Pharmacy & Therapeutics Committee Meeting

Zoom Conference

February 10, 2022 7:00 a.m.

Agenda	a Items	Individual Responsible
1. Call	to Order	Nathan Chamberlain, MD
2. Con	flict of Interest Disclosure	Rachel Kile, PharmD
3. App	proval of December 2021 Minutes	Nathan Chamberlain, MD
4. CSF	I System P&T Committee – January 2022 Decision Brief	Page4
A. B. C.	nulary Decisions & Therapeutic Interchanges Remifentanil (Ultiva®)	
	lication Use Pharmacist-Driven PPI & H2RA Deescalation Protocol	18
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8. Polic	ies	
	Anticoagulation Management. Bradycardia Management Protocol. Contrast Media Administration. Drug and Food Interaction/Education.	
9. Nutr	ition	
Δ	Nutrition Care Manual	38

Next Meeting Date: April 7, 2022 at 7:00 a.m.

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: December 9, 2021

CALLED TO ORDER: 7:01 a.m. LOCATION: Physician's Dining Room + conference call 7:34 a.m. ADJOURNED:

Physician Member Attendance:	Non-Physician Member Attendance:	Guests:
X Nathan Chamberlain, MD- Chairman X Mark Anderson, MD- Infectious Disease X Justin Blinn, MD- Anesthesiology David Dodson, MD- Hospitalist F. Lee Hamilton MD- Hospitalist X William Haren, MD- Psychiatry X Matthew Kodsi, MD-Quality X Aditya Mandawat, MD- Interventional Cardiology X Chad Paxson, MD- Intensivist/Pulmonology/ICU Vimal Ramjee, MD- Cardiology James Wahl, MD- Hospitalist, GA X Richard Yap, MD- Hospitalist	X Karen Babb, PharmD- Manager Jamie Barrie, PharmD- Manager, Hixson X Patrick Ellis, PharmD- Director Rodney Elliott- Purchasing X Karen Frank, RN- Quality X Lori Hammon, RN- Quality X Farrah Reidt, Clinical Nutrition Shannon Harris, RN- Infection Prevention Rhonda Hatfield, RN-CNO Kevin Hopkins, RT- Director of Resp Therapy Rachel Kile, PharmD- Clinical Manager Daniel Marsh, PharmD- Operations Manager Carey Smith, RPh- Manager, Georgia Chris Chastain- Administrative Coordinator	Linda Johnson, PharmD Natasha McGhee, RN Tina Mathew, Pharmacy Resident Doug Dertien, Pharmacy Resident Sabrina Curtis, Pharmacy Resident Jessica Duke, Pharmacy Resident

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 October 2021 minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	November 2021 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	 Remifentanil (Ultiva®): Remifentanil is a potent IV μ-opiate receptor agonist. The analgesic effects of remifentanil are rapid in onset and offset so it is beneficial in cases in which the patients need to be awake or under lighter sedation/analgesia during the surgery. With the development of our neurosurgery service line, this medication has been requested by Dr. Babu for specific surgical cases. The cost is higher than conventional IV opioids or dexmedetomidine. It was recommend that remifentanil be restricted for ordering as follows: a. Ordering restricted to Anesthesia providers for	Approved	Complete
Medication Use	Impact of MRSA Nasal PCR & Pharmacist Interventions on IV Vancomycin Use: Linda Johnson presented the results of a medication/diagnostic use evaluation. The purpose of this evaluation was to assess the impact of the pharmacist-driven protocol to automatically order MRSA nasal PCRs combined with antimicrobial stewardship interventions on IV vancomycin days of	Informational	Complete

	therapy for the management of pneumonia. Results demonstrated a lower median IV vancomycin duration, less vancomycin levels ordered, and a 100% physician acceptance rate. There was no difference in LOS or re-escalation to vancomycin. The NPV of the MRSA nasal PCR was 100%.		
Medication Safety	1. ADR Summary: Karen Babb presented the adverse drug reaction summary results for July-Sept 2021. There were no trends to report, with the exception of an increase in inpatients on warfarin with an INR >4. For the patients in which a pharmacist was consulted to dose, there were no predictable trends.	Informational	Complete
Policies	1. Diet Orders: Farrah Reidt presented updates to the Diet Orders policy, which focused on inclusion of "supplements" which can be ordered by the dietitian.	Approved	Complete
	2. Hypertonic Saline For Adults: The maximum infusion rate of hypertonic saline to be administered via a central line was clarified by the indication: for hyponatremia, 50 ml/hr; for acute neurologic indications, 70 ml/hr. For neurologic indications, the parameters for holding the infusion and notifying the provider were updated to include a serum sodium of <135 mEq/L.	Approved	Complete
	 Titrating Medications: Rachel reviewed proposed updates to this policy which included: a. Parameters for physician notification b. Guidelines for paused titrating medications c. Removal of argatroban (was previously removed from formulary) d. Removal of bumetanide (not a titrating medication; remains on formulary) e. Removal of non-weight-based dosing instructions for epinephrine and norepinephrine 	Approved	Complete
	 Antimicrobial Stewardship Program: Updated to include applicability of the ASP program to the Georgia campus. 	Approved	Complete
Miscellaneous	1. HIT Antibody Testing Update: Ann Durham provided an update to the committee on the recent change to heparin induced thrombocytopenia (HIT) antibody testing. All HIT Ab tests are now processed at Erlanger Hospital instead of being sent off the Quest. This is not an ELISA test, so the optical density (OD) values will no longer be reported. Confirmatory SRA testing will automatically be re-drawn (requires a second patient stick) if the HIT Ab is positive. SRA tests will now be sent off to LabCorp, which is interfaced with Epic. Rachel will provide the committee with a journal article provided by Ann that reviews the HIT Ab test.	Informational	Complete

There being no further business, the meeting was adjourned at 7:33 a.m. The next P&T meeting is February 10, 2022 @ 7:00 a.m.

Respectfully submitted, Patrick N. Ellis, PharmD, Director of Pharmacy; Rachel Kile, PharmD, Pharmacy Clinical Manager

Approved by, Nathan Chamberlain, MD, Chairman

CSH SYSTEM PHARMACY AND THERAPEUTICS COMMITTEE DECISION BRIEF

January 2022 Decisions

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

Madication		Formulary Decision					Thursday to
Medication name	Medication Used For	Do Not Stock	Formulary Restricted	Formulary Unrestricted	Nonformulary	Restrictions (if applicable)	Timeline to Implementation
Amivantamab- vmjw	EGFR and MET receptor bispecific antibody antineoplastic		Rybrevant			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
Asparaginase erwinia chrysanthemi (recombinant)- rywn	Leukemia	Rylaze					Within 60 days of System P&T Committee approval
Bezlotoxumab	Reduction of the recurrence of <i>C. Difficile i</i> nfection		Zinplava			Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization Inpatient setting - Administration in the outpatient setting is preferred Outpatient administration is not possible during active C. Difficile treatment To ID physicians where available Patient must meet ALL of the following: Have a positive stool test for C. Difficile toxin. Receiving active treatment for C. Difficile infection with oral vancomycin, metronidazole, or fidaxomicin. Have a history of one or more CDI episodes in the past 6 months Age 65 years or above* In addition, the patient must either Meet ONE of the following:	Within 90 days of System P&T Committee approval

DECISION DIVIES

D.A. diestien	Medication		Formula	ary Decision			Timeline to
name	Medication Used For	Do Not Stock	Formulary Restricted	Formulary Unrestricted	Nonformulary	Restrictions (if applicable)	Implementation
						Required ICU admission as a result of the current CDI episode Presence of pseudomembranous colitis on endoscopy Immunocompromised status OR Meet TWO of the following: Body temperature greater than 38.3°C (100°F) Serum albumin < 2.5g/dl WBC > 15,000 cells/ul *May consider for patients with a primary or recurrent CDI episode who are immunocompromised or who have severe disease on a case-by-case basis regardless of age. Bezlotoxumab should be used with caution in patients with underlying congestive heart failure (CHF). The benefits of using bezlotoxumab in this patient population should be weighed against the risk of CHF. Bezlotoxumab should not be given to patients who meet ONE of the following exclusion criteria: Patients who are not expected to survive for 72 hours Pregnant and lactating women	
Bisoprolol/ Hydrochlorothia zide tablets	Hypertension			Bisoprol/ Hctz	Ziac	Bisoprolol/HCTZ therapeutic interchange	Within 90 days of System P&T Committee approval

DEVISION DINE

Medication		Formulary Decision					Timeline to
name	Medication Used For	Do Not Stock	Formulary Restricted	Formulary Unrestricted	Nonformulary	Restrictions (if applicable)	Implementation
Cabotegravir and rilpivirine	HIV infection		Cabenuva			Ambulatory Clinic setting Initiation of therapy is restricted to ID/HIV specialist or other provider with experience in HIV management Administer at an appropriate injection setting by medical professional (local site to determine site based on community HIV resources) Not to be initiated in the inpatient setting. In the occasion that a patient is hospitalized, therapy they will be bridged with daily oral cabotegravir/rilpivirine within 14 days of their anticipated next injection (obtain patient specific supply from specialty pharmacy if necessary)	Within 90 days of System P&T Committee approval
Ipratropium bromide inhaler	COPD				Atrovent HFA	Atrovent therapeutic interchange	Within 60 days of System P&T
Ipratropium/ albuterol sulfate inhaler	COPD				Combivent HFA	Combivent therapeutic interchange	Committee approval
Molnupiravir	COVID-19 treatment		Lagevrio			Inpatient If a patient requires hospitalization after starting treatment per the CommonSpirit Health COVID-19 treatment guidelines, the full treatment course of ritonavir-boosted nirmatrelvir (Paxlovid) or molnupiravir can be completed at the health care provider's discretion Outpatient Per most recent CommonSpirit Health COVID-19 treatment guidelines subsequent to payor approval when appropriate	Within 90 days of System P&T Committee approval

DEGISION DINE

Medication		Formulary Decision					Timeline to
name	Medication Used For	Do Not Stock	Formulary Restricted	Formulary Unrestricted	Nonformulary	Restrictions (if applicable)	Implementation
Nirmatrelvir- ritonavir	COVID-19 treatment		Paxlovid			COVID-19 Indications Inpatient If a patient requires hospitalization after starting treatment per the CommonSpirit Health COVID-19 treatment guidelines, the full treatment course of ritonavir-boosted nirmatrelvir (Paxlovid) or molnupiravir can be completed at the health care provider's discretion Outpatient Per most recent CommonSpirit Health COVID-19 treatment guidelines subsequent to payer approval when appropriate	Within 90 days of System P&T Committee approval
Tixagevimab and cilgavimab	COVID-19 pre-exposure prophylaxis		Evusheld			COVID-19 Indications Inpatient Per the CommonSpirit Health COVID-19 treatment guidelines Outpatient Per most recent CommonSpirit Health COVID-19 treatment guidelines subsequent to payer approval when appropriate	Within 90 days of System P&T Committee approval
COVID-19 vaccine	COVID-19 infection prevention		Janssen COVID-19 vaccine	COVID-19 vaccine, MRNA (Pfizer & Moderna)		Restricted to individuals in need of COVID-19 vaccination who are unable (e.g., allergy) or unwilling to receive an mRNA COVID-19 vaccine	Within 90 days of System P&T Committee approval
Dexamethasone ophthalmic	Ocular inflammation				Dexycu		Within 60 days of System P&T Committee approval
Dextrose (sweet cheeks)	Hypoglycemia		Sweet cheeks			Patients less than the age of 2	Within 90 days of System P&T Committee approval

DECIDION DINE

Medication		Formulary Decision					Time allows to
name	Medication Used For	Do Not Stock	Formulary Restricted	Formulary Unrestricted	Nonformulary	Restrictions (if applicable)	Timeline to Implementation
Dostarlimab-gxly	PD-1 blocking antibody antineoplastic		Jemperli			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
Fibrinogen concentrate	Fibrinogen replacement in acute bleeding				Fibryga		Within 60 days of System P&T Committee
concentrate	episodes				Riastap		approval
Indium 111 octreotide	Radio-diagnostic agent		Indium in-111 dtpa, indium in-111 oxyquinoline, indium-111 chloride			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
Margetuximab- cmkb	Metastatic HER2- positive breast cancer		Margenza			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
Oritavancin (Kimyrsa)	Antibiotic active against gram-positive bacteria				Kimyrsa		Within 60 days of System P&T Committee approval
Satralizumab	Neuromyelitis optica spectrum disorder				Enspryng		Within 60 days of System P&T Committee approval
Trilaciclib	To reduce the incidence of chemotherapy- induced bone marrow suppression		Cosela			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

THERAPEUTIC INTERCHANGES

Bisoprolol/HCTZ

Order	Interchange to
Ziac 5/6.25 mg	Generic bisoprolol fumarate 5 mg/hydrochlorothiazide 6.25 mg tablet
Ziac 10/6.25 mg	Generic bisoprolol fumarate 10 mg/hydrochlorothiazide 6.25 mg tablet

Atrovent HFA

Order	Interchange to
Atrovent® 1 inhalation 4 times daily	Ipratropium SVN 4 times daily
Atrovent® 1 inhalation 4 times daily	Spiriva® MDI once daily

Combivent HFA

Order	Interchange to
Combivent® 1 inhalation 4 times daily	Albuterol/ipratropium SVN 4 times daily
Combivent® 1 inhalation 4 times daily	Albuterol MDI 4 times daily and Spiriva® MDI once daily

FORMULARY UPDATE

THERAPEUTIC CLASS: µ-opiate receptor agonist

GENERIC NAME: Remifentanil

PROPRIETARY NAME: Ultiva®

BACKGROUND/RATIONALE:

Remifentanil was approved to CHI Memorial formulary last December 2021, with restriction criteria. Since that time, our neurosurgeon and anesthesiologists have requested expansion of utilization criteria to all neurosurgical cases of the head (not spines) in order to ensure fast wake up and quicker neurological assessment regardless if the patient is awake or asleep for the surgery.

CURRENT FORMULARY USE CRITERIA:

- Ordering restricted to Anesthesia providers
- Craniotomies with very low associated post-op pain
- Awake fiberoptic intubations

RECOMMENDATION/DISCUSSION:

It is recommended to revise the current restriction criteria for remifentanil to the following:

- Ordering restricted to Anesthesia providers
- Craniotomies associated with very low associated post-op pain plus the need for rapid emergence and full neurological assessment
- Awake fiberoptic intubations

Utilization of remifentanil will be monitored and reviewed to ensure alignment with the above criteria and will be reported to anesthesia leadership routinely.

Long-Acting Insulins

FORMULARY UPDATE

CURRENT FORMULARY AGENT:

Lantus® (insulin glargine)

BACKGROUND:

Lantus is the preferred insulin in the long-acting insulin category used throughout CommonSpirit Health. Recently, another insulin glargine formulation became available – Semglee (insulin glargine-yfgn, Mylan), a biosimilar agent. In July 2021, the FDA approved Semglee as the first interchangeable biosimilar product in the United States. Per the FDA, an interchangeable biosimilar product may be substituted for the reference product *without* the intervention of the prescriber.

The March 2021 CommonSpirit Health P&T Committee approved Lantus and Semglee as long acting insulin class representatives. The conversion to Semglee as the long acting insulin class representative is now recommended to move forward as a FY22 CommonSpirit Health Pharmacy Clinical Initiative.

PRODUCT COMPARISON: Indications and storage requirements are the same for all insulin glargine products.

PHARMACOECONOMICS/COST:

Product (Drug, Strength, Form)	Cost per vial	Purchase History (12 mos)	Estimated cost savings (12 mos)
LANTUS 100 UNITS/ML SUBCUT VIAL (10 ml vial)	\$77.84	873 vials	n/a
SEMGLEE 100 UNITS/ML SUBCUT VIAL (10 ml vial)	\$67.69	N/A	\$8,860.95

CONCLUSION/RECOMMENDATION:

Semglee (insulin glargine-yfgn) is fully interchangeable with Lantus, similar to a generic substitution. Semglee will replace Lantus as the long-acting insulin product at CHI Memorial hospitals.

It is recommended to update the existing automatic therapeutic interchange for long acting insulins as follows:

Insulins: Long-Acting					
Insulin glargine (Lantus®)	Insulin glargine-yfgn (Semglee®) Same dosing frequency (1:1 dose conversion)				
Insulin detemir (Levemir®)	Insulin glargine-yfgn (Semglee®) Same dosing frequency (1:1 dose conversion)				
Insulin glargine (Toujeo®) 300 units/ml	Insulin glargine-yfgn (Semglee®) Same dosing frequency (1:1 dose conversion)				
Insulin degludec (Tresiba®) 100 units/ml or 200 units/ml	Insulin glargine-yfgn (Semglee®) Same dosing frequency (1:1 dose conversion)				
Insulin degludec/insulin aspart (Ryzodeg® 70/30) (dose based on degludec component; 10 units = 10 units of degludec)	Insulin glargine-yfgn (Semglee®) Same dosing frequency (1:1 dose conversion) * short-acting component should be ordered separately *				
Insulin glargine (Basaglar®)	Insulin glargine-yfgn (Semglee®)				

Same dosing frequency (1:1 dose conversion)

Lower Dose PCC (Kcentra®) for Direct Oral Anticoagulant (DOAC) Reversal

BACKGROUND:

The PCC dose currently recommended per the CHI Memorial Antithrombotic Reversal & Surgical Management Guidelines for reversal of oral Factor Xa inhibitors or DOACs is a weight-based dose of 50 units/kg (maximum dose 5,000 units) for major (life-threatening) bleeding. Dosing strategies used across CommonSpirit Health are variable, including weight-based doses of 25 units/kg, 35 units/kg, and 50 units/kg along with fixed-doses of 2000 units.

The optimal dose of Kcentra for reversal of DOACs has not been clearly established and guideline recommendations are variable (Table 1). The dose of 50 units/kg was initially recommended based on animal models and studies in healthy patients. Several studies have since demonstrated hemostatic success with lower doses. Overall, regardless of dosing scheme, average hemostasis ranges from 68-95%. Newer data suggests that lower doses are safe and effective for all indications (Table 3). Studies that have been conducted with a cap dose of 2000 units (including ICH-associated bleeding) have demonstrated safety and efficacy for DOAC reversal.

For patients with unknown or unclear history of DOAC use, or if the time of last dose is unknown or more than 24 hours ago, it is reasonable to check an Anti-Xa level prior to administration of Kcentra. In the absence of drug-specific anti-Xa testing, a Heparin Anti-Xa level may be used to determine qualitative presence of a Factor Xa inhibitor. For Heparin Anti-Xa levels below the threshold of clinical significance (Table 2), it is considered safe for invasive procedures at high risk of bleeding, therefore additional reversal is not indicated and Kcentra may be safely omitted.

Table 1. DOAC Reversal Guideline Summary

Guideline	Indication	Recommendation
Neurocritical Care Society and Society of Critical Care Medicine (2016)	ICH	Xa: aPCC or PCC4 (50 units/kg)
American Society of Hematology (2018)	Life-threatening bleeding	Xa: PCC4
European Stroke Organization (2019)	ICH	Xa: PCC4 (37.5-50 units/kg)
AHA/ACC/HRS (2019)	Life-threatening bleeding or surgery	Xa: no recommendations on aPCC or PCC4
Anticoagulation Forum (2019)	Major and life- threatening bleeding	Xa: PCC4 (2000 units)
American College of Cardiology (2020)	Major bleed	Xa: PCC4 (2000 units) or aPCC (50 units/kg)

Table 2. Anti-Xa Level Thresholds of Clinical Significance

Anticoagulant	Anti-Xa Specific Threshold for relevant anticoagulant effect	Equivalent Heparin Anti-Xa Level Threshold
Apixaban	> 30 ng·mL-1	≥ 0.2 IU·mL-1
Rivaroxaban	> 30 ng·mL-1	≥ 0.3 IU·mL-1
Fondaparinux	> 0.1 μg·mL-1	≥ 0.1 IU·mL-1

Table 3. Clinical Studies Evaluating Low Dose PCC for DOAC Reversal

Study	Dose	# pts	Type of Bleed	Median Dose	DOAC	Median time from last dose	Outcomes
Majeed 2017	<65kg: 1500 IU ≥65kg: 2000 IU	92	Acute or active major bleeding (MB); 70.2% ICH	26.7 IU/kg	53.6% rivaroxaban, 46.4% apixaban	12.5 hours	69.1% hemostatic efficacy overall; ICH: 72.9%
Schulman 2018	2000 IU; Repeated dose per provider discretion - given in 2 instances	71	MB; 55% ICH	26.4 IU/kg	56% rivaroxaban, 44% apixaban	16.9 hours	"Good" effectiveness of PCC per provider assessment = 65% overall; ICH 67%; GI Bleed 69%
Berger 2020	25 IU/kg	20	ICH	25.9 IU/kg	68.2% rivaroxaban, 22.7% apixaban	Not reported	94.7% hemostatic efficacy across entire population
Kim 2020	Fixed-dose: 2000 IU, may repeat x1 if hemostasis not achieved Weight-based dose: 35 or 50 IU/kg based on bleed severity for FXa	46	Need of surgical intervention or procedure, trauma, GI bleeding, or ICH (38.2% fixed vs 36.8% weight-based)	29.8 IU/kg (fixed) vs 43.6 IU/kg (weight-based)	Not reported	Not reported	Hemostatic efficacy 95.0% fixed vs 76.9% weight-based (p=0.091)
Wilsey 2020	Low-dose: 20-34 IU/kg High-dose: 35-50 IU/kg	99	Major bleeding or need for urgent surgery 60.8% vs 73% with ICH	26.6 IU/kg (fixed) vs 47.6 IU/kg (weight-based)	Low-dose 47.7% apixaban High-dose 76.2% apixaban	15 hours	Good or Moderate hemostatic success per Schulman et al definitions; 75.4% low vs 78.6% high (p=0.715) hemostatic efficacy between low and high-dose ICH: 77.4% vs 74.1% (p=0.766)
Hormese 2021	High-dose: 50 IU/kg (max 5000) Low-dose: 25 IU/kg (max 2500) w/ optional repeat dose of 25 IU/kg if satisfactory reversal not achieved with initial dose	47	Life-threatening bleeding; 73.9% high vs 70.8% low with ICH	High dose: 49.2 IU/kg Low dose: 24.2 IU/kg	Low dose: 82.6% apixaban High-dose: 66.7% apixaban	72.3% within 24 hours of reversal	Excellent or Good hemostatic success per Sarode et al definitions; 91.3% vs 87.5% ICH: 100% vs 88.2%
Cascone 2021	Low-dose: 25 IU/kg Standard-dose: 50 IU/kg	93	Spontaneous or traumatic ICH		Low dose: 40.3% apixaban High dose: 58.1% apixaban	14.5 hrs	Hemostatic efficacy 82.3% vs 83.9% (p=0.846)

PHARMACOECONOMICS/COST:

From June-December 2021, 35 Kcentra doses of 2000 units or greater were administered. Of those 35 doses, 31 were for DOAC reversal (50 units/kg).

Product & Dose	Utilization (7 months)	Medication Cost (per 7 months) (\$2/unit)	Estimated annual cost savings (12 mos)	Estimated monthly cost savings
Kcentra 50 units/kg	123,430 units administered	\$246,860	n/a	n/a
Kcentra 2000 units x1 dose (repeat dosing only occurred in ~3-5% of patients in studies)	62,000 units (estimated 31 doses)	\$124,000	\$210,800	\$17,500

CONCLUSION:

The recommended starting dose of Kcentra for DOAC reversal is a lower dose 25 units/kg actual body weight (maximum dose of 2500 units). A single repeated dose of up to 25 units/kg (maximum dose of 2500 units; maximum total dose of 5000 units) may be recommended within 6 hours after the initial dose if adequate hemostasis is not achieved and/or maintained. A fixed dose strategy of 2000 units with the option to repeat 2000 units (maximum total dose of 4000 units) should also be considered. All doses should be rounded to the nearest vial size (as we currently do). A dose of 25 units/kg with a max of 2500 units equates to a 100 kg patient which is a reasonable assumption on average patient weight.

The physician leadership of the following service lines have approved a lower fixed dose (2000 units) strategy): AA, EP, CV surgery, critical care, ED. Neurology and neurointerventional prefer fixed dosing, but use of 2500 units instead of 2000 units, for ICH based on the studies which evaluated lower dose weight-based dosing at 25 units/kg with a max dose of 2500 units. Neurosurgery is in agreement.

At CHI Memorial, there is an estimated annual cost savings of approximately \$210,000 if Kcentra dosing for DOAC reversal is changed from 50 units/kg to a 2000 units fixed dose.

RECOMMENDATION:

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

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

The CHI Memorial Antithrombotic Reversal & Surgical Management Guidelines for reversal of oral Factor Xa inhibitors or DOACs and the Anticoagulation Management policy will be updated.

Medications for COVID-19: Update

Emergency Use Authorization (EUA) Medications					
	Current Process	Recommended Action			
Tocilizumab (Actemra)	Pharmacist automatic therapeutic	Maintain current process			
Baricitinib (Olumiant)	interchange to either product based on product availability				
Bamlanivimab/etesevimab	Federal government (HHS)	Approve pharmacist automatic			
Casirivimab/imdevimab (Regen-COV)	manages supply and determines which product will be shipped to each state. State of TN and GA then	therapeutic interchange of products based on product availability and anticipated efficacy against			
Sotrovimab	allocates mAb to select sites.	variant(s) of concern (per CDC/FDA guidance).			
Nirmatrelvir and ritonavir (Paxlovid)* Molnupiravir	Non-formulary. Federal government (HHS) manages supply and determines which product will be shipped to	Do not add to formulary. Allow continuation of patient's home supply upon hospital admission, if ordered to continue by			
	each state. State of TN then allocates products to select sites.	the admitting physician. Patients must provide their own supply.			

^{*}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 (Adult formulation)	Formulary for inpatient use; includes booster doses	Maintain current process			
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			

<u>Use/Restriction Criteria Approved by COVID-19 Medications Subcommittee</u>

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 (+)
- **\(\leq 5**\) 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.

Remdesivir Criteria: Incidental COVID+ (symptomatic) while admitted for non-COVID diagnosis (developed 2/1/22):

(SOTROVIMAB preferred, when available)

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)
- Immunocompromised regardless of vaccine status (defined below)
- Unvaccinated (aged ≥ 75 alone or $\geq 65 + \text{risk factor(s)}$)

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.

Immunocompromising Conditions (per NIH)

Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)

Patients receiving Bruton tyrosine kinase inhibitors

Chimeric antigen receptor T cell recipients

Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication

Patients with hematologic malignancies who are on active therapy

Lung transplant recipients

Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)

Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents Patients with severe combined immunodeficiencies

Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3

Risk Factors (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html) Overweight and obesity Cancer Chronic kidney disease **Pregnancy** Sickle cell disease or thalassemia Chronic liver disease Dementia or other neurological conditions Smoking Solid organ or stem cell transplantation **Diabetes** Down syndrome Stroke or cerebrovascular disease **Heart conditions** Substance use disorders **HIV** infection **Tuberculosis Immunocompromise** Older adults (>65 years) Mental health disorders

Pharmacist-Driven Stress Ulcer Prophylaxis De-escalation Protocol

Background/Rationale:

No published clinical trials have established a mortality benefit for the use of stress ulcer prophylaxis (SUP) in the intensive care unit (ICU); however, there are concerns regarding potential complications with its use. The SUP-ICU trial found no statistically significant difference in clinically significant bleeding between patients who received SUP compared to those who did not receive SUP.

- Risks of PPI therapy include:
 - o Increased risk of Clostridium difficile
 - Increased risk of developing hospital acquired pneumonia (HAP)
 - o Hypomagnesemia
 - Vitamin B12 deficiency

Additionally, it is estimated that approximately 60% of SUP is inappropriately continued post-ICU discharge, and 35% of patients are discharged home on inappropriate SUP.

Proposal:

- Refer to Chart 1.
- Pharmacists will follow eligible critically-ill patients and assess the need for SUP (defined as IV or PO famotidine or pantoprazole) daily.
- Pharmacists will automatically discontinue orders for SUP within the ICU if the predefined criteria in Chart
 1 is not met.
- The pharmacist will notify the provider of any action taken.

Evaluation:

- Data will be collected pre and post-protocol implementation to assess the number of patients continued on SUP without an indication 24 hours after initiation of H2RA/PPI based on the predefined criteria.
- The following secondary outcomes will also be assessed:
 - o Patients on PPIs who developed in-hospital pneumonia or CDI
 - Incidence of clinically significant GI bleeding
 - o Patients transferred out of ICU on SUP without an indication
 - o Patients discharged home on SUP without an indication
- Results will be shared with the P&T Committee for discussion upon completion of the evaluation.

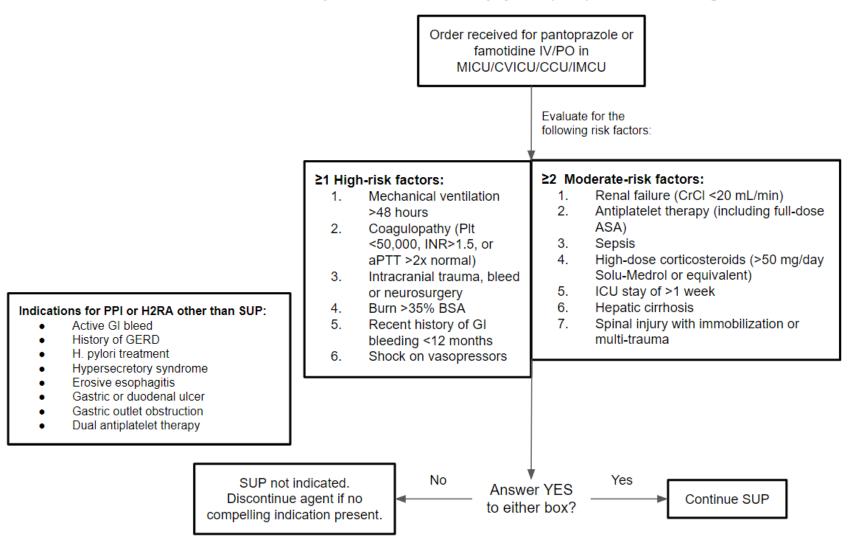
Recommendation/Discussion:

This quality improvement initiative has been shown to reduce inappropriate SUP use without increasing the risk of clinically significant bleeding within other healthcare institutions. It is recommended to adopt the proposed protocol and therefore approve a pharmacist-driven automatic discontinuation of famotidine and/or pantoprazole when the patient meets the specified criteria.

These recommendations have been reviewed and are supported by Dr. Jesse Tucker, Dr. Chad Paxson, and Dr. Lee Hamilton.

Chart 1. Proposed Pharmacist-Driven Stress Ulcer Prophylaxis (SUP) De-escalation Criteria

Proposed Stress Ulcer Prophylaxis (SUP) De-escalation Algorithm



References:

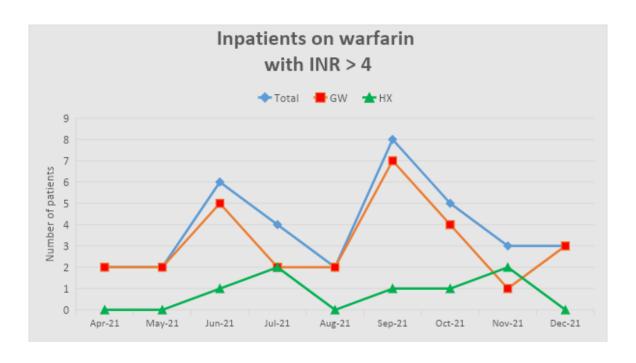
- 1. Krag M, Marker S, Perner A, et al. Pantoprazole in Patients at Risk for Gastrointestinal Bleeding in the ICU. N Engl J Med. 2018;379(23):2199-2208.
- 2. Alshamsi F, Belley-Cote E, Cook D, et al. Efficacy and safety of proton pump inhibitors for stress ulcer prophylaxis in critically ill patients: a systematic review and meta-analysis of randomized trials. Crit Care. 2016;20(1):120.
- 3. Buendgens L, Bruensing J, Matths M, et al. Administration of proton pump inhibitors in critically ill medical patients is associated with increased risk of developing Clostridium difficile-associated diarrhea. J Crit Care. 2014 Aug;29(4):696.e11-5.
- 4. Eom C, Jeon C, Lim J, et al. Use of acid-suppressive drugs on risk of pneumonia: a systematic review and meta-analysis. CMAJ. 2011;183:310-319.
- 5. Abraham N, Hlatky M, Antman E, et al. American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. ACCF/ACG/AHA 2010 expert consensus document on concomitant use of proton pump inhibitors and thienopyridines: a focused update of the 2008 ACCF/ACG/AHA expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use; a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. Circulation. 2010;56:1051-66.
- 6. Howell M, Novak V, Grgurich P, et al. Iatrogenic gastric acid suppression and the risk of nosocomial Clostridium difficile infection. Arch Intern Med. 2010; 170:784-790.
- 7. Marik P, Vasu T, Hirani A, et al. Stress ulcer prophylaxis in the new millennium: a systematic review and meta-analysis. Crit Care Med. 2010;38(11):2222-2228.
- 8. Miano T, Reichert M, Houle T, et al. Nosocomial pneumonia risk and stress ulcer prophylaxis: a comparison of pantoprazole vs ranitidine in cardiothoracic surgery patients. Chest. 2009 Aug;136(2):440-7.
- 9. Arthur Grube R, May D. Stress ulcer prophylaxis in hospitalized patients not in intensive care units. Am J Health-Syst Pharm. 2007; 64: 1396-400.
- 10. Qadeer M, Richter J, Brotman D. Hospital-acquired gastrointestinal bleeding outside the critical care unit: risk factors, role of acid suppression, and endoscopy findings. J Hosp Med. 2006; 1:13-20.
- 11. Allen M, Kopp M, Erstad B. Stress ulcer prophylaxis in the postoperative period. Am J Health-Syst Pharm. 2004; 61:588-96.
- 12. Daley R, Rebuck J, Welage L, et al. Prevention of stress ulceration: current trends in critical care. Crit Care Med. 2004; 32: 2008-13.
- 13. ASHP Commission on Therapeutics. ASHP therapeutic guidelines on stress ulcer prophylaxis. Am J Health-Syst Pharm. 1999;56:347-79.
- 14. Cook D, Fuller H, Guyatt G, et al. Risk factors for gastrointestinal bleeding in critically ill patients. N Engl J Med. 1994; 330: 337-41.

ADR Summary October - December 2021

		Inpatient ADRs/A	DEs reported thr	ough IRIS Oct-Dec 2	2021		
Incident Number	Event Date	Drug	Reaction	Primary Injury	Level of Harm	Facility	Unit
210117188	12/17/2021	Dexmedetomidine	infiltration	redness at IV site	2	GW	CVICU
210113990	12/9/2021	Amiodarone	infiltration	extravasation	3	GW	CSSU

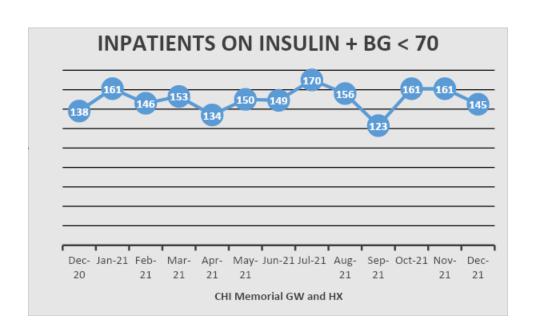
	Inpatient ADRs/ADEs reported through EPIC Oct-Dec 2021							
Patient HAR	Event Date	Drug	Reaction	Level of Harm	Facility Name	Unit		
20991213495	10/12/2021	cefepime	neurotoxicity w/myoclonic jerking	3	GW	6NO		
20991356596	12/2/2021	vit K	diffuse body aches immediately after IV dose	2	GW	2 SO		

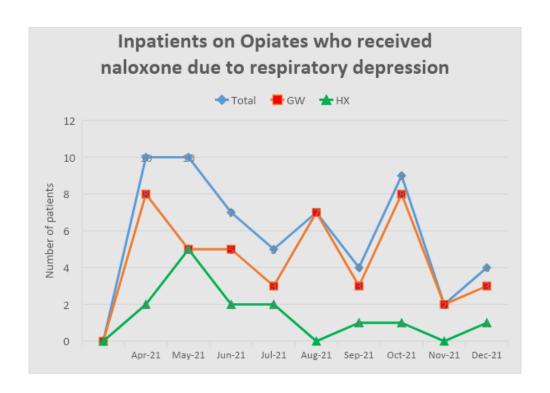
TARGETED ADRs/ADEs INPATIENT



INPA	TIENT	elevat	ed INRs also receiving warfarin Oct, Nov, Dec 2021	RX Dosing
Month	MRN	Location	Notes	
Oct	6054666	3 SO	Pharmacy not dosing. Here for joint replacement, on sliding scale warfarin.	N
Oct	6655090	6 NO	Also on Heparin drip for bridge therapy. Dced once INR became supratherapeutic.	N
Oct	5825506	IMCU	Also on Amiodarone. Dose adjusted after pharmacy consulted.	N
			Pharmacy not dosing. Here for ablation. Took half of regular dose at home night	
Nov	5935293	SSU	before. Elevated INR AM of procedure.	N
			Pharmacy not dosing. Started on cefuroxime which could be a contributor. When	
Nov	5644757	NPU3	Pharmacy notified provider of elevated INR, we were asked to take over dosing.	N

^{*}These are the patients that a pharmacist was NOT consulted to dose warfarin.





Performance Improvement Chapter PI.01.01.01 for The Joint Commission:

The hospital collects data on the following: adverse events related to using moderate or deep sedation or anesthesia.

• Of the above inpatients on opiates who received naloxone, we are now reviewing the chart to determine if naloxone was administered within 12 hours of a patient receiving anesthesia.

	Naloxone administrations Oct, Nov, Dec 2021				
Date	MRN	Location	Notes	Given within 12 hrs of anesthesia?	
10/1/2021	5747904	2 SO	Narcan 0.1 mg INJ x1 in response to patient's mentation.	Y	
10/15/2021	6654378	2 SO	Administered narcan secondary to over sedation (lethargic, SBP in 60s). Halved oxycodone dose (now 5 mg) given @ 1000. Pt found lethargic @ 1200. @ 1400 patient did not wake when RN entered room = unarousable + BP 70/50 + RR 8. Second dose of Narcan was then given. Patient is narcotic dependent.	N	
10/29/2021	5770760	2 SO	Patient unarousable. Responded positively to Narcan.	N	
10/20/2021	5650053	3 SO	Oversedation from opioids responded to Narcan 2 mg. D/c'd oxy + morphine. Trial low-dose Norco, cont Ultram	Y	
10/13/2021	6407597	6 NO	Patient became responsive sp Narcan 0.2 mg IV x2	N	
10/27/2021	5764115	6 NO	Pt was given ativan + dilaudid for anxiety and pain yelling out, then narcan x2	N	
10/22/2021	6647520	7 NO	Pt received Narcan x4 doses w/o significant improvement in his mental status. Then moved to IMCU for pressor requirements.	N	
10/31/2021	6194231	MICU	Administered narcan due to hemodynamic instability. She had large melanotic bowel movement, which contributed to the unstable hemodynamics.	N	
10/10/2021	5772628	HXNU2	Narcan 0.1 mg x1. Believe patient took some form of sedating medication (not provided by hospital). Pt UDS (+) for BZDPs and opiates. Numerous previous ER visits for overdose. Pt has narcan at home, but "does not intend to use any drugs".	N	
11/3/2021	5640032	MICU	NSTEMI patient. Made DNR.	N	
11/20/2021	5764644	4 SO 5 SO	Received 2 doses. Recently received Xanax, Roxicodone, and Zanaflex, as these are home meds patient takes regularly. Admitted for encephalopathy.	N	
12/3/2021		PACU	Found unresponsive due to alcohol and Pain medications, seen in ED and recovered.	N	
12/29/2021	5959904		Received 1 dose of dilaudid, then 2 doses of naloxone 2 hours later.	Y	
12/25/2021	5601867	MICU	Found to be unresponsive, but later determined patient had a stroke.	N	
12/15/2021	6278136	HXNU3	Found unresponsive in bathroom. States she took a "little blue pill from friend"	N	

DEFINITIONS:

Adverse Drug Reaction: any unexpected, unintended, undesired, or excessive response to a drug that

- a. Requires discontinuing the drug (therapeutic or diagnostic)
- b. Requires changing the drug therapy
- c. Requires modifying the dose (except for minor dosage adjustments)
- d. Necessitates admission to a hospital
- e. Prolongs stay in a health care facility
- f. Necessitates supportive treatment
- g. Significantly complicates diagnosis
- h. Negatively affects prognosis
- i. Results in temporary or permanent harm, disability, or death

Consistent with this definition, an allergic reaction (an immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.

Adverse Drug Event: A patient injury resulting from a medication, where the patient outcome is death, life threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage.1

ADR reports may be generated by different mechanisms as deemed appropriate by Pharmacy and the Medication Safety Committee, such as:

- a. Suspected ADRs will be reported in IRIS when they occur by any physician or hospital employee who handles or administers medications.
- b. Potential ADRs may be identified by monitoring utilization of trigger medications, such as naloxone, phytonadione, flumazenil, etc.
- c. Occurrence rates of specific patient care events (ie. INRs >4, BG <70 + insulin, etc), may be monitored to evaluate safety of specific treatment modalities.

ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting, Medication Safety—Guidelines, pg 264-266

Level of Harm as defined in IRIS:

Et i ti ti i i i i i i i i i i i i i i i
Level 00 – Near Miss
Level 01 – No Detectable Harm
Level 02 – Minimal Harm
Level 03 – Moderate Harm
Level 04 – Severe Harm
Level 05 – Death

ANTICOAGULATION MANAGEMENT				
		Page 1 of 4		
Policy Number: MM-05401		Date Last reviewed/Revised: 05/192/22	Valid Until: 05/222/25	
Campus: CHI Memorial Glenwood CHI Memorial Hixson Check all that apply				
Department(s) Affected: All Clinical Areas		Review Period: Every 3 years		

OUTCOME: To reduce the likelihood of patient harm associated with the use of anticoagulation therapy.

PURPOSE:

To implement a defined anticoagulant management program to individualize the care provided to each patient receiving anticoagulant therapy.

- To reduce compounding and labeling errors, the hospital uses only oral unit dose products, pre-filled syringes, or pre-mixed infusion bags when these types of products are available.
 - a. Warfarin: Tablets are only dispensed in unit-of-use packaging by pharmacy and may not be split to obtain doses (unless by pharmacy and packaged accordingly). If the total dose is unable to be provided via a single unit dose package, multiple unit-dose packages may be combined to obtain the desired dose (Example: A 7.5 mg dose = one 5 mg tablet + one 2.5 mg tablet).
 - b. Intravenous Heparin: Only the standard pre-mixed 50 unit/ml heparin drip concentration (25,000 units/500 ml) can be used for therapeutic purposes at MHCS and can be only stocked within the pharmacy department and within designated Pyxis machines. Heparinized saline 2 unit/ml (1000 units/500 ml NS) is stocked for use only in cardiac cath labs, surgery, vascular procedure areas and central supply.
 - c. Heparin Vials: Only the following concentration vials are stocked for use-at MHCS: 1000 unit/ml (10 ml and 30 ml vials), 5,000 unit/ml (1 ml vial), and 100 unit/ml (5 ml vial). Only the concentrations that are routinely used within each area will be loaded into the Pyxis machines on the corresponding patient care units and procedural areas. Heparin vials will only be loaded into secured Pyxis-drawers_(mini-drawers & CUBIE pockets) within the automated dispensing cabinet Pyxis-machines as per the High Risk Medications Policy.
 - d. Low Molecular Weight Heparin (enoxaparin): Each weight-based dose is rounded to the nearest 10 mg and the closest commercially available syringe is dispensed.
- The hospital uses approved protocols for the initiation and maintenance of anticoagulation therapy appropriate to the medication used, to the condition being treated, and to the potential for medication interactions.
 - a. Warfarin: Pharmacy-based warfarin dosing service is offered as a consult-service for hospital management of warfarin. All patients receiving warfarin are monitored through computer generated alerts regarding potential opportunities to improve warfarin management and prevent potential adverse drug reactions. The reports are reviewed daily by a pharmacist and the prescribers will be contacted as needed regarding the need for changes in the patient's warfarin management as clinically necessary.
 - b. Warfarin Dosing Guidelines: Guideline for healthcare professionals to utilize when dosing inpatient warfarin. As a guideline, it gives general information for managing warfarin, but all final dosing decisions are made by the provider based on their clinical judgment subject to the condition being treated and to the potential for medication interactions.
 - c. Heparin: One standard weight_-based heparin protocol_drip order set is used for the therapeutic use of heparin_at MHCS. An electronic copy of the weight-based protocol is The medication administration record (MAR) generatesd for each patient outlining the patient specific initial drip rate and bolus dose(s). Non weight-based protocol heparin infusions are only initiated pursuant of to orders with clear instructions including specific monitoring and titration parameters for such orders. See High Alert Medications policy for nursing documentation requirements for dose adjustments, pump setting changes, etc.

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- d. Low Molecular Weight Heparin (enoxaparin): Lovenox (enoxaparin) dosing protocol available for physician use. The hospital approved dosing for renal failure (CrCl < 30 ml/min) and dosing in obese patients (BMI > 50 kg/m2) is as follows:
 - Renal failure (prophylaxis): Any prophylactic dose (40 mg daily, 30 mg BID, etc.) of enoxaparin may automatically be adjusted by pharmacy to the appropriate renal adjustment dose.
 - ii. Renal failure (treatment dose): Pharmacy may automatically adjust patients with CrCl < 30 ml/min to 1 mg/kg once daily. If CrCl < 20 ml/min, pharmacy will order an anti-Xa level to determine if once daily dosing with enoxaparin is appropriate. Abnormal lab results will be communicated directly to physician.</p>
 - iii. Obesity (prophylaxis): Recommended dose of 40 mg BID.
 - iv. Obesity (treatment): Actual body weight to be used for dosing in patients >150 kg. Anti-Xa levels will be monitored following 3rd dose to ensure adequate dosing for patients > 190 kg.
- e. Fondaparinux: DVT prophylaxis assessment orders available for physician use. All patients receiving fondaparinux are monitored through the daily generation of reports that highlight the current prophylaxis or treatment dose, recent serum creatinine and platelet counts, and patient weight to ensure that the dose is appropriate based on use, renal function, and weight. The hospital approved dosing for renal failure (CrCl < 30 ml/min) is as follows:</p>
 - Renal failure (prophylaxis): Pharmacy may automatically substitute Lovenox 30 mg daily for CrCl of 10-30 ml/min. The prescriber must be contacted if CrCl < 10 ml/min.
 - Renal failure (treatment dose): Prescriber contacted for recommendation to use the heparin weight based protocol as an alternative.
- f. Argatroban: Standard weight based argatroban protocol is available for use in patients requiring therapeutic anticoagulation with suspected or confirmed heparin-induced thrombocytopenia (HIT) or other intolerance to heparin. Non weight-based orders not conforming to the standard weight based protocol are only initiated pursuant of orders with clear instructions including specific monitoring and titration parameters for such orders. See <u>High Alert Medications</u> policy for nursing documentation requirements for dose adjustments, pump setting changes, etc.
- g-f. Angiomax (bivalirudin): Standard weight based bivalirudin protocol is available for use in patients requiring therapeutic anticoagulation with suspected or confirmed heparin-induced thrombocytopenia (HIT) or other intolerance to heparin. Non weight-based orders not conforming to the standard weight based protocol are only initiated pursuant of orders with clear instructions including specific monitoring and titration parameters for such orders. See <u>High Alert Medications</u> policy for nursing documentation requirements for dose adjustments, pump setting changes, etc. Applies only to the <u>bivalirudin</u> weight based protocol and not for <u>bivalirudin</u> use in PCI or other invasive procedures such as vascular <u>surgery cardiac</u> surgery, etc.
- h.g. Direct oral anticoagulants DOACs (apixaban, rivaroxaban, dabigatran): All orders for DOACs will be evaluated daily by pharmacy staff for appropriateness based on indication, dose, and renal function. Any orders requiring adjustments due to indication or renal function will be communicated to providers for clarification.
- For patients starting on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy.
 - a. Baseline INR: Baseline INR is defined as an INR drawn within 72 hours prior to warfarin initiation. This INR is required and automatically ordered for all patients with new inpatient orders for warfarin. Initial warfarin doses will not be dispensed until the INR result has been evaluated by a pharmacist. If INR > 3, the pharmacist will make a professional decision if order is appropriate or if provider needs to be contacted prior to dispensing. For patients undergoing elective orthopedic procedures a pre-operative INR no more than 2 weeks prior to surgery will be used as a baseline INR
 - Current INR: Daily INR values are required and automatically ordered by pharmacy (if not already done) while receiving warfarin. If the INR is stable, it may be ordered every other day.
- When dietary services are provided by the hospital, the service is notified of all patients receiving warfarin and responds according to the established <u>FOOD AND DRUG INTERACTION / EDUCATION (MM-05450)</u>.
- When heparin is administered intravenously and continuously, the hospital uses ONLY programmable infusion pumps in order to provide consistent and accurate dosing.
- For patients who are receiving heparin, enoxaparin, or DOACs the following baseline and ongoing laboratory tests are required:

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- a. Heparin (weight based protocol): Monitoring parameters and frequency of monitoring as outlined within the standard heparin weight based protocol as follows:
 - Baseline labs: PTT, PTINR, CBC prior to initiating protocol (if not drawn within last 48 hours). If baseline PTT > 50 or INR > 2 or platelets < 100,000, notify physician before initiating protocol. If two consecutive PTT's > 1086 or < 574, physician will be notified.
 - <u>ii.</u> Subsequent labs: CBC every third day. Initial PTT 6 hours after initial heparin bolus OR any rate change. If PTT within therapeutic range, PTT will be repeated in 12 hours.

ii.iii. If a baseline or subsequent lab cannot be drawn for any reason, notify provider.

- b. Heparin infusions other than weight based protocols: All non-weight based protocol heparin infusion orders must be accompanied with clear monitoring instructions including frequency of PTT testing and titration parameters for such orders.
- Enoxaparin & Fondaparinux: Baseline serum creatinine and platelet count within 24 hours of initiation and at least every 7 days. Required labs will be automatically ordered by pharmacy (if not already done) while receiving enoxaparin and fondaparinux.

C.

- d. DOACs: Baseline serum creatinine within 24 hours of initiation and at least every 3 days. Required labs will be automatically ordered by pharmacy (if not already done).
- Guidelines for reversal of anticoagulation of bleeding events & perioperative management: See table 1 below for approved recommendations.
- The hospital provides education regarding anticoagulation therapy to prescribers, required clinical staff, patients, and families.
 - Clinical Staff: Nursing, Pharmacy and Dietary staff will be assigned required education covering patient safety and clinical effects of patients receiving anticoagulation.
 - Patients/families: At the point of discharge, patients/families will receive education from their primary nurse if the patient is to continue warfarin, enoxaparin, or DOAC beyond discharge. Educational materials are located in eCRS (Mosby's Nursing Consult).
- The hospital evaluates its anticoagulation safety practices, takes appropriate action to improve its practices, and measures the effectiveness of those actions on a regular basis.

Table 1.

Anticoagulant Bleeding & Perioperative Management Recommendations* 02/2249

Drug Class	Non-Urgent	Urgent - Bleeding or immediate surgery necessary	Comments
Anti-platelet Agents	Hold 5 days prior to procedure* Plavix® (clopidogrel) Brilinta® (ticagrelor) Hold 7 days prior to proc.* Efficit® (prasugrel) Aggrenox® (ASA/dyprid.)	Consider platelet transfusion	Caution advised in patients with cardiac stents Abrupt discontinuation can increase risk of acute stent thrombosis
Unfractionated Heparin	Infusion: Stop infusion 2 – 6 hours prior to procedure SQ doses: Hold the evening dose prior to the procedure	Protamine sulfate: 1 mg for every 100 units of heparin given in previous 3 hrs (max dose: 50 mg single dose or 100 mg in 2 hr period)	aPTT can be utilized to determine degree of anticoagulation
Low Molecular Weight Heparins	The last dose should be given 24 hours before the procedure. i.e., enoxaparin at a dose of 1 mg/kg ONCE 24 hrs prior to surgery if dose was 1 mg/kg BID. The last dose should be given by the procedure. The last dose should be given by the procedure.	 Wait 24 hours if possible Consider protamine sulfate if delay not possible for high bleed risk procedure (only partially reverses LMWH) Protamine sulfate (based on last dose): LMWH administered ≤ 8 hrs: 1 mg protamine per 1 mg LMWH LMWH administered > 8 hrs: 0.5 mg protamine per 1 mg LMWH 	Elimination can be further delayed in patients with acute or chronic kidney disease Anti Xa assay can be used to assess degree of anticoagulation
Indirect Factor Xa			
Arixtra [®] (fondaparinux)	Hold 36-48 hours prior to procedure	No specific antidote Lilla – limited data available consider low dose (1-2 mg) and assess response	 Elimination can be further delayed in patients with acute or chronic kidney disease
Vitamin K Antago	onist		

Tide: ANTICOAGULATION MANAGEMENT

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Warfarin	Stop 5 days prior to procedure Check INR 1-2 days prior, and if INR greater than 1.5, give Vitamin K 1-2 mg PO May consider bridge therapy with LMWH in high risk patients	If procedure can be delayed 6-24 hours, Vitamin K 5-10 mg PO/IV If procedure cannot be delayed or life threatening bleeding (ICH, etc.), give FFP or PCC prior to procedure. If PCC used give Vitamin K 5-10 mg IV to sustain anticoagulation reversal NOTE: Memorial recommendations are now for fixed-dose PCC as noted below. Baseline INR not required; repeat dosing may be considered if INR remains elevated following initial dose PCC Dosing for life threatening bleeding: 1500 units unless indicated below 2000 units for any patient with ICH diagnosis Body weight > 90 kg INR > 5 (if initial INR known)	PCC should only be used for life threatening bleeding (ICH, etc.) or if urgent surgery needed and IV vitamin K or FFP not appropriate (surgery needed within 4-6 hours) Caution: Risk of thrombosis when PCC used, particularly in patients with history of thrombosis.		
Drug Class	Non-Urgent	Urgent - Bleeding or immediate surgery necessary	Comments		
Thrombin Inhibite					
Pradaxa® (Dabigatran)	Hold for 1-2 days prior to procedure for CrCl greater than 50 ml/min Hold for 3-5 days prior to procedure for CrCl less than 50 ml/min	Idarucizumab (Praxbind®): 5 grams IV x 1 dose Limited data to repeat 5gm dose 12-24 hrs after first dose IF bleeding persists in combination with elevated coagulation parameters Hemodialysis	Thrombin Time (preferred) or aPTT can be used to rule out substantial residual effect		
Factor Xa Inhibito	ors	-			
Xarelto [®] (Rivaroxaban)	Hold for at least 24 hours prior to procedure with normal renal function (>90 ml/min). Consider holding 2- 3 days for patients with CrCl 30-90 ml/min.	PCC Dosing—for major bleeding: 50 units/kg for major bleeding. Max dose: 5000 units2000 units -2500 units for ICH (spontaneous or traumatic) -May repeat the same dose once within 6 hours of the initial dose if hemostasis is not achieved and/or maintained	PT can be used to rule out substantial residual effect. Normal value may rule out clinically relevant residual anticoagulant effect. PT not intended to be used for dosage adjustment.		
Eliquis [®] (Apixaban)	Hold for at least 48 hrs prior to procedures with high risk of bleeding; 24 hrs prior to procedures with low risk of bleeding. Consider holding 2-3 days if CrCl < 60 ml/min regardless of procedure type or 3 or more days if CrCl < 50 ml/min.	Vitamin K not effective if given PCC Dosing for major bleeding: -2000 units -2500 units for ICH (spontaneous or traumatic) -May repeat the same dose once within 6 hours of the initial dose if hemostasis is not achieved and/or maintained PCC 50 units/kg for major bleeding. Max dose: 5000 units Vitamin K not effective if given	PT can be used to rule out substantial residual effect. Normal value may rule out clinically relevant residual anticoagulant effect. PT not intended to be used for dosage adjustment.		
Savaysa® (Edoxaban)	Hold for at least 48 hrs prior to procedures with high risk of bleeding; 24 hrs prior to procedures with low risk of bleeding. Consider holding 1-2 days for CrCl > 50 ml/min and 3 or more days if CrCl ≤ 50 ml/min.	No specific antidote/ Not dialyzable PCC Dosing for major bleeding: -2000 units -2500 units for ICH (spontaneous or traumatic) -May repeat the same dose once within 6 hours of the initial dose if hemostasis is not achieved and/or maintained PCC 50 units/kg for major bleeding. Max dose: 5000 units Vitamin K not effective if given	PT can be used to rule out substantial residual effect. Normal value may rule out clinically relevant residual anticoagulant effect. PT not intended to be used for dosage adjustment.		
	Coagulopathies Not Associated with Oral Anticoagulants				
Cardiopulmonary bypass associated coagulopathy (intra-op or post- op cardiac	Vitamin K FFP	PCC – 1000 units and assess response May repeat dose if clinically necessary Vitamin K – consider in addition to PCC	PT can be used to rule out substantial residual effect. Normal value may rule out clinically relevant residual anticoagulant effect. PT not intended to be used for		

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surgery) dosage adjustment.

*This is intended to provide the clinician with possible strategies for patient management and does not establish a fixed set of guidelines that preempt physician judgment. Consider risk of thrombosis when reversal agents utilized.

Key Contact(s): Manager of PharmacyMarket Pharmacy Clinical Manager

Approved/Reviewed by: Director of Pharmacy & MM Chapter Leader; Nursing Professional Practice Council; Pharmacy / Nursing Committee

Related Document(s): High Alert Medications (MM-04502)

Joint Commission Standard: National Patient Safety Goal (NPSG) 03.05.01; Med Management: MM.01.01.01, MM.01.01.03

Date First Effective/Revisions: 3/09, (3/12) (5/13) (4/14)(2/15) (2/17) (11/18) (5/19) (2/22)

BRADYCARDIA MANAGEMENT PROTOCOL					
		Page 1 of 1			
Policy Number:		Date Last reviewed/Revised: 2/22	Valid Until: 2/23		
Campus: CHI Memorial Glenwood CHI Memorial Hixson Check all that apply					
Department(s) Affected: All Departments Review Period: every 3 years					

OUTCOME:

Standing orders to be used for immediate intervention in response to a symptomatic bradycardia patient event.

DEFINITIONS:

- Bradycardia: heart rate (HR) less than 60 beats per minute (bpm)
- Symptomatic bradycardia: HR < 40 AND one of the following: Systolic blood pressure <70, altered mental status, signs of shock, ischemic chest discomfort, OR acute heart failure

PERSONNEL: Medications to only be ordered by ACLS certified nurses

POLICY:

Standing orders for symptomatic bradycardia interventions may be initiated by a registered nurse that has ACLS certification in any inpatient or outpatient care area for any symptomatic bradycardia event, while awaiting physician contact. Physician should be notified ASAP.

PROCEDURE & TREATMENTS:

All RNs:

- Maintain patent airway- assist breathing as necessary
- Maintain oxygen SpO2 > 92%
- Contact Primary MD and call a RRT
 Connect patient to crash cart with pacing pads and leads
- Ensure IV access
- Obtain 12 Lead EKG

ACLS Certified RN:

- Identify heart rate is < 40 bpm
- Identify patient is symptomatic: SBP < 70, altered mental status, signs of shock, ischemic chest discomfort, or acute heart failure
- If HR < 40 and patient is symptomatic, administer Atropine 1 mg IVP. May repeat every 3-5 minutes to a max dose of 3 mg.
- 10. Atropine may be removed from the Pyxis Med Station via override function.
- 11. Physician must sign/authenticate the orders as soon as possible following enactment of the standing
- 12. If at any time the patient's symptoms deteriorate and the patient experiences respiratory or cardiovascular compromise a CODE BLUE should be called for additional support.
- 13. Document medication administration appropriately in the electronic medical record.
- 14. Return unused items to Pyxis Med Station

Key Contact: Clinical Educator Critical Care

Approved/Reviewed by: Pharmacy & Therapeutics, Pharmacy Director; Code Blue Committee; NPPC, Chief Nursing Officer Related Forms: AHA ACLS Guidelines, AHA Bradycardia Protocol

Date First Effective & Revision/Review dates: 2/22

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→ IAGNOSTIC RADIOGRAPHY

•	BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
\oplus	Enema Barium	rectal	2000 ml	EZ Paque
	Enema Air Contrast	rectal	1900 ml	Liquid Polibar
	Esophagram	Oral	355 ml	Liquid EZ Paque or EZ HD
	Esophagram Gastro	Oral	120 ml	Gastrografin
	Enema Gastro	Rectal	480 ml	Gastrografin (Water



POLICY

Title: CONTRAST MEDIA ADMINISTRATION

Policy Number: PC-07335 Page 7 of 8

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
			to 2000 ml)
Upper GI	Oral	135 ml	Liquid EZ Paque or EZ HD
Upper Gl Gastro	Oral	120 ml	Gastrografin
Small Bowel	Oral	432 ml	Liquid EZ Paque
Small Bowel Gastro	Oral	240 ml	Gastrografin
Barium Pill	Oral	700 mg	EZ Disk Barium Sulfate Tablet
UGI- gas	Oral	4 g	EZ Gas II
Modified Barium Swallow	Oral	90 cc	Varibar Thin
Modified Barium Swallow	Oral	90 cc	Liquid EZ Paque
Modified Barium Swallow	Oral	90 cc	EZ HD
Modified Barium Swallow	Oral	1 Tsp	EZ Paste
IVP	IV	100 ml	Isovue 300
Myelogram Cervical	Intrathecal	10 ml	Isovue-M 300-or Omnipaque 300
Myelogram Thoracic	Intrathecal	10 ml	Isovue-M 200-or Omnipaque-300
Myelogram Lumbar	Intrathecal	10 ml	Isovue-M 200-or Omnipaque 300
Venogram	IV	100 ml	Isovue 300 or 370
VCUĞ	Bladder	550 ml	Cystografin
Cystogram	Bladder	550 ml	Cystografin
Tube Placement	Intracavital	120 ml	Gastrografin
Arthrogram with MR	Intracapsular	10 ml	Isovue 300 and Multihance
Arthrogram without MR	Intracapsular	20 ml	Isovue 300
Port Patency	IV	20 ml	Isovue 300 or 370
HSG	Intrauterine	30 ml	Isovue 300
Lumbar Puncture	Intrathecal	Radiologis t	Isovue-M 200-or
		discretion	Omnipaque 300

DRUG AND FOOD INTERACTION / EDUCATION				
		Page 1 of 2		
Policy Number: MM-05450		Date Last reviewed/Revised: 2/22	Valid Until: 2/25	
Campus: CHI Memorial Glenwood CHI Memorial Hixson Check all that apply			gia	
Department(s) Affected: Nutrition Services, Nursing, Pharmacy Review Period: Every 3 years				

OUTCOME:

Patient education will be provided to patients receiving medications determined to have potential drug-food interactions prior to discharge.

DEFINITION:

SIGNIFICANT DRUG-NUTRIENT INTERACTIONS: Those occurring with relative frequency or occurring less frequently, but with potentially grave consequences.

Medications determined by the Pharmacy and Therapeutics Committee to have clinically significant drugnutrient interactions:

Generic Name	Brand Names	
Warfarin	Coumadin, Jantoven	
Metronidazole	Flagyl	
Linezolid	Zyvox	
Monoamine Oxidase Inhibitors (MAOI's) such as:		
Phenelizine	Nardil	
Tranylcypromine	Parnate	
Rasagiline	Azilect	
Selegiline	Eldepryl, Zelapar	

POLICY:

Patient and family education will be provided as outlined in PATIENT EDUCATION PROGRAM (PC-07230).

- Patients receiving the medications listed above will be provided information on clinically significant drug-nutrient interactions using approved resources as noted in <u>PATIENT EDUCATION PROGRAM (PC-07230)</u>.
 - a. Nutrition clinical staff will provide patient education on Monoamine Oxidase Inhibitors and Linezolid (Zyyox)
 - b. Nursing will provide patient education on Warfarin (Coumadin, Jantoven) and Metronidazole (Flagyl)
- Inpatients receiving the medications listed above will be flagged daily in the Kardex file in Nutrition Services (Hixson and North Georgia) to prevent them from receiving foods that might result in a medication interaction. At the Memorial Glenwood campus this information will be entered into the CBORD System.
 - a. Grapefruit juice is not available on the patient menu.
 - Herbal supplements will be reviewed as part of the Registered Dietitian nutritional assessment as requested.
 - Patients on Warfarin will be served no more than 1 serving of food HIGH in Vitamin K per day.
 - Patients with a known reaction to aspartame (NutraSweet) will not be served products containing aspartame.
 - Any patient with a known allergy or reaction to aspartame (trade name "Nutrasweet") should be so identified in order for Nutrition Services to make appropriate substitutions for products containing <u>Nutrasweet</u>.
 - ii. The allergy should be entered into the "Allergy" section of the patient profile in the

Tide: DRUG AND FOOD INTERACTION / EDUCATION

Policy Number:

MM-05450 Page 2

EHR.

- Nutrition Services will not serve food products containing <u>Nutrasweet</u>, including but not limited to Equal, diet soft drinks and other diet beverages, diet jellies/syrups, and diet <u>Jello</u>.
- Clinical dietitians and dietetic technicians will provide counseling to patients on other drug / food interactions as requested.
- Inpatient education documentation is recorded on the Intervention Education: Interdisciplinary as outlined in <u>PATIENT EDUCATION PROGRAM (PC-07230)</u>

Key Contact(s): Food & Nutrition Services

Approved/Reviewed by: Nursing Professional Practice Council; Director of Pharmacy; Pharmacy & Therapeutics Committee;

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Joint Commission Standard: Medication Management (MM)

Date First Effective: 1/89 (2/04) (11/08) (1/13) (8/15) (7/18) (7/18) (3/19)(2/22)

SEDATIVES / HYPNOTICS FOR SLEEP					
<u></u>					
		Page 1 of 2			
Policy Number: MM-05410		Date Last reviewed/Revised: 2/22	Valid Until: 2/25		
Campus: CHI Memorial Glenwood CHI Memorial Hixson Check all that apply					
Department(s) Affected:		Review Period:			
All Clinical Areas	Every 3 years				

OUTCOME:

Sedatives/hypnotics for sleep in hospitalized patients will be used safely and in an effort to reduce the risk of fall and injury, especially in the elderly population of patients.

POLICY:

- No sedative/hypnotic will be administered for sleep to any patient 65 or greater. Exceptions are limited to the following:
 - Receiving as a home medication (note items 5.b, 6)
- 2. All sleep medications must have a written order by physician.
- All sleep medication included on physician order sets must have a check box (□) for physician to individually designate appropriateness for medication.
- Zolpidem (Ambien®)
 - The maximum Zolpidem (Ambien ®) dose is 5 mg for any patient. This dose may not be repeated.
 - Patients currently receiving as a home medication any dose greater than 5mg will only be provided 5mg maximum dosage.
- Diphenhydramine (Benadryl®)
 - a. Only patients currently receiving diphenhydramine as a home medication may continue to receive this medication as a sedative/hypnotic. Patients who do not take diphenhydramine as a home sedative/hypnotic will not be allowed to receive this medication as a sedative/hypnotic.
 - b. The maximum Diphenhydramine (Benadryl®) dose is 25 mg for any patient. This dose may not be repeated. Patients currently receiving as a home medication any dose greater than 25 mg will only be provided 25 mg maximum dosage.
- Approved formulary therapeutic substitutions are listed below and will be automatically interchanged as outlined:

Drug/ Dose Written	Therapeutic Interchange
Ramelteon (Rozerem®) 8 mg	Melatonin ® 3 mg
Zaleplon (Sonata®) 5 mg	Zolpidem (Ambien®) 5 mg
Zaleplon (Sonata®) 10 mg	Zolpidem (Ambien®) 5 mg
Triazolam (Halcion®) 0.25 mg	Zolpidem (Ambien®) 5 mg
Eszopiclone (Lunesta ®) 1 mg	Zolpidem (Ambien®) 2.5 mg
Eszopiclone (Lunesta®) 2 mg	Zolpidem (Ambien®) 5 mg
Eszopiclone (Lunesta®) 3 mg	Zolpidem (Ambien®) 5 mg
Flurazepam (Dalmane®) 15 mg or 30 mg	Zolpidem (Ambien®) 5 mg
Estazolam (Prosom®) 1 mg or 2 mg	Temazepam (Restoril®) 15 mg
Temazepam (Restoril®) 7.5 mg	Zolpidem (Ambien®) 5 mg
Temazepam (Restoril®) 15 mg or 30 mg	Temazepam (Restoril®) 15 mg
Zolpidem CR (Ambien CR®) 6.25 mg or 12.5	Zolpidem (Ambien®) 5 mg

Title: SEDATIVES / HYPNOTICS FOR SLEEP Policy Number: MM-05410 Page 2

Suvorexant (Belsomra) 10 mg	Zolpidem (Ambien®) 5 mg
Suvorexant (Belsomra) 20 mg	Zolpidem (Ambien®) 5 mg

Key Contact: Pharmacy Review Team

Reviewed by: Pharmacy & Therapeutics Committee, Nursing Professional Practice Council, Director of Pharmacy Reference(s):

- Young, Julie, S., Bourgeois, James, A., Hilty, Donald, M., & Hardin, Kimberly, A. (2009). Sleep in Hospitalized Medical Patients, Part 2: Behavioral and Pharmacological Management of sleep Disturbances. Society of Hospital Medicine, 4(1), 50-59
 Nagel, Corey, L., Markie, Megan, B., Richards, Kathy, C., & Taylor, Jan, L. (2003). Sleep Promotion in Hospitalized Elders.
- MEDSURG Nursing, 12(5), 270-290
- 2.3. Sateia MJ, Buvsse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice quideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice quideline. J Clin Sleep Med. 2017;13(2):307–349.
 Joint Commission Standard: Medication Management (MM)

Date First Effective/Revisions: 9/10, (1/12), (4/13) (2/16)(1/19) (2/22)

RESPIRATORY DISTRESS PROTOCOL - PULMONARY SERVICES				
Page 1 of 1				
Policy Number: PUL-01928		Date Last reviewed/Revised: 2/224	Valid Until: 2/2 <u>3</u> 4	
Campus: CHI Memorial Glenwood CHI Memorial Hixson Check all that apply				
Department(s) Affected: Pulmonary Services		Review Period: every 3 years		

OUTCOME: To open and maintain obstructed airways.

PERSONNEL: Registered Respiratory Therapists.

POLICY:

When a patient is having respiratory distress hospital personnel may notify the Respiratory Therapist for that area stat to evaluate the patient.

PROCEDURE:

Respiratory Therapist will evaluate the patient and initiate treatment for wheezing and/or signs of bronchospasm, or stridor.

RESPIRATORY DISTRESS PROTOCOL:

- 1. Notify Respiratory Therapist STAT to evaluate patient.
- Respiratory Therapist to initiate treatment(s) below based on the following patient assessment criteria:
 - a. Oxygen:
 - SpO2 or SaO2 < 90%
 - ii. PaO2 < 60 mmHg
 - iii. Respiratory Distress
 - iv. AMI, Acute Coronary Syndrome, or Angina
 - v. Altered mental status, or suspected stroke
 - b. Bronchodilator:
 - i. For wheezing and/or signs of bronchospasm administer Albuterol 2.5mg/NS via nebulizer.
 - For signs of stridor administer *Racemic Epinephrine 1.125mg (0.5ml 2.25%) via nebulizer, if no signs of cardiac rhythm disturbances.
 - c. Arterial Blood Gas (ABG)
 - SpO2 < 90%
 - ii. Respiratory rate (f) > 30 breaths per minute
 - iii. Altered mental status
 - iv. Change in level of consciousness (LOC)
 - v. Hemodynamic instability
- Respiratory Therapist to notify physician/Licensed Independent Practitioner (LIP). Respiratory
 therapist to enter the order for the treatment(s) in the electronic health record (EHR) and sign the
 order in a manner which requires the physician/LIP to cosign the order.

Key Contact: Pulmonary Management Team

Approved/Reviewed by: Pulmonary Medical Director; P&T Committee

Date First Effective & Revision/Review dates: 1/12 (4/15) (1/16) (11/18) (04/19) (2/21) (2/22)

Nutrition Care Manual Updates: November 10, 2021

NCM® Diet Manual Updates

IDDSI Levels

- Level 4 Pureed (Green)
- Level 6 Soft and Bite-Sized (Blue) Definition
- Thickened Liquids

NCM Diet Manual Crosswalk

NCM Diet Order Terminology and Definitions

NCM® Condition Section Clinical Updates

Review new and updated clinical content featuring comprehensive nutritional management and evidence-based practice recommendations with our new consolidated format for the following conditions:

- Cirrhosis (Updated)
- Diverticular Conditions (Updated)
- Obesity & Overweight (Updated)

New and Improved NCM® Client Education Handouts

Now access 28 more vegetarian (lacto-ovo) and vegan menus for NCM® client education handouts:

- Bariatric Surgery Soft Diet Stage Nutrition Therapy
- Post-Surgery Meal Plan: 6 Months After Surgery and Beyond
- Tyramine-Restricted Nutrition Therapy
- Cholesterol-Lowering Nutrition Therapy
- Heart Failure Nutrition Therapy for the Undernourished
- Hearth Healthy Reduced Sodium Nutrition Therapy
- Milk Allergy Nutrition Therapy
- Fish Allergy Nutrition Therapy
- Wheat Allergy Nutrition Therapy
- Esophageal Surgery Nutrition Therapy
- Lactose-Controlled Nutrition Therapy
- Difficulty Eating Nutrition Therapy
- Jaw Fracture Nutrition Therapy
- Pulmonary Nutrition Therapy

Expanded and updated NCM® client education handouts:

Cirrhosis

• Cirrhosis Nutrition Therapy (Updated)

Dysphagia

• IDDSI Level 4 Pureed (Green) Nutrition Therapy (Updated)

Normal Nutrition

• MyPlate for Meal Planning (New)

Weight Management

- High-Calorie, High-Protein Nutrition Therapy (Updated; consolidated with Suggestions for Increasing Calories and Protein)
- Setting Goals for Weight Management (New)
- Tips to Support Weight Loss (Updated; previously Weight Loss Tips and consolidated with Weight Management Cooking Tips)

Transgender Nutrition Handouts

• Nutrition education handouts developed and provided by the Saint Louis University Transgender Health Collaborative. These handouts provide nutrition guidance for transgender and gender diverse individuals.

Additional Client Education Handout Information

- Spanish translations will soon be available for the client education handouts included in this update along with Arabic, Chinese, and Vietnamese translations for most popular client education handouts.
- The redesigned PDF format will soon be available for the client education handouts included in this update.

NCM® Resources Updates

- Dietary Guidelines for Americans, 2020
- Academy Publications: A new section that lists Academy publications related to various conditions.

Relocated NCM® Content

 Kosher Dietary Guidelines was moved from the Normal Nutrition Client Education section to the Resources section under Cultural Foods Practices.

Retired NCM® Content

NCM Diet Manual

- National Dysphagia Diets
- o National Dysphagia Diet Advanced
- o National Dysphagia Diet Mechanically Altered
- o National Dysphagia Diet Pureed

Condition Sections

The following condition sections were retired based on consensus among the members of the NCM® Board of Editors due to underutilization: Cancer Sites: Bladder, Brain, Carcinoid Tumors, Hepatobiliary/Gallbladder/Cholangiocarcinoma, Lung, Neuroendocrine Tumors, Ovarian, Prostate, Renal, Testicular, and Vaginal & Endometrial.

Client Education Handouts

Cardiovascular

• Coronary Artery Bypass Graft (CABG) Nutrition Therapy (Consolidated; View Cardiac-TLC Nutrition Therapy)

Renal

- Nephrotic Syndrome Exchange Meal Pattern
- Nephrotic Syndrome Nutrition Therapy

Dysphagia

- National Dysphagia Diet Advanced Nutrition Therapy
- National Dysphagia Diet Mechanically Altered Nutrition Therapy
- National Dysphagia Diet Pureed Nutrition Therapy

The following client education handouts were retired based on consensus among the members of the NCM® Board of Editors due to underutilization: 1,300 Calorie Sample Meal Plan, 1,700 Calorie Sample Meal Plan, 1,900 Calorie Sample Meal Plan, Amputations, Bulimia Nervosa Nutrition Therapy, Corn Allergy Nutrition Therapy, Corn Allergy Tips, Dentures Nutrition Therapy, Difficulty Eating Nutrition Therapy: Considerations for People with Diabetes, Dry Mouth, Egg Allergy Nutrition Therapy, Egg Allergy Tips, Exercise for HIV/AIDS Patients, Food Safety for HIV/AIDS, Galactose-Controlled Nutrition Therapy, Guidelines for High-Calorie Nutrition Therapy, Heart-Healthy Eating: Soy Protein, HIV/AIDS Managing Diarrhea, HIV/AIDS Managing Nausea and Vomiting, HIV/AIDS Medications and Food Interactions, HIV/AIDS Micronutrients (Vitamins and Minerals), Kitchen Tips, Milk Allergy Tips, Multiple Gestation Nutrition Therapy, Nephrotic Syndrome Exchange Meal Pattern, Nephrotic Syndrome Nutrition Therapy, Nutrition Recommendations After Oral Surgery, Nutrition Recommendations to Reduce Side Effects of Medications, Nutrition Recommendations when Wearing Partial Dentures, Osteoarthritis Nutrition Therapy, Phenylketonuria (PKU) Tips, Pica Nutrition Therapy, Sickle Cell Disease Nutrition Therapy, Soy Allergy Nutrition Therapy, Tree Nut Allergy Nutrition Therapy, Tree Nut Allergy Tips, and Wheat Allergy Tips.

NCM® Transition to IDDSI Framework

As of October 2021, International Dysphagia Diet Standardization Initiative (IDDSI) is the only texture-modified diet recognized by the Academy of Nutrition and Dietetics and the only texture-modified diet included in the NCM[®]. The National Dysphagia Diet (NDD) and associated resources have been removed from the NCM[®].

NCM® Technological Updates

Due to functionality changes in Internet Explorer, some calculators and other functions in NCM® may not perform as expected. Consider converting to a supported browser for optimal performance. Supported browsers include Microsoft Edge, Mozilla Firefox, Apple Safari, and Google Chrome.

We hope you enjoy the 2021 Nutrition Care Manual® Updates!

Sincerely, The NCM® Team