hepatic Impairment[2]	Mild or Moderate	90 mcg	60 mcg	210 mcg
	Severe	120 mcg	60 mcg	240 mcg
Patients with Severe Hepatic Impairment[2]	Mild or Moderate	60 mcg	60 mcg	180 mcg
	Severe	90 mcg	60 mcg	210 mcg
Geriatric Patients (>= 65 years old)	Mild, Moderate, or Severe	120 mcg	60 mcg	240 mcg

1) 120 mcg and 180 mcg dosage strengths can be cut in half to obtain the 60 and 90 mcg respectively
2) Hepatic impairment: Mild (Child-Pugh Class A); Moderate (Child-Pugh Class B); Severe (Child-Pugh Class C)

Renal Impairment: Dexmedetomidine pharmacokinetics were not significantly different in patients with creatinine clearance < 30 mL/minute compared to those with normal renal function

RECOMMENDED MONITORING: Vital signs, patient alertness

PHARMACOECONOMICS/COST:

Product (Drug, Strength, Form)	NDC	Price per film	Price per box
IGALMI 120 mcg SL film #10	81092-1120-1	$105	$1050
IGALMI 120 mcg SL film #30	81092-1120-3	$105	$3150
IGALMI 180 mcg SL film #10	81092-1180-1	$105	$1050
IGALMI 180 mcg SL film #30	81092-1180-3	$105	$3150

CONCLUSION & RECOMMENDATION:
Acute agitation associated with psychiatric conditions such as bipolar disorder or schizophrenia is a common challenge encountered by medical providers. There are a wide variety of assessment tools available to diagnose agitation including the overt agitation severity scale, the agitated behavior scale, the Richmond agitation and sedation scale, and the positive and negative syndrome scale excited scale (PEC). Current management strategies for acute agitation include non-pharmacological and pharmacological therapy. Non-pharmacological strategies such as patient isolation, verbal de-escalation, and reducing aggravating environmental stimuli are generally recommended prior to pharmacological management. Pharmacological intervention is only recommended when rapid control of agitation, aggression, or excitement is required and include benzodiazepines, first-generation antipsychotics, second-generation antipsychotics, or a combination of these. In the management of acute agitation due to psychiatric conditions such as schizophrenia or bipolar disorder, the use of verbal de-escalation for patients who are able to communicate their needs should be the first line of treatment. If this fails, the use of oral second generation antipsychotics (olanzapine, risperidone) would be preferred over more invasive intramuscular formulations for cooperative patients. The use of benzodiazepines or first generation antipsychotics is typically reserved as second line options for treatment of acute agitation.

Dexmedetomidine sublingual film (Igalmi) is approved for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults, and is a part of the alpha 2 adrenergic receptor antagonist class of medications. The level of cooperation required to administer a medication sublingually limits the generalizability of the results to patients who are able or willing to self-administer. Also, efficacy and tolerability were assessed following a single episode of agitation that provides no information on the efficacy and safety of longer-term use of sublingual dexmedetomidine. Additionally, a large placebo effect was observed in both trials further supporting the recommended use of nonpharmacological techniques as part of the management of agitation.

Though the results of the Serenity I and II trials show efficacy in the management of acute agitation in patients with schizophrenia or bipolar 1 and 2 disorder, the place in therapy of Igalmi remains unclear. At this time there is a lack of data directly comparing the safety and efficacy of sublingual dexmedetomidine to current therapies used for either approved indication.

Patients enrolled in both trials presented from a variety of settings (outpatient clinics, mental health clinics, psychiatric or medical emergency services, inpatients newly admitted for acute agitation, or already hospitalized for underlying conditions). Due to this study design and patient enrollment, it is unclear how many patients were cared for in the emergency department setting which makes generalization to emergency department use difficult and it is difficult to generalize for patients other than agitation related to schizophrenia or bi-polar disorder. Additionally, due to the variety of agitation assessment tools used at different practice sites such as the Richmond agitation and sedation scale, it is difficult to translate PEC outcomes to clinical practice universally.

Due to the lack of data clearly indicating a defined place in therapy for this new therapy, it is recommended that this therapy be non-formulary, in alignment with the system P&T Committee decision. As new data emerges (comparative data, etc.) this decision may be reevaluated by the system P&T committee at a future date.

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)?	N/A	
Pharmacist/Technician Education?	N/A	
Ordering & Prescribing		
Restriction to particular specialty, indication, or particular patient population?	Yes	Approved only for acute agitation in patients with schizophrenia and bipolar I & II

Medication Management Step	Identified Risk	Steps for Prevention
Dosing Issues (e.g. renal, hepatic dosage adjustment, max dose warnings)?	Yes	Dose adjustments recommended for hepatically impaired, or elderly patients
Drug Interactions?	Yes	EHR warnings for interactions with QT prolonging agents, anesthetics, sedatives, hypnotics, or opioids
Pregnancy?	No	
Absolute Contraindications?	No	
Requires Order Set, Protocol, concomitant therapy with another drug?	No	
LASA* nomenclature issues?	Yes	Shares the generic name with Precedex
Prescriber education?	N/A	
Processing, Preparing, & Dispensing		
High-risk drug double check?	N/A	
Drug Interaction check in place?	Yes	Concomitant use of drugs that prolong the QT interval, anesthetics, sedatives, hypnotics, or opioids
LASA* computer warnings?	N/A	
Administration Notes for MAR (e.g. handling precautions, surrounding food or other drugs)?	Yes	Sublingual film can break down when exposed to moisture
Packaging/Labeling (e.g. prepacking)?	N/A	
Dispensing (e.g. auxiliary labeling, light protection, refrigeration)?	N/A	
Documentation required (e.g. double check, worksheet)?	N/A	
Pharmacist/Technician Education?	N/A	
Administration		
Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, or other administration information?	N/A	
Special delivery system (e.g. pump)?	None	
Documentation required? (e. g. double check)	None	
Nurse education?	Yes	Igalmi is for sublingual or buccal administration. Do not chew or swallow Igalmi. Do not eat or drink for at least 15 and 60 minutes after sublingual and buccal administration respectively
Monitoring		
Interactions, adverse effects, efficacy, changes in renal function, or similar?	Yes	Monitor vital signs and patient alertness

Medication Management Step	Identified Risk	Steps for Prevention
Follow-up laboratory tests?	None	
Education?	None	
Operational Impact		
Unique procurement process? (e.g. orphan medication)	None	
Unique equipment required?	None	
Complex preparation process required	None	

IVIG Formulary Update

BACKGROUND:

CommonSpirit Health was recently informed that the current vendor (Octapharma; Healthtrust) of the CHI facilities' preferred IVIG product, Octagam, will be discontinuing its established contract as of the end of this calendar year. CommonSpirit Health System Pharmacy leadership was able to secure a new contract for CHI facilities with CSL Behring for Privigen at the same cost per gram for non-340b facilities ($74 per gram).

CURRENT CHI MEMORIAL FORMULARY:

Primary IVIG product: Octagam
Alternative IVIG product: Gamunex-C for patients intolerant or unresponsive to Octagam
Non-formulary IVIG product: Privigen

RECOMMENDATION & CONCLUSION:

Inpatients:
It is recommended to approve Privigen to formulary as the preferred IVIG product.
Gamunex-C will remain as the alternative product restricted only to patients intolerant or unresponsive to Privigen.

Outpatients:
It is recommended to approve Privigen to formulary as the preferred IVIG product, subsequent to insurance approval or prior authorization for FDA approved indications or payer approved off-label indications.
Gamunex-C will remain as the alternative product restricted only to patients intolerant or unresponsive to Privigen.

CommonSpirit Health DRUG CLASS REVIEW

OPHTHALMIC NON-ANTI-INFECTIVE AGENTS

BACKGROUND:
The November 2022 CSH System P&T committee reviewed ophthalmic non-anti-infective agents for formulary maintenance and standardization opportunities across the system. The table on this page represents non-formulary agents (left column) with the corresponding recommended therapeutic interchange (right column). The listed medications represent formulary variances from the current CHI Memorial formulary.

FORMULARY VARIANCES:

1. FML ophthalmic formulations
    a. Recommendation/Discussion: Very low utilization (<1 dose administered/month) and non-formulary status very unlikely to impact patient care. All doses have been home medications. Substitute dexamethasone ophthalmic suspension per interchange table.
2. Lotemax (loteprednol) formulations
    a. Recommendation/Discussion: Low utilization (~2 doses dispensed/month) and non-formulary status very unlikely to impact patient care. Substitute dexamethasone ophthalmic suspension per interchange table.
    b. Dr. Bowers prefers use for corneal transplants. We are currently working with Dr. Bowers to evaluate any supporting evidence that loteprednol maintains lower intraocular pressures than dexamethasone. Utilization is ~1 bottle per month and may require non-formulary use for this specific indication.

Therapeutic Interchanges

Ordered	Provided
FML Forte 0.25%	Dexamethasone 0.1% suspension 2 drops at frequency ordered up to four times a day
FML Liquifilm 0.1%	
FML S.O.P. 0.1% ointment	
Lotemax 0.5% suspension	
Lotemax 0.5% gel	
Lotemax 0.5% ointment	
loteprednol etabonate 0.5% suspension	

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: IV Iron Replacement Products

- **Sodium ferric gluconate (Ferrlecit)**
- **Iron dextran (InFed)**

Summary: The above medications are the P&T Committee-preferred IV iron products for inpatients. Both products are currently experiencing a critical shortage. Iron dextran has been unavailable for months, and the sodium ferric gluconate supply has recently been depleted.

Recommendation: Although currently non-formulary across CHI Memorial for inpatient and outpatient use, it is recommended to approve an automatic pharmacist therapeutic interchange to substitute iron sucrose (Venofer) 200 mg IV every other day for new orders for IV iron replacement when sodium ferric gluconate and iron dextran are out of stock and unavailable from all suppliers.

MEDICATION #2: Injectable lorazepam (Ativan)

Summary: The injectable lorazepam supply has recovered. This summer, the P&T Committee emergently approved the below restrictions for injectable lorazepam use. The restrictions were implemented to ensure appropriate utilization in the long-term, in addition to mitigating utilization in the short term during the critical shortage.

- Pharmacists may automatically substitute orders for injectable lorazepam to oral lorazepam in a 1:1 ratio if the patient can take oral/NG/FT medications, unless indicated for seizure or alcohol withdrawal
- IV lorazepam is permanently formulary restricted for the treatment of only acute seizures, alcohol withdrawal, or chemotherapy-induced nausea and/or vomiting
- Lorazepam infusions are permanently non-formulary (due to availability of safer alternatives for agitation such as propofol, dexmedetomidine, ketamine and risk of propylene glycol toxicity)
- Benzodiazepine equivalents: Lorazepam 1 mg = Midazolam 1 mg = Diazepam 5 mg

Discussion/Recommendation: In order to ensure adequate supply and appropriate use, it is recommended to maintain the currently approved formulary restrictions for injectable lorazepam. Dr. Haren proposes the benzodiazepine equivalents to be modified as follows: Lorazepam 1 mg = Midazolam **2 mg** = Diazepam 5 mg.

MEDICATION #3: Injectable diazepam (Valium)

Summary: The injectable diazepam supply has recovered. This summer, the P&T Committee emergently approved the below temporary restrictions for injectable diazepam use:

- IV diazepam is formulary restricted for the treatment of only acute seizures

Discussion/Recommendation: Since the implementation of restrictions was intended to be temporary, it is recommended to remove the currently approved formulary restrictions for injectable diazepam.

Medications for COVID-19: Update

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

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

COVID-19 Vaccines		
	Current Process	**Recommended Action**
Pfizer-BioNTech COVID-19 Vaccine	Formulary for inpatient use	Maintain current process
Pfizer-BioNTech COVID-19 Bivalent BOOSTER Vaccine	N/a	Add to formulary for inpatient use
Moderna COVID-19 Vaccine	Non-formulary for inpatient use	Maintain current process
Janssen (J&J) COVID-19 Vaccine	Non-formulary for inpatient use	Maintain current process

Use/Restriction Criteria Approved by COVID-19 Medications Subcommittee

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

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

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

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

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

Ritonavir-boosted nirmatrelvir (Paxlovid) Criteria: Inpatients (approved 4/12/22):

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

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

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

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

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

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

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

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

Sotrovimab Criteria (approved 4/12/22):
Update [4/5/2022] Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant

Inclusion criteria:

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

Exclusion criteria:

- Hospitalized due to COVID-19

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

Inclusion criteria:

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

Exclusion criteria:

- Hospitalized due to COVID-19

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:

Pharmacist Clinical Intervention Documentation
Aug-Nov 2022

LOC NAME	*INTERVENTION TYPE*	***INTERVENTION SUBTYPE***	*RESPONSE*	Grand Total
CHI Memorial Hospital	Anticoagulation	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted	1
	Medication Related Problems	Drug Optimization		1
		Discontinue Therapy	Accepted	2
		Drug Optimization	Accepted	1
	Opioid Stewardship	Discontinue Therapy	**Rejected**	1
CHI Memorial Hospital Hixson	Medication Related Problems	Clarify Drug Order	Accepted	1
Grand Total				**15**

Clinical Intervention Detail:

LOC NAME	INTERVENTION TYPE	INTERVENTION SUBTYPE	RESPONSE	ORDER NAME	DOCUMENTATION
CHI Memorial Hospital	Anticoagulation	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted		"Diagnosis of submassive PE with improvement in thrombus. Today is day 4 of heparin gtt. Dr. Ramjee switched patient to Eliquis at 5 mg BID dose. Ended up speaking with him to see if we could at least do 10 mg BID x 3 more days. He agreed but then asked for education on Eliquis dosing and indications and length of therapy for the higher dose of Eliquis. Provided all of this information and then adjusted dosing on MAR. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization		BIVALirudin (ANGIOMAX) 250 mg in sodium chloride 0.9% (NS) 250 mL infusion	"Angiomax was not running this morning - warfarin being given tonight- plts 100K (using for mechanical mitral valve (not HIT)) - talked to RN - She wasn't sure the angiomax should be running since getting warfarin. - I told her to turn on the angiomax now and still give the warfarin, and I told her she is supposed to be giving both. She turned it on the previous rate ordered, but she did not have a therapeutic pTT rate yet - she will verify with a new pTT in 3 hrs. "
CHI Memorial Hospital	Anticoagulation	Drug Optimization	Accepted		"Pt has plt of 57, MD note stated this am not dvt prophylaxis due to high risk of bleed, the heparin was still on mar. Called dr donnellan and he stated stop heparin, pt had bone marrow procedure yesterday and will be receiving IT Chemo "
CHI Memorial Hospital Hixson	Medication Related Problems	Clarify Drug Order	Accepted		"Asked to d/c rocephin since patient on Zosyn. MD thought he had d/ced rocephin but this was not the case. RN called down b/c she could not pull the po cardizem out of the pyxis. When I looked at the MAR I noticed the cardizem had been d/ced, and this was the same patient that MD thought they had d/ced rocephin on. I clarified with MD, and the rocephin should be d/ced and cardizem restarted. "
CHI Memorial Hospital	Medication Related Problems	Discontinue Therapy	Accepted	cilostazoL (PLETAL) tablet 100 mg	"There is a BBW of Pletal and any severity of HF. Patient takes pletal at home and NP restarted it here. Looks like HF is possibly a new diagnosis for the patient. Informed NP it should be stopped and really stopped outpatient as well d/w C/I and BBW with HF. NP is stopping it. "
CHI Memorial Hospital	Medication Related Problems	Discontinue Therapy	Accepted	Warfarin Daily Dose Reminder	"Dr. Ballard ordered warfarin sliding scale for this patient who has Hemophilia A requiring factor VIII infusions. I discontinued the order and notified Dr. Ballard. "
CHI Memorial Hospital Hixson	Medication Related Problems	Discontinue Therapy	Accepted	midazolam (VERSED) 100 mg in sodium chloride 0.9% (NS) 100 mL infusion	"Versed gtt ordered for patient experiencing withdrawal. Contacted MD about this to notify this could not be done due to patient not intubated and other medications have not been tried first. "
CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted		"Received an order for Keppra 2g x1 and Vimpat 500mg q12h from the ED by Dr. Watson. Dose appeared very high, therefore looked at drug resources to make sure dose was ok. All of the resources I found provided max dose of 200-400 mg daily, and so contacted Dr. Watson about this. He stated that this was an order received by Dr. Shah. Still unsure of the dose, I contacted the Neurology on-call service where I was able to get in contact with Dr. Devlin. I explained the situation with him regarding my concerns and he agreed that this dose was not correct. At this point, he got Dr. Watson, Dr. Shah, and I in a single call in order to clarify this. Dr. Shah stated that he wanted the Vimpat as a single 300 mg dose following the Keppra load (total 3 g), further followed by Keppra 1500 mg q12 hours

					as a maintenance dose. As a result, I adjusted Dr. Watson's orders for the Vimpat, and entered Keppra 1500 mg q12 as a verbal order from Dr. Shah. "
CHI Memorial Hospital	Medication Related Problems	Dose Optimization (renal, hepatic, age, weight, etc.)	Accepted		"Dr Tyler ordered dilaudid 4 mg IV for this patient, I contacted her and explained 1 mg dilaudid = ~ 10 mg morphine. She thought he was receiving 4 mg iv , however patient was on 4 mg po, she changed the order to 1mg iv x 1. "
CHI Memorial Hospital	Medication Related Problems	Drug Interaction Problem Resolved	Accepted	primidone (MYSOLINE) tablet 150 mg	"Eliquis ordered and patient on primidone. Contacted MD about this interaction and recommended either switching to warfarin or stopping primidone (if for essential tremors and patient okay with stopping). MD stated to d/c the primidone. "
CHI Memorial Hospital	Medication Related Problems	Drug Interaction Problem Resolved	Accepted		"This patient takes Genvoya at home and plavix, there is a significant drug interaction between plavix and Genvoya, Genvoya may decrease plavix levels, called Cathy Patty and she said she would speak to dr atchley and dr Madan. Looks like effient would be an alternative Spoke with Cathy Patty and dr atchley change the plavix to effient "
CHI Memorial Hospital	Medication Related Problems	Drug Optimization	Accepted		"Home med eliquis re-ordered by dr mcnamara, pt admitted for nausea, rectal bleeding and positive occult stool at 0945 am today, I contacted dr mcnamara and he agreed to hold the eliquis 5mg bid for now "
CHI Memorial Hospital Hixson	Medication Related Problems	Drug Optimization	Accepted	ondansetron PF (ZOFRAN) injection 4 mg	"Pt's Qtc interval: 604 ms- received PRN order for Zofran. Got this changed to Promethazine. "
CHI Memorial Hospital	Opioid Stewardship	Discontinue Therapy	Rejected	fentaNYL (DURAGESIC) patch 25 mcg/hr	"Please consider stopping duragesic. Prior to patch start, pt had only 1 dose of percocet (8 hrs prior and no morphine). As patient is opioid naive, would recommend managing pain with IV/PO prns. -RX Intervention closed automaticallyPatient discharged on duragesic 25 x 6 days and percocet 5 for up to 10 days. "
CHI Memorial Hospital	Opioid Stewardship	Medication History Obtained	Accepted		"Patient was direct admit to IMCU - started on narcan gtt. Home meds documented as ms IR 15 BID + prn oxy. Didn't make sense. Verified that patient actually on MS Contin 15 BID per CSMD. Spoke with Brandy who verified that MS Contin was actually written on ED tech paperwork. Med was just entered wrong on PTA med list. Fixed. Alerted Brad, MIC pharm, to change. He will f/u on narcan gtt duration. "