Pharmacy & Therapeutics Committee Meeting

Private Dining Room

October 7, 2021 7:00 a.m.

Next Meeting Date: TBD at 7:00 a.m. in the Private Dining Room

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: August 19, 2021 CALLED TO ORDER: 7:05 a.m.
LOCATION: Zoom conference call ADJOURNED: 7:38 a.m.

Physician Member Attendance:		Non-Physician Member Attendance:			Guests:
X	**Nathan Chamberlain, MD- Chairman**	X	**Karen Babb, PharmD- Manager**	Shannon Harris, RN-Infection Prevention	**Tina Mathew, Resident**
X	**Mark Anderson, MD- Infectious Disease**		Jamie Barrie, PharmD- Manager, Hixson	X **Rhonda Hatfield, RN-CNO**	**Jessica Duke, Resident**
X	**Justin Blinn, MD- Anesthesiology**	X	**Patrick Ellis, PharmD-Director**	Kevin Hopkins, RT- Director of Resp Therapy	**Doug Dertien, Resident**
	David Dodson, MD- Hospitalist		Rodney Elliott- Purchasing	X **Rachel Kile, PharmD-Clinical Manager**	**Courtney Guile, Student**
X	**F. Lee Hamilton MD- Hospitalist**	X	**Karen Frank, RN-Quality**	X **Daniel Marsh, PharmD- Operations Manager**	
X	**William Haren, MD- Psychiatry**	X	**Lori Hammon, RN-Quality**	X **Carey Smith, RPh- Manager, Georgia**	
X	**Matthew Kodsi, MD-Quality**	X	**Farrah Reidt, Clinical Nutrition**		
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**				

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

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
Minutes	The June 2021 minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	**July 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 and Therapeutic Interchanges" section of the minutes below, or will be reviewed at an upcoming P&T committee meeting.	Approved	Complete
Formulary Decisions & Therapeutic Interchanges	**1. Non-Ionic CT Contrast Media:** Rachel reviewed the CommonSpirit Health formulary decision to remove Omnipaque and replace it with Isovue. The committee approved alignment with this decision which will require purchasing of Isovue 300 and Isovue-M 300 (for intrathecal use) to replace Omnipaque 300. A Visipaque formulary restriction for patients intolerant of low-osmolar contrast media was also approved. The EHR and current order sets will be updated to reflect these recommendations. A $75,000 annual cost savings is anticipated.	Approved	Complete
	2. Crotalidae Immune F(ab')2- Equine (Anavip®): The CommonSpirit Health system P&T committee approved a single antivenom to formulary, Anavip. The FDA recently expanded the indication for Anavip to include all North American Pit Vipers from the original indication for treatment of rattlesnake envenomations only. Based on the lower cost of initial therapy for more severe envenomations, it was recommended to convert our formulary antivenom agent from CroFab to Anavip.	Approved	Complete
	3. Eptinezumab (Vyepti®): Eptinezumab is the first IV infusion formulation of a calcitonin gene-related peptide receptor antagonist for migraine prophylaxis. Rachel reviewed the clinical and safety data and pricing. It was recommended to add eptinezumab to formulary, with restrictions to the outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization.	Approved	Complete
	4. Sacubitril/valsartan (Entresto®): The label for sacubitril/valsartan was recently updated to allow use in heart failure regardless of ejection fraction (EF) based on the PARAGON-HF trial results. It	Approved	Complete

	was recommended to revise the current restriction criteria for sacubitril/valsartan by removing the existing criterion limiting use to EF <40%. This order question will be removed from the order in the EHR.		
	5. Polidocanol injectable foam (Varithena®): Varithena is an injectable sclerosing agent utilized by vascular. It was recommended to approve to formulary with restrictions to outpatient procedures with confirmed payer approval for treatment of superficial symptomatic venous insufficiency, varicose veins, or incompetent tributaries and perforators in the legs.	Approved	Complete
	6. Venetoclax (Venclexta®): Venetoclax is an oral B-cell lymphoma-2 protein inhibitor approved for CLL, SLL, and AML. Rachel reviewed the clinical and safety data. It was recommended to add to formulary with use restrictions as follows: restricted to hematology oncology service for CLL, SLL, or AML, for first cycle or for admitted patients and next cycle is needed (unable to defer to outpatient administration or obtain from specialty pharmacy). For continuation of therapy during hospitalization, the patient's own medication supply must be utilized if on therapy prior to hospitalization.	Approved	Complete
	7. Budesonide, glycopyrrolate, and formoterol (Breztri®): Breztri is a triple combination ICS, LAMA, plus LABA approved for maintenance treatment of COPD. It was recommended to approve an automatic therapeutic interchange for all Breztri® orders to the formulary products tiotropium/olodaterol (Stiolto Respimat®) 5 mcg/5 mcg (2 puffs) via oral inhalation once daily plus mometasone HFA (Asmanex) 200mcg /inhalation two inhalations BID.	Approved	Complete
	8. Biosimilar formulary addition: Rituximab-arrx (Riabni), a biosimilar agent for the reference product Rituxan, was approved to formulary. Any formulary restrictions currently in place for Rituxan will be applied to Riabni.	Approved	Complete
Medication Safety	1. **ADR Summary:** Karen Babb reviewed the adverse drug reaction summaries for Apr-Jun 2021 and no new trends were observed.	Informational	Complete

There being no further business, the meeting was adjourned at 7:38 a.m. The next P&T meeting is **October 7, 2021 @ 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

September 2021 Decisions

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

Medication Name	Medication Used For	Formulary Decision				Comments/Restrictions/ Therapeutic Interchange	Timeline to Implementation
		Do Not Stock	Formulary Restricted	Formulary Unrestricted	NonFormulary		
"Banana bag"	Alcohol withdrawal				"Banana bag"	"Banana bag" interchange	Within 90 days of decision
Bupivacaine and meloxicam injection	Pain	ZYNRELEF					Within 60 days of decision
Cetirizine injection	Antihistamine				QUZYTTIR		Within 60 days of decision
Inebilizumab	Neuromyelitis optica spectrum disorder		UPLIZNA			Outpatient setting subsequent to insurance approval or prior authorization	Within 90 days of decision
Ivermectin	Anthelminthic		IVERMECTIN, STROMECTOL			• Restricted to treatment of parasitic infections, such as Strongyloides stercoralis, Onchocerca volvulus, Pediculus capitis, Pediculus corporis, Pediculosis pubis, Sarcoptes scabiei, Wuchereria bancrofti, larva currens, larva migrans, acne rosacea, ascariasis, enterobiasis, trichuriasis and scabies. • In conjunction with an infectious disease consult (if available), ivermectin may be used for prophylactic treatment	Within 90 days of decision

Medication Name	Medication Used For	Formulary Decision				Comments/Restrictions/ Therapeutic Interchange	Timeline to Implementation
		Do Not Stock	Formulary Restricted	Formulary Unrestricted	NonFormulary		
						for immunocompromised patients with COVID-19 who are from strongyloides endemic areas.	
Gadobenate dimeglumine	MRI contrast			MULTIHANCE ASD, MULTIHANCE			Within 90 days of decision
Gadobutrol			GADAVIST			Breast, myocardial CAD imaging	
Gadodiamide			OMNISCAN, OMNISCAN N+			Kidney, intrathoracic, intra-abdominal and pelvic imaging	
Gadopentetate dimeglumine					MAGNEVIST, MAGNEVIST ASD, MAGNEVIST PBP		
Gadoterate meglumine					DOTAREM		
					CLARISCAN		
Gadoteridol				PROHANCE, PROHANCE ASD			
Gadoxetate disodium			EOVIST, EOVIST ASD			Restricted for use when liver imaging specifically is desirable.	
Perflutren	ECHO contrast			Perflutren lipid microspheres (DEFINITY)			Within 90 days of decision
			Perflutren protein type A (OPTISON DS)			Use in patients with PEG sensitivity	

Medication Name	Medication Used For	Formulary Decision				Comments/Restrictions/ Therapeutic Interchange	Timeline to Implementation
		Do Not Stock	Formulary Restricted	Formulary Unrestricted	NonFormulary		
Sulfur hexafluoride micro			LUMASON			Use in hepatic ultrasonography	

THERAPEUTIC INTERCHANGE

Order	Interchange to
"Banana bag"	• Thiamine 100 mg-200 mg IV or PO daily for 3-5 days for (Wernicke Encephalopathy Prevention) • Thiamine 200 mg-500 mg IV Q8 hrs for at least 3 days (Wernicke Encephalopathy Treatment) • Folic acid 400 mcg-1000 mcg IV or PO daily for 3-5 days • Magnesium electrolyte replacement protocol • IV fluids

EXECUTIVE SUMMARY

Aminolevulinic acid (ALA) hydrochloride (Gleolan) is an oral optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery. During glioma surgery, ALA is used with a standard surgical operating microscope adapted with a blue light emitting source (power density 40-80 mW/cm2) and filters for excitation of light at wavelength 375 to 440 nm, and observation at wavelengths of 620 to 710 nm. This allows tumor tissue to be visualized as red-violet fluorescence in real-time. Tissue lacking sufficient PpIX concentrations appear blue.

The safety of Gleolan is supported by data from 5 open-label clinical studies, which included 527 patients with glioma who received ALA. Adverse reactions that occurred in > 1% of patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting. Adverse reactions occurring in the first 6 weeks after surgery in < 1% of patients were: chills, photosensitivity reaction, solar dermatitis, hypotension, abnormal liver function test, and diarrhea. One patient experienced respiratory failure due to drug overdose.

The efficacy was evaluated in 3 clinical studies in patients who had a preoperative MRI compatible with high-grade glioma (WHO Grades III or IV) and were undergoing surgical resection. Study 3 was a randomized, multicenter study in 415 patients with a preoperative diagnosis of high-grade glioma by MRI. Patients were randomized in 1:1 ratio to ALA fluorescence arm or to white light control arm. In patients with confirmed high-grade glioma randomized to the ALA fluorescence arm, presence of fluorescence at a biopsy level was compared to tumor status using histopathology as the reference standard. The extent of resection among patients with confirmed high-grade glioma in the ALA fluorescence arm was compared to that among patients in the control arm, with the "completeness" of resection being determined by a central blinded read of early post-surgical MRI. Percentage of patients who had "completeness" of resection was 64% in the ALA arm and 38% in the control arm, with the difference of 26% [95% CI: (16%, 36%)]. Completeness of tumor tissue resection is significantly higher in patients pre-treated with ALA compared with conventional treatment (white light debulking and biopsies obtained under fluorescent light with fluorescein dye).

The potential for phototoxic reactions requires unique pre and post-operative patient management:

- ALA is administered 2-4 hours before the onset of anesthesia.
- Outpatients must be admitted to the hospital prior to surgery in order to receive preoperative treatment. Critical Care placement is recommended, for continuity, as these patients will recover in Critical Care postoperatively.
- Inpatients may receive preoperative treatment at their current location.
- Patients must be protected from natural and artificial light sources and monitored for phototoxic reactions for 48 hours after receiving ALA.

RECOMMENDATION

☒ Formulary, Restricted

Restrictions

May be used inpatient and outpatient for high-grade glioma patients undergoing fluorescence-guided surgical resections

- Inpatient: Restricted to hospitals that are confirmed to have the appropriate microscope and filters and to neurosurgeons who have completed the training program provided by the distributor NX Development Corp. **The dispensing pharmacist must confirm that the requesting neurosurgeon is an Approved User prior to Gleolan being dispensed.**
- Outpatients: Restricted to FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Outpatients must be admitted to the hospital prior to surgery in order to receive preoperative treatment.

Monograph

GENERIC NAME(S)
Aminolevulinic acid hydrochloride

PROPRIETARY NAME(S)
Gleolan

THERAPEUTIC CLASS
Optical imaging agent/Photosensitizing Agent

SIMILAR DRUGS
None

INDICATIONS

FDA Approved

- Optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery

Non-FDA Approved

- For ablation of high-grade dysplasia and early cancer in patients with Barrett's esophagus
- For treatment of head and neck cancer, including esophageal cancer

POPULATION STUDIED
Adults

CLINICAL PHARMACOLOGY

	Aminolevulinic acid hydrochloride oral
Absorption	In 12 healthy subjects, the absolute bioavailability of ALA following the recommended dose of Gleolan solution was 100.0% 1.1 with a range of 78.5% to 131.2%. Maximum ALA plasma concentrations were reached with a median of 0.8 hour (range 0.5 – 1.0 hour).
Distribution	In in vitro experiments using ALA concentrations up to approximately 25% of the maximal concentration that occurs in plasma following the recommended dose of Gleolan solution, the mean protein binding of ALA was 12%.
Metabolism	Exogenous ALA is metabolized to PpIX, but the fraction of administered ALA that is metabolized to PpIX is unknown. The average plasma AUC of PpIX is less than 6% of that of ALA.
Excretion	In 12 healthy subjects, excretion of parent ALA in urine in the 12 hours following administration of the recommended dose of Gleolan solution was 34 8% (mean std dev) with a range of 27% to 57%.

SPECIAL POPULATIONS

	Aminolevulinic acid hydrochloride oral
Pregnancy	There are no available human data on Gleolan in pregnant women to inform a drug associated risk of adverse developmental outcomes. In animal reproduction studies, no adverse developmental effects were observed with oral ALA HCl administration to pregnant rabbits during organogenesis at doses 3 times the maximum recommended human oral dose. The estimated background risk of major birth defects and miscarriage for the indicated populations are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.
Lactation	There are no data on the presence of ALA HCl in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Gleolan and any potential adverse effects on the breastfed infant from Gleolan or from the underlying maternal condition. To decrease exposure to Gleolan to the breastfed infant, advise a lactating woman to pump and discard breast milk after the administration of Gleolan for 24 hours (i.e., 5 to 6 half-lives).
Pediatrics	The safety and effectiveness of Gleolan in pediatric patients have not been established.
Geriatrics	Of 527 subjects in clinical studies of Gleolan, 182 were 65 to < 75 years of age and 7 were ≥ 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. No dose adjustment is required in elderly patients.

Hepatic Impairment	The contribution of the liver to the elimination of ALA following Gleolan dosing is unknown. ALA clearance may be reduced in patients with hepatic impairment; it is not known if dose adjustment is needed.
Renal Impairment	Because approximately one third of the ALA dose is excreted in urine as parent drug, ALA clearance may be reduced in patients with renal impairment; it is not known if dose adjustment is needed.
Other	**N/A**

CLINICAL STUDIES

The efficacy of 20 mg / kg ALA HCl was evaluated in 3 clinical studies (Study 1-3) involving patients, ages 18 to 75 years old, who had a preoperative MRI compatible with high-grade glioma (WHO Grade III or IV) and were undergoing surgical resection. Study 1 was an open-label study of 33 patients with newly diagnosed high-grade glioma and Study 2 was an open-label study of 36 patients with recurrent high-grade glioma. In Studies 1 and 2, after initial debulking was carried out under white light, biopsies were obtained under fluorescent light from fluorescent and nonfluorescent sites. Presence of fluorescence (positive/negative) was compared to tumor status (true/false) using histopathology as the reference standard. True positives and false positives among fluorescent biopsies and true negatives and false negatives among nonfluorescent biopsies are provided in Table 1. Study 3 was a randomized, multicenter study in 415 patients with a preoperative diagnosis of high-grade glioma by MRI. Patients were randomized in 1:1 ratio to ALA fluorescence arm or to white light control arm. Biopsies were obtained from tumor-core, tumor-margin and regions just distant to the tumor margins. In 349 patients high-grade glioma was confirmed by a blinded central read and histopathology. The remaining patients were diagnosed with metastatic disease, abscess, low-grade glioma or other conditions.

In patients with confirmed high-grade glioma randomized to the ALA fluorescence arm, presence of fluorescence at a biopsy level was compared to tumor status using histopathology as the reference standard (Table 1). In 4 patients with low-grade glioma (WHO Grade I or II) who received ALA, 9 out of 10 biopsies were false negative. The extent of resection among patients with confirmed high-grade glioma in the ALA fluorescence arm was compared to that among patients in the control arm, with the "completeness" of resection being determined by a central blinded read of early post-surgical

MRI. Percentage of patients who had "completeness" of resection was 64% in the ALA arm and 38% in the control arm, with the difference of 26% [95% CI: (16%, 36%)].

Table 1. Presence of Fluorescence Compared to Histopathology (biopsy level)

	Study 1 (n=297)*	Study 2 (n=370)*	Study 3 (n=479)*
Number of Fluorescent Biopses	**185**	**354**	**319**
True Positive	**178**	**342**	**312**
False Positive	**7**	**12**	**7**
Number of Nonfluorescent Biopses	**112**	**16**	**160**
True Negative	**27**	**3**	**30**
False Negative	**85**	**13**	**130**

n = number of total (fluorescent and non-fluorescent) biopsies

COMPARATIVE EFFICACY

In a prospective, open label study by Stummer et al. 33 patients received Gleolan at a dose of 20 mg/kg. Eligible patients were aged 18-75 years with a Kamofsky Performance scale of $\geq$ 60, suggesting malignant glioma without tumor-specific pretreatments. Following debulking surgery and biopsies, tissue of weak and strong fluorescence were identified to analyze their positive predictive value (PPV) for identifying a tumor, spectrometric fluorescence was measured at 318 locations and 300 biopsies were collected. The overall PPV for fluorescence showed to be 96.2%, 100% for strong fluorescence and 91% for weak fluorescence. With all samples of strong fluorescence correctly predicted a tumor. Serious adverse events were reported in 22.2% of participants which included convulsions, aphasias, hemiparesis, cerebral infarction, aspiration pneumonia, or hypotension with resolution post-surgery.

CONTRAINDICATIONS

- Patients with hypersensitivity to the active substance
- Patients with acute or chronic types of porphyria

WARNING AND PRECAUTIONS

- Due to the risk of phototoxic reactions, do not administer phototoxic drugs for 24 hours during the perioperative period. Reduce exposure to sunlight or room lights for 48 hours after administration.
- Errors may occur with the use of Gleolan for intraoperative visualization of malignant glioma, including false negatives and false positives. Non-fluorescing tissue in the surgical field does not rule out the presence of tumor in patients with glioma. Fluorescence may be seen in areas of inflammation or metastases from other tumor types.
- Hypersensitivity reactions, including serious hypersensitivity reactions have occurred; these reactions include anaphylactic shock, swelling, and urticaria. Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.

ADVERSE REACTIONS

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Gleolan is supported by data from 5 open label clinical studies, which included 527 patients with glioma who received ALA. Adverse reactions that occurred in > 1% of

patients in the week following surgery were pyrexia, hypotension, nausea, and vomiting. Adverse reactions occurring in the first 6 weeks after surgery in < 1% of patients were: chills, photosensitivity reaction, solar dermatitis, hypotension, abnormal liver function test, and diarrhea. One patient experienced respiratory failure due to drug overdose.

Neurologic Events

Nervous system disorders occurred in 29% of patients within the first week after surgery. Events occurring in > 1% of patients included aphasia (8%), hemiparesis (7.8%), hemianopsia (3.2%), headache (2.7%), seizure (1.9%), hemiplegia (1.9%), monoparesis (1.3%) and hypoesthesia (1.1%). Brain edema occurred in < 1 % of patients in the first 6 weeks after surgery. In a randomized clinical trial (Study 3), the numbers of serious neurologic adverse events in the post-operative period were higher in patients randomized to ALA fluorescence arm compared to the control arm. An imbalance was notable for the adverse events of aphasia, ataxia, convulsion and hemianopsia, and is likely related to the higher amount of brain resection performed in the ALA arm. At longer follow up periods, the numbers between the two arms appeared similar.

Elevated Liver Enzymes

Worsening of ≥ 2 Common Toxicity Criteria (CTC) grades in alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT) occurred in (15.8% and 11.6%, respectively) within the first week after surgery. Absolute levels ranged from 2 times to greater than 10 times the upper limit of normal (ULN) for each parameter. At 6 weeks, ALT remained elevated in 2.9% of patients (range 2 to greater than 5 X ULN), and GGT was elevated in 7.5% of patients (range 2 to greater than 10 X ULN). No cases of liver failure occurred.

CLINICALLY SIGNIFICANT DRUG INTERACTIONS

Interacting Drug	Effect
Phenytoin and other anti-convulsants	May decrease PpIX concentrations
Phototoxic drugs – St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, sulphonamides, fluoroquinolones, and tetracyclines	Due to the risk of phototoxic reactions, do not administer phototoxic drugs for 24 hours during the perioperative period. Reduce exposure to sunlight or room lights for 48 hours after oral administration.

DOSING AND ADMINISTRATION

Adult Dosing/Indication and Administration

The recommended reconstituted oral dose of Gleolan solution is 20 mg/kg body weight, administered 3 hours (range 2 to 4 hours) prior to induction of anesthesia. More than 1 reconstituted vial may be required based on the patient's body weight.

RECOMMENDED MONITORING

- Signs/symptoms of hypersensitivity

- Potential rise in ALT

PRODUCT AVAILABILITY

- Supplied as 1,500 mg of lyophilized ALA HCl powder (equivalent to 1,170 mg ALA) for oral solution in a 50-mL vial
- Available to order for delivery to centers from which at least one neurosurgeon has successfully completed the GLEOLAN NEUROSURGEON TRAINING PROGRAM and is on the Gleolan Approved User List. The Gleolan Approved User List is maintained, monitored and updated by NXDC. **The dispensing pharmacist must confirm that the requesting neurosurgeon is an Approved User prior to Gleolan being ordered.**

MEDICATION ERROR POTENTIAL

Look-alike / Sound-alike (LASA) Error Risk Potential

Methyl aminolevulinate

Drug Safety/Risk Evaluation and Mitigation (REMS)

None

Black Box Warnings

None

FAILURE, MODE AND EFFECTS ANALYSIS (FMEA)

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
Therapeutic interchange?	N/A	
Special Ordering Requirements?	N/A	
Storage		
LASA* separation of stock?	No	

Special storage (e.g. refrigeration, protect from light, controlled substance)?	No	Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F).
Pharmacist/Technician Education?	No	
Ordering & Prescribing		
Restriction to particular specialty, indication, or particular patient population?	Yes	Restricted to hospitals that are confirmed to have the appropriate microscope and filters and to neurosurgeons who have completed the training program provided by the distributor NX Development Corp. **The dispensing pharmacist must confirm that the requesting neurosurgeon is an Approved User prior to Gleolan being dispensed.** May be used inpatient and outpatient for high-grade glioma patients undergoing fluorescence-guided surgical resections. For outpatients: restricted to FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. Outpatients must be admitted to the hospital prior to surgery in order to receive preoperative treatment. Critical Care placement is recommended, for continuity, as these patients will recover in Critical Care postoperatively.
Dosing Issues (e.g. renal, hepatic dosage adjustment, max dose warnings)?	No	
Drug Interactions?	Yes	Phenytoin, anticonvulsants and phototoxic drugs are potential drug interactions
Pregnancy?	Yes	There are no available human data on Gleolan in pregnant women to inform a drug associated risk of adverse developmental outcomes. The estimated background risk of major birth defects and miscarriage for the indicated populations are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in

		clinically recognized pregnancies is 2-4% and 15-20%, respectively.
Absolute Contraindications?	No	
Requires Order Set, Protocol, concomitant therapy with another drug?	No	
LASA* nomenclature issues?	No	
Prescriber education?	Yes	Providers will need to complete specific training to use aminolevulinic acid hydrochloride
Processing, Preparing, & Dispensing		
High-risk drug double check?	No	
Drug Interaction check in place?	Yes	
LASA* computer warnings?	Yes	Can build in EPIC - LASA for Methyl aminolevulinate
Administration Notes for MAR (e.g. handling precautions, surrounding food or other drugs)?	No	
Packaging/Labeling (e.g. prepacking)?	No	
Dispensing (e.g. auxiliary labeling, light protection, refrigeration)?	No	
Documentation required (e.g. double check, worksheet)?	No	
Pharmacist/Technician Education?	No	
Administration		
Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, or other administration information?	No	
Special delivery system (e.g. pump)?	No	
Documentation required? (e. g. double check)	No	
Nurse education?	No	
Monitoring		
Interactions, adverse effects, efficacy, changes in renal function, or similar?	Yes	• Monitor for signs/symptoms for hypersensitivity
Follow-up laboratory tests?	Yes	• Monitor for increased ALT and GGT
Education?	No	

PHARMACOECONOMICS/COST

Product and Comparator Purchase Prices

Product (Drug, Strength, Form)	GPO Price	340B Price
aminolevulinic acid hydrochloride 1500mg/vial	$2,789	

Medication specific billing codes: (C code, J codes, NTAP payment availability, modifiers (e.g., JG, TW))
Hospitals: ICD-10 code – 8E090EM
Physicians:

- CPT code
  - 64999 unlisted procedure, nervous system
  - 76499 unlisted procedure, radiographic procedure

- Modifier: 22
- The codes must be used during dictation of the case.

Section	8	Other Procedures
Body System	E	Physiological Systems and Anatomical Regions
Operation	0	Other Procedures: Methodologies which attempt to remediate or cure a disorder or disease

Body Region	*Approach*	*Method*	*Qualifier*
1 Nervous System	X External	Y Other Method	7 Examination
2 Circulatory System	3 Percutaneous	D Near Infrared Spectroscopy	Z No Qualifier
9 Head and Neck Region	0 Open	C Robotic Assisted Procedure	Z No Qualifier
9 Head and Neck Region	0 Open	E Fluorescence Guided Procedure	M Aminolevulinic Acid Z No Qualifier

Utilization and Historical Purchases (Wholesaler purchases, may not represent 100% of organizational spend)
No purchases

REFERENCES

1. Gleolan. Package Insert. NX Development Corp; 2019
2. Nabavi A, Thurm H, Zountsas B, et al. Five-aminolevulinic acid for fluorescence-guided resection of recurrent malignant gliomas: a phase II study. Neurosurgery. 2009;65(6):1070-1077.
3. Stummer W, Pichlmeier U, Meinel T, Wiestler OD, Zanella F, Reulen H-J. Fluorescence-guided surgery with 5-aminolevulinic acid for resection of malignant glioma: a randomised controlled multicentre phase III trial. The Lancet Oncology. 2006;7(5):392-401.
4. Stummer W, Ullrich W, Pietsch, T. 5-Aminolevulinic Acid-derived Tumor Fluorescence: The Diagnostic Accuracy of Visible Fluorescence Qualities as Corroborated by Spectrometry and Histology of Postoperative Imaging. Neurosurgery. 2014;74(3):310-320.

FORMULARY UPDATE

THERAPEUTIC CLASS: Sodium-Glucose Co-transporter 2 (SGLT2) Inhibitors

GENERIC NAME: Empagliflozin

PROPRIETARY NAME: Jardiance®

BACKGROUND/RATIONALE:

In February, the CHI Memorial P&T Committee voted to approve the below current restriction criteria for empagliflozin (Jardiance). The CommonSpirit Health System formulary status for empagliflozin is formulary, unrestricted.

CURRENT CHI MEMORIAL RESTRICTION CRITERIA**:**

1. All home medication orders for any SGLT2 inhibitor will be interchanged to empagliflozin for continuation during admission, if ordered to continue. (Per approved therapeutic interchange)
2. New inpatient orders for empagliflozin will be permitted, given the following patient conditions are met:
    a. The patient is currently on and compliant with GDMT appropriate to his/her disease state(s) and has indications for additional therapy
    b. eGFR is >= 45 and renal function is stable or improving
    c. For heart failure, ejection fraction is </= 40%
    d. Patient does not have recurrent UTIs
    e. Patient does not have history of, or at high risk for, DKA
    f. Patient does not have hypovolemia
    g. Patient does not have severe PAD, foot ulcerations, or at risk of amputation

Late last month, the EMPEROR-Preserved trial results were published. This trial evaluated patients with class II–IV heart failure and an ejection fraction of *greater than* 40% receiving empagliflozin (10 mg once daily) or placebo, in addition to usual therapy. The primary outcome was a composite of cardiovascular death or hospitalization for heart failure. Empagliflozin demonstrated a statistically significant difference, primarily driven by reduced risk of hospitalization for heart failure. This effect was present regardless of presence or absence of diabetes. The 2021 ADA Standard for Medical Care in Diabetes states that SGLT2 inhibitors are not recommended for routine in-hospital use. Furthermore, the FDA warns that SGLT2 inhibitors should be stopped 3 days before scheduled surgeries.

PHARMACOECONOMICS/COST:

Product	Cost per tablet	Cost per 7 days of therapy
Jardiance (empagliflozin) 10 mg or 25 mg tablet	$13.31	$93.16

RECOMMENDATION/DISCUSSION:

Based on the recent results from the Emperor-Preserved trial, it is recommended to revise the current restrictions for empagliflozin to remove the heart failure ejection fraction restriction as follows:

1. All home medication orders for any SGLT2 inhibitor will be interchanged to empagliflozin for continuation during admission, if ordered to continue.
2. New inpatient orders for empagliflozin will be permitted, given the following patient conditions are met (which will be built into the EHR as ordering questions to address):
    a. The patient is currently on and compliant with GDMT appropriate to his/her disease state(s) and has indications for additional therapy
    b. eGFR is >= 45 and renal function is stable or improving
    c. Patient does not have recurrent UTIs
    d. Patient does not have history of, or at high risk for, DKA
    e. Patient does not have hypovolemia
    f. Patient does not have severe PAD, foot ulcerations, or at risk of amputation

FORMULARY INTERCHANGE

THERAPEUTIC CLASS: Short acting muscarinic antagonist, and short-acting beta-2 adrenergic agonist

GENERIC NAME: Albuterol sulfate and ipratropium bromide

PROPRIETARY NAME: Combivent Respimat®

BACKGROUND/RATIONALE:

Combivent Respimat® is indicated for the treatment of chronic obstructive pulmonary disease. It is a non-formulary product locally as well as for the CommonSpirit system formulary. CHI Memorial hospitals have been utilizing Combivent Respimat® for COVID positive patients who have underlying COPD or asthma, and are not ventilated.

PHARMACOECONOMICS/COST:

CHI Memorial utilizes the common canister process for metered dose inhalers (MDIs) such as albuterol sulfate. This process allows one inhaler canister to be utilized for multiple patients (sterility is ensured by RT staff). Patients are charged per "puff" instead of per inhaler.

Unlike albuterol sulfate metered dose inhalers, Combivent Respimat® should not be used via a common canister due to the respimat formulation. One inhaler is utilized per patient.

Atrovent HFA (ipratropium bromide metered dose inhaler) can be administered via a common canister administered by RT staff.

Medication Name	Cost
Combivent Respimat®	$344.94 per patient
Atrovent HFA®	$391.48 per 200 metered actuations ($1.95 per puff)
Ventolin HFA®	$19.18 per 60 metered actuations ($0.32 per puff)

RECOMMENDATION/DISCUSSION:

It is recommended to approve an automatic therapeutic interchange for Combivent Respimat® as follows:

- In COVID positive patients who have underlying COPD or asthma and are **not** ventilated, interchange orders for Combivent Respimat to Ventolin HFA (albuterol sulfate) (1 puff) plus Atrovent HFA (ipratropium bromide) (1 puff) at the same ordered frequency.
- In COVID positive patients who have underlying COPD or asthma and **are** ventilated, maintain the current therapeutic interchange to Duoneb.
- In COVID negative patients, maintain the current therapeutic interchange to Duoneb.

Ivermectin restrictions

Ivermection restricted dispensing:

Notice of Pharmacy Restricting Dispensing of Ivermectin For the Treatment of Parasitic Infections

Pharmacies nationwide are currently facing a shortage of the drug ivermectin, which is a medication used to treat certain parasitic infections. In accord with guidance from both the FDA and CDC, **our pharmacy is not accepting or filling ivermectin prescriptions for the treatment of COVID-19**.

Ivermectin is not approved by the FDA for the prevention or treatment of COVID-19. There recently has been an increase in prescribing Ivermectin, however, there is insufficient scientific evidence to support the use of Ivermectin to treat COVID-19. Additionally, Ivermectin has potentially toxic side effects such as nausea and vomiting, and diarrhea, and overdoses are associated with hypotension, decreased consciousness or confusion, hallucinations.

The FDA and the CDC have issued advisories indicating that Ivermectin is not authorized or approved for the prevention or treatment of COVID-19. The National Institutes of Health (NIH), World Health Organization, and Merk (the manufacturer of the drug) all state there is insufficient evidence to support the use of Ivermectin to treat COVID-19. The American Medical Association (AMA), American Pharmacists Association (APhA) and the American Society of Health System Pharmacists (ASHP) strongly oppose the ordering, prescribing, or dispensing of Ivermectin to prevent or treat COVID-19 outside of a clinical trial.

For more information, we encourage patients to consult the FDA's Consumer Update on Why you Should Not Use Ivermectin to prevent or treat COVID-19 located at: *https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19*

NIH guidance is located at: *https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/*

Merk statement is located at: *https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/*

CDC report of severe illness associated with the use of products containing Ivermectin to prevent or treat COVID-19 is located at: https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf

Ivermection restriction criteria:

RECOMMENDATION

☒Formulary, Restricted; Ivermectin

Restrictions

- Restricted to the treatment of parasitic infections, such as *Strongyloides stercoralis, Onchocerca volvulus, Pediculus capitis, Pediculus corporis, Pediculosis pubis, Sarcoptes scabiei, Wuchereria bancrofti, larva currens, larva migrans*, acne rosacea, ascariasis, enterobiasis, trichuriasis and scabies.
- In conjunction with an infectious disease consult (if available), ivermectin may be used for prophylactic treatment for immunocompromised patients with COVID-19 who are from stronyloidiasis endemic areas.

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 owns all COVID mAb supply and determines which product will be shipped to each state. State of TN then allocates mAb to sites.	Approve pharmacist automatic therapeutic interchange to either product based on product availability
Casirivimab/imdevimab (Regen-COV)		

Criteria Approved by COVID-19 Medications Subcommittee

Remdesivir Criteria (updated 8/25/2021)**:**
-5 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 (+)
- Requiring/rapidly rising O2 requirements: at least 5L of oxygen to maintain an O2 Sat of 92%
- ≤7 days since symptom onset or positive test (whichever comes first)
- Patients must be initiated on steroids unless contraindicated
    - Dexamethasone 6 mg IV/PO (PO preferred due to availability) daily

Exclusion criteria:
- ICU admission
- High-flow oxygen therapy via vapotherm, noninvasive ventilation invasive mechanical ventilation, ECMO
- 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

Tocilizumab & Baricitinib for COVID-19 Use Criteria

Due to a nationwide critical drug shortage of tocilizumab, the following automatic therapeutic interchange has been approved by the Pharmacy and Therapeutics Committee (P&T) to be utilized when tocilizumab supply is unavailable:

- For patients meeting criteria for both baricitinib and tocilizumab
    - Orders for tocilizumab for COVID will be converted to baricitinib dose adjusted automatically per P&T approved protocol unless
        - eGFR <15 ml/min/1.73 m2 or requiring renal replacement therapy
        - Lymphopenia (absolute lymphocyte count < 200cells/μL)
        - History within last 12 weeks of VTE (DVT/PE) or history of recurrent VTE (>1)
        - Unable to tolerate PO and no enteral access
- For patients ***NOT MEETING CRITERIA*** for either baricitinib or tocilizumab
    - The hospitalist must get approval from the on-call provider prior to pharmacist dispensing the medication. Pharmacist will let the ordering provider know who to contact.

Tocilizumab (Actemra) Use Criteria

Approved 2/10/2021; updated 3/29/2021; updated 5/31/2021; **updated 8/18/2021**

- COVID-19+
- Within 72 hours of supplemental oxygen requirement
- Patient rapidly decompensating within the past 24 hours
    - Rapidly increasing O2 requirements
    - Progressive pulmonary infiltrates over the past 24 hrs on chest x-ray
- Tocilizumab must be initiated within 24 hours of initiation of high flow nasal cannula, non-invasive ventilation
- C- reactive protein level must be ≥ 75 mcg/ml
- Patient must be receiving corticosteroids unless contraindicated
- Exclusions:
    - Mechanical ventilation/ECMO
    - AST/ALT >5x ULN
    - Neutropenia (ANC <500 cells/μL)
    - Thrombocytopenia (platelet count <50,000cells/μL)
    - Serious non-COVID-19 infection (ex: bacterial, fungal, TB etc.)
    - Treatment with a biologic immunomodulating drug in past 30 days (including baricitinib)
    - High risk for gastrointestinal perforation

Dose = 8 mg/kg IV dose (max 800 mg); single dose. Do not repeat dose.

Baricitinib (Olumiant) Use Criteria

Approved 8/18/2021

- COVID-19+
- Within 72 hours of supplemental oxygen requirement
- Patient rapidly decompensating within the past 24 hours
    - Rapidly increasing O2 requirements
    - Progressive pulmonary infiltrates over the past 24 hrs on chest x-ray
- Baricitinib must be initiated within 24 hours of initiation of high flow nasal cannula, non-invasive ventilation

- C- reactive protein level must be ≥ 75 mcg/ml
- Patient must be receiving corticosteroids unless contraindicated
- Exclusions:
    - Mechanical ventilation/ECMO
    - eGFR <15 ml/min/1.73 m2 or requiring renal replacement therapy
    - AST/ALT >5x ULN
    - Neutropenia (ANC <500 cells/μL)
    - Lymphopenia (absolute lymphocyte count < 200cells/μL)
    - Serious non-COVID-19 infection (ex: bacterial, fungal, TB etc.)
    - Treatment with a biologic immunomodulating drug in past 30 days (including tocilizumab)
    - History within last 12 weeks of VTE (DVT/PE) or history of recurrent VTE (>1)
    - Unable to tolerate PO and no enteral access

Dose = 4 mg PO daily x 14 days or until discharge from hospital (whichever is shorter); adjust dose for renal insufficiency as described in table below

		Dose adjustment
Estimated glomerular filtration rate (eGFR)	≥60 mL/min/1.73 m2	4 mg once daily
	30 to 60 mL/min/1.73 m2	2 mg once daily
	15 to 30 mL/min/1.73 m2	1 mg once daily
	< 15 mL/min/1.73 m2	Not recommended

<u>Medication Protocols</u> – TJC Annual Protocol Review

October 2021

[See Appendix A for Policies]

Protocol	Key contact(s)	Action Required
MCT RIS Contrasts Order Set/ Contrast Media Administration Policy	Jeff Harwood Dr. Rowlett Pharmacy	Order set and policy up to date. No medication edits are required.
Anaphylaxis & Acute Drug Hypersensitivity Protocol	Pharmacy	Remove meperidine for rigors. Recent recommendations prefer methylprednisolone to be used for rigors. Update order set and policy.
Hypoglycemia Protocol	Diabetes education, Pharmacy	No medication edits are required. Order set and policy up to date.
Narcan (Naloxone) Opioid Reversal Protocol	Pharmacy; Clinical educator critical care	Remove the requirement of donning PPE for unknown narcotic exposure. No medication edits are required. Update order set and policy.

Guideline 11: Pharmaceutical vendor guidance

COMMONSPIRIT HEALTH
ADMINISTRATIVE GUIDELINES

SUBJECT: Pharmaceutical vendors	**GUIDELINE NUMBER:** TBD
EFFECTIVE DATE: TBD	**ORIGINAL EFFECTIVE DATE:** TBD

☐ National/System Offices ☒ Acute Care Facilities ☒ Non-Acute Care Facilities

PURPOSE/RATIONALE

A. To establish expectations for pharmaceutical vendor representatives conducting or soliciting business at CommonSpirit Health
B. To establish guidelines to ensure high quality care, to preserve patient safety, to protect patient rights, to provide patient privacy, dignity and confidentiality and to provide an environment with limited commercial influence and bias.
C. To establish guidelines to ensure vendors and their sales representatives adhere to established CommonSpirit Health division and facility policies and procedures and that those vendors and their sales representatives abide by all applicable state and federal laws and regulations and other regulatory standards of practice.

I. DEFINITION

Pharmaceutical vendor - Individuals employed by commercial corporations whose responsibility may include the sale, marketing, provision of information, or other form of promotion of medication products and select medication related devices

II. GUIDANCE

a. Each facility, market, division or service area is to have its own policy and procedure for pharmaceutical vendor site visits, which are expected to include implementation and enforcement details.
b. The access of professional pharmaceutical representatives within CommonSpirit Health facilities and on its property is under the strict control of CommonSpirit Health.
c. The goal is to eliminate unnecessary vendor traffic while allowing staff the opportunity to discuss medication therapy, when deemed necessary (e.g., internal staff are unable to fulfill the needed) and at the discretion of CommonSpirit management, with professional pharmaceutical representatives.
d. Pharmaceutical representatives must contact Pharmacy Administration prior to visiting any CommonSpirit Health hospital location, either in person or virtually. They may not visit a CommonSpirit Health Hospital, in person or virtually, in a professional capacity without the approval of Pharmacy Administration.
    i. For clinics and auxiliary facilities without direct relationships with Pharmacy Administration, the local policy and procedure will identify the approval process for visit requests.
e. All representatives are provided (either physically or electronically) the local Professional Pharmaceutical Representatives Policy and Procedure (which, at a minimum, complies with these guidelines) at their first visit to ensure they understand all policies governing representatives.
f. The Professional Pharmaceutical Representative is required to provide evidence of satisfactorily meeting required health status and vaccinations and background checks via electronic credentialing system prior to first visit to a CommonSpirit Health facility. The Pharmaceutical Representative will sign a log indicating receipt and understanding of the policy and procedure via an electronic credentialing system (e.g. RepTrax or Vendormate). Each time the pharmaceutical representative accesses the electronic credentialing system, the pharmaceutical representative will sign off on (indicating receipt and understanding of) the most current policy and procedure.

g. Pharmaceutical representatives must obtain a badge upon entrance to the hospital, clinic or other care site per local policy. If representatives are not certified with the CommonSpirit Health facility's electronic credentialing system, they cannot make an appointment until certification is complete and up to date.
    i. If a facility does not have an electronic credentialing system, vendors are required to obtain approval with pharmacy management prior to their scheduled appointment
h. Pharmaceutical representatives are not allowed to provide food/drinks to staff within CommonSpirit Health facilities.
i. Pharmaceutical representatives are not allowed to provide non-educational gifts to any staff in CommonSpirit Health facilities.
j. Pharmaceutical representatives cannot promote medications that are not on the CommonSpirit Health system, division or local formulary (non-formulary medications). Non-formulary medications may be discussed in context to other relevant medication for educational purposes only if prior approval is obtained and if the information presented is fair and balanced.
k. Pharmaceutical representatives are not allowed in patient care areas at the hospital, clinics or other care sites to meet with nursing or medical staff unless prior approval is granted by Pharmacy Administration.
    i. Appointments must be held in areas where patient confidentiality is protected to meet HIPAA guidelines.
l. The pharmaceutical representative is authorized to visit only the pre-approved department where they have an appointment and discuss only the pre-approved topic. Visits to other departments without prior approval is prohibited.
m. The representative must sign out of the electronic credentialing system upon completion of the appointment or check out in person with pharmacy management if the facility does not have an electronic credentialing system.
n. Medication samples are discouraged in clinics because studies have shown samples can influence prescribing behavior. If it is decided locally to allow medication samples to be distributed to patients, the process must follow locally approved policy and procedures.
o. Medication samples are not allowed in the inpatient setting.
p. No exhibits or promotional material may be set up or left on CommonSpirit Health property.
q. Any deviations from the local policy may result in permanent suspension of the representative's visiting privileges at CommonSpirit Health sites.
    i. The representative's manager and the pharmaceutical company's national team will be notified of any violation.
    ii. If a violation of the policy/procedure occurs, a permanent ban is possible.
    iii. This suspension pertains not only to the current company with which the representative is employed, but to any future company as well.
    iv. Further, a pharmaceutical company may be banned from a facility if their business practices are inconsistent with this CommonSpirit Health guidance.
r. If a vendor representative is in a CommonSpirit Health facility as a private citizen visiting a patient or is personally receiving care, these restrictions do not apply. However, no business can be conducted, even if asked by a practitioner.
s. All CommonSpirit Health healthcare staff are responsible for ensuring vendor compliance with this guidance and the local policy and procedures. If non-compliance is observed, it must be reported in a timely manner to Pharmacy Administration or appropriate manager.

POLICY

Title: HYPERTONIC SALINE ~~(3% NS)~~ FOR ADULTS			
		Page 1 of 2	
Policy Number: MM-05465		Date ~~Last~~ reviewed/Revised: ~~9/20~~10/21	Valid Until: ~~9/23~~10/24
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas		Review Period: Every 3 years	

OUTCOME:
To outline the necessary requirements for the safe ordering, dispensing and administration of hypertonic saline solution (HTS), which is a concentrated electrolyte solution and a high risk medication.

POLICY:

Ordering Requirements and Restrictions

1.) Hyponatremia Treatment
HTS may be ordered by any prescriber for the treatment of symptomatic hyponatremia although any orders from providers other than nephrology or critical care must use the hospital approved "Hypertonic Saline (3% NS) IV Infusion– Hyponatremia Treatment" order set. All orders must have total volume/dose or duration in the order. All orders must comply with minimum requirements for laboratory monitoring.

2.) Acute Neurologic Indications
HTS (3% NS) for acute neurological indications other than hyponatremia treatment (increased intracranial pressure or other acute neurological deficits, etc.) should be ordered using the Hypertonic Saline Panel - Neurology Indication (Elevated ICP) order panel. Mandatory laboratory monitoring is still required as indicated below.
   a. Undiluted **23.4%** hypertonic saline may be given emergently by a Neurology or Neurosurgery provider through a central line as a single 15 to 60 mL bolus dose infused over 10 to 20 minutes.

3.) Maximum infusion rates:
   a. Peripheral line: ≤ 30 ml/hr
   b. Central line: ≤ 50 ml/hr

4.) Maximum order volume:
   a. No more than 500 ml of HTS may be ordered for treatment of hyponatremia. If the ordered volume exceeds 500 ml, prescriber will be contacted after initial infusion of 500 ml for continuation order.
   b. HTS for acute neurologic indications may be ordered as a continuous infusion exceeding 500 ml if ordered by neurology provider. Mandatory laboratory monitoring is still required for duration of infusion.

Laboratory and Patient Assessment Monitoring

1.) Required labs*:
   a. Baseline serum sodium required prior to treatment initiation
   b. BMP at least every 4 hours for duration of HTS infusion (if not already ordered). May be ordered more frequently at discretion of provider.

** If labs are not ordered by provider these may be ordered by pharmacy.*

2.) The infusion must be held and provider notified for the following conditions:

Hyponatremia Treatment:
a. Serum sodium increases by more than 2 mEq/L in any 4 hour period
b. Serum sodium increases by more than 8 mEq/L during 24 hour period.
c. Serum sodium ≥ 130

Neurologic Indications:
a. Serum sodium ≥ 155 mEq/L
b. Serum osmolality > 320

3.) Nursing - patient assessment:
   a. Strict input and output every 4 hours
   b. Neurological checks Q 4 hours for duration of infusion

Storage and Dispensing

1.) Only pharmacy will stock pre-mixed HTS for intravenous use. Pharmacy will dispense the exact volume to be administered (transferred to an empty IV bag) and no more than a 500 ml premix bag at one time.

2.) Specific for hyponatremia indication: Further doses will only be sent after pharmacist review of sodium levels to prevent overly rapid correction (as outlined above).

Administration

1.) Administration via central line is preferred. If central line is not available, infusion via the largest peripheral vein available is acceptable for durations < 24 hours. If prolonged infusion is required, central line administration is highly recommended.

2.) HTS is a High Alert medication. An independent double check (documentation of 2nd nurse verification) is required and will be performed/documented with every new bag administration and at shift change (verification of pump setting and drug).

Key Contact: Pharmacy Review Team
Approved/Reviewed by: P & T Committee, Director of Pharmacy
Related Document(s): HIGH ALERT MEDICATIONS (MM-05402)
Date First Effective & Revision/Review dates: 5/17, (9/20), 10/21

2. Richmond Agitation-Sedation Scale (RASS): scale used to measure the agitation or sedation level of a patient, used most often in mechanically ventilated patients in order to avoid over and under-sedation.
3. Aldrete: scale for the measurement of recovery after anesthesia which includes activity, respiration, consciousness, blood circulation, and color.
4. Neonatal Pain, Agitation, Sedation Scale (NPASS): used to assess both pain and sedation levels in neonates when NIPS or FLACC may not be accurate or appropriate.

ASSESSMENT:

1. Pain is assessed in all patients.
2. Initial patient pain/comfort assessment will be completed and documented within 4 hours of admission.
3. Pain must be assessed and documented every shift within 4 hours of start of shift, and as needed based on patient presentation/condition.
4. Patients with PCA, Epidural, or continuous narcotic infusions must be assessed for pain and sedation (using POSS) at least every 2 hours. Refer to policies EPIDURAL ANALGESIA (MM-05408) and PCA – PATIENT CONTROLLED ANALGESIA – HOSPIRA LIFECARE PCA® WITH MEDNET® SOFTWARE (MM-05403).
5. Document pain assessment at the time of drug or non-drug intervention. Document sedation assessment (using POSS) at the time of opioid administration. The patient's pain/comfort will be assessed and rated using the appropriate pain/comfort rating scale. Key points for assessing pain characteristics:
   a. **P** – Proactive/Palliative factors: "What makes your pain better or worse?"
   b. **Q** – Quality: "Tell me what your pain feels like."
   c. **R** – Region/Radiation: "Where are you hurting?"
   d. **S** – Severity: Determine the patient's level of pain using a pain scale appropriate to patient's age, developmental levels, and comprehension.
   e. **T**- Timing: "Is your pain constant, intermittent, continuous, or a combination?"
   f. **U**- You: "How is the pain affecting you (**U**)?"

INTERVENTION:

1. Respond promptly to reports of pain.
2. Administer analgesics as ordered and document.
   a. Orders with multiple PRN analgesics should be specified for mild, moderate, or severe pain indications, otherwise, a clarification is required before administration.
   b. If multiple PRN orders exist for each mild, moderate, or severe pain indications, refer to the Therapeutic Duplication of PRN Medication Orders policy.
   ~~b.~~ c. Upon patient request, nurse may administer pain medication ordered for a lower pain score (not higher pain score) than the value reported by the patient. (Example: Acetaminophen is ordered as needed for mild pain (1-3), and tramadol is ordered for moderate pain (4-6). Patient reports pain score of 5 and requests acetaminophen rather than tramadol. Acetaminophen may be given.)
3. Utilize non-drug techniques for pain control, which may include reposition, heat, ice, massage, emotional support, immobilization, exercise, diversion, or relaxation. Guided imagery and therapeutic music are also available through Chaplain Services with a referral.
4. Use age appropriate guidelines for pain/comfort management.

TEACHING:

1. Instruct patient/family/significant other in use of pain scale. Refer to the Pain rating sign located in the patient care areas. Instruct patient/family/significant other to report pain, including changes in pain, and side effects.
2. Inform patient/family/significant other about options to control pain, and that they may discuss concerns and preferences with the health care team.
3. Inform patient/family/significant other that the patient's safety and prevention of complications from pain management modalities will take precedence over pain management. However, some type of "intervention" (drug or non-drug technique) will be made if unacceptable levels of pain are communicated.
4. Instruct patient/family/significant other receiving narcotics/opioids to call for assistance to ambulate.

CHI Memorial

POLICY

Title: **TOTAL PARENTERAL NUTRITION (TPN) – PERIPHERAL PARENTERAL NUTRITION (PPN) - ADULT**			
		Page 1 of 3	
Policy Number: PC-07012		Date Last reviewed/Revised: ~~1/24~~10/21	Valid Until: ~~1/24~~10/24
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: Nursing, Pharmacy, Nutrition		Review Period: every 3 years	

OUTCOME

To provide guidelines for administration of a nutritionally complete formula to meet nutritional requirements; to promote wound healing and body growth. The patient will achieve or maintain ideal body weight, maintain fluid and electrolyte balance, and remain free of local and systemic infection.

DEFINITIONS:

Total Parenteral Nutrition is administration of complete nutrition through a central vein when oral or enteral routes are not feasible. TPN is a nutritional solution containing concentrations **exceeding** 10% dextrose, 5% protein, or both.

Peripheral Parenteral Nutrition (PPN) is a nutritional solution that has a concentration of 10% dextrose, and 5% protein **or less** while maintaining an osmolality of < 900 milliosmoles per liter. PPN maintains adequate nutritional status in patients who can tolerate relatively high fluid volume, in those who usually resume bowel function and oral feedings after a few days, and in those who are susceptible to infections associated with a central line.

POLICY/PROCEDURE:

1.) TPN is ordered by MD or Pharmacist ~~on specific TPN Order Form documenting required information as detailed on the form~~. When a provider writes an order for pharmacy to manage TPN, this will be interpreted as a request for the pharmacist to write daily TPN orders, monitor for any side effects and make any necessary formulation adjustment during the course of therapy.
2.) TPN must be given via a central vascular line/device. Pharmacist may order a peripherally inserted central catheter (PICC) for TPN administration if a central line is not already placed. TPN may be administered continuously or cyclically for a specified period of time as ordered by the provider. Cyclic TPNs should only be used for patients already on stable cyclic TPN therapy or transitioned to cyclic formulas after the patient has achieved goal nutritional therapy without significant concerns regarding maintaining glycemic control. If concerns arise regarding new orders to cycle TPNs these issues will be discussed directly with the ordering provider.
3.) PPN may be delivered through a peripheral site (dedicated IV line). The maximum administration period for PPN should be 7 to 10 days, unless supplemental oral or enteral feeding is also provided. PPN should not be used in volume-restricted patients because PPN requires large fluid volume.
4.) The pharmacist will calculate the initial formula using the appropriate evidence based guidelines for intravenous nutrition, taking into account treatment goal and patient clinical data. Pharmacists will collaborate with the clinical dietitians to ensure the patient's nutritional goals are met during therapy.
5.) The pharmacist will monitor the patient while receiving TPN therapy and order any appropriate labs and communicate to the physician via the progress notes.
6.) Infusion pumps should be used for any TPN or PPN.
7.) Any un-infused solution should be discarded if not used within 24 hours of administration.

GLYCEMIC MANAGEMENT:

Pharmacists may order or make insulin therapy adjustments for the following conditions when clinically appropriate as indicated below. However, if hospitalist or other provider(s) are currently managing insulin or other therapies for glycemic control any modifications in therapy will be discussed with the provider prior to

POLICY

Title: KETAMINE LOW DOSE (SUB-ANESTHETIC DOSING) FOR PAIN - ADULTS			
		Page 1 of 3	
Policy Number: MM-05467		Date Last reviewed/Revised: 10/21	Valid Until: 10/24
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas		Review Period: every 3 years	

OUTCOME:
To provide guidance in the care of patients receiving low-dose (sub-anesthetic) Ketamine as an infusion, IV bolus, or intranasal (IN) administration for treatment of pain.

DEFINITIONS:
Ketamine produces analgesia by binding to receptors in the peripheral and central nervous systems. These receptors are the opioid receptors as well as the N-methyl D-aspartate (NMDA) receptor in the dorsal horn of the spinal cord. NMDA receptors participate in the development and maintenance of what can be called "pathologic pain" after tissue injury which is increased pain perception as a result of pain sensitization. Ketamine inhibits the binding of excitatory amino acids to the NMDA receptors, reducing the impact of painful stimuli. This blocking action is thought to be the mechanism behind its analgesic properties. Ketamine also inhibits the reuptake of dopamine and serotonin and elevates circulating epinephrine and norepinephrine levels. This, increases the heart rate, blood pressure, cardiac output and vascular resistance.

Ketamine is highly lipid soluble and crosses the blood-brain barrier. The onset is quick, within 30 seconds after intravenous administration with full effect within one minute and duration of up to 60 minutes. Immediate effects of ketamine include analgesia, sedation, pupil dilation, nystagmus, lacrimation, salivation, and increased muscle tone. There may also be dissociative side effects such as hallucinations. Consideration should be given to decreasing the total opioid dose as ketamine has an opioid effect.

INDICATIONS INCLUDE: postoperative pain, and acute or chronic pain.

PERSONNEL:
A distinct separation between pain management dose and the anesthetic dose provides a measure of assurance that the medication administration will not venture into the anesthetic usage which is beyond the scope of practice for a nurse. Doses as outlined in this policy do not apply to moderate sedation use of ketamine and thus ketamine for pain indications may be given by any nurse in the allowed clinical areas as outlined in this policy.

PROCEDURE:

A. Initial Patient Assessment
1. Assess patient according to the Pain Management policy (PC-07201)
2. Assess patient for risk of adverse event. Caution is strongly advised in the administration of Ketamine in patients with any of the following:
    a. Cardiovascular or respiratory compromise
    b. Psychosis, post-traumatic stress disorder (PTSD) or schizophrenia
    c. For any concerns, contact prescriber.

B. Initiating Therapy
1. Review MD Order and prepare for administration.
2. A benzodiazepine may be prescribed and considered to reduce the incidence of hallucinations per provider's discretion.

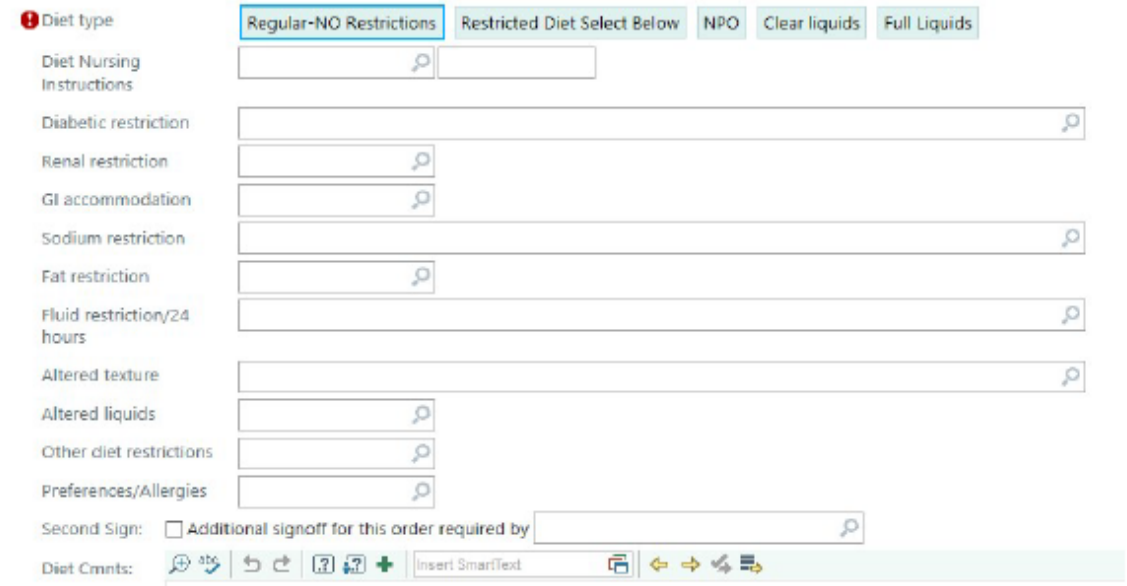
	Continuous Infusion	IV Bolus Administration	Slow IVP	Intranasal (IN) administration via nasal atomizer device
Patient Location	ICU or PACU	No restrictions	PACU	No restrictions
Ordering	Therapy initiation and dose adjustments per anesthesia service or critical care providers only.	No restrictions	Anesthesia providers	No restrictions
Normal Dose	0.1 - 0.3 mg/kg/hr	0.1 – 0.3 mg/kg via infusion over 10-30 mins	0.1 – 0.3 mg/kg over 3-5 mins	0.5 mg/kg
Maximum Dose	0.4 mg/kg/hr	30 mg	30 mg	50 mg
Repeat Dose / Titration		May repeat dose in 20-30 min if pain returns. 50% dose reduction should be considered.	May repeat dose in 20-30 min if pain returns. 50% dose reduction should be considered.	May repeat dose in 20-30 min if pain returns. 50% dose reduction should be considered.
Monitoring Parameters	BP, HR, RR, O2 Sat, pain level, sedation level appropriate for current level of care			
Monitoring Frequency & Discontinuation	Initiation: Monitor within 60min Titration: Monitor within 60min Routine: -Not titrating: q2h for the 1st 24h then q4h -Increase in dose: q2h for 24h after stable dose is achieved, then q4h -More frequently as clinically indicated	Initial dose: Monitor q15min x2 Repeat doses: Monitor q1h x1 Discontinuation: Monitoring may be discontinued and patient may be transferred or discharged 60 min following IV bolus administration if clinically appropriate.	Initial dose: Monitor q15min x2 Repeat doses: Monitor q1h x1 Discontinuation: Monitoring may be discontinued and patient may be transferred or discharged 60 min following IV bolus administration if clinically appropriate.	Initial dose: Monitor q15min x2 Repeat doses: Monitor q15min x2 Discontinuation: Monitoring may be discontinued and patient may be transferred or discharged 60 min following IN administration if clinically appropriate.
Documentation	BP, HR, RR, O2 Sat, pain level, sedation level appropriate for current level of care			
Reportable Conditions	Notify ordering MD if any of the following occur: 1. Excessive sedation 2. Psychological side effects i.e. hallucinations, vivid dreams, aggressive behavior 3. Sustained hypertension (>20% increase in blood pressure) 4. Increased pain level or unrelieved pain			

CHI Memorial

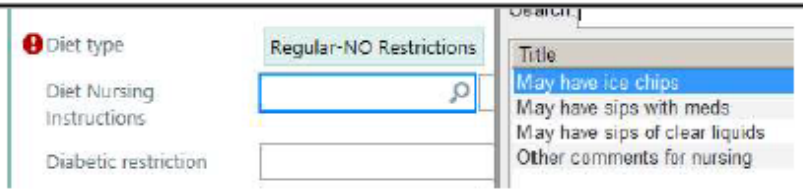
Look Alike/Sound Alike Drug List

Drug Name	Drug Name	Potential Errors	Prevention Strategies
CeleBREX®	CeleXA® and CereBYX®	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
cloniDINE	KlonoPIN®	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Diamox®	Diuril®	Similar names	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR
DOBUTamine	DOPamine	Similar names	1. Tall man letting in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
DOXOrubicin *Liposomal*	DOXOrubicin *Conventional* and DAUNOrubicin	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Do NOT store next to each other. 3. Name alert on MAR
hydrOXYzine	hydrALAzine	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Keppra®	Ketamine®	Similar names	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR 4. Witness required for ketamine
metroNIDAZOLE	metFORMIN	Similar names and strengths	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
MuciNEX®	MucoMYST®	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
oxyCODONE controlled-release	oxyCODONE immediate-release	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Plavix®	Pradaxa®	Similar names and strengths	1. Pyxis pop-up warning. 2. Do NOT store next to each other. 3. Name alert on MAR
predniSONE	prednisoLONE	Similar names	1. Tall man lettering in Pyxis, Epic & Talyst. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
Remicade®	Rituxan®	Similar names	1. Tall man lettering in Epic. 2. Do NOT store next to each other. 3. Name alert on MAR
Versed®	Vecuronium®	Similar names	1. Tall man lettering in Pyxis 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR

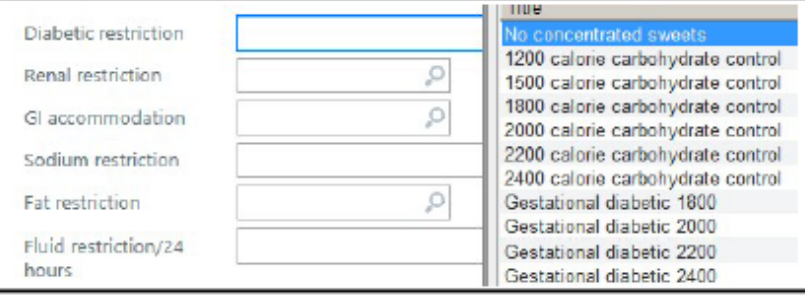
General:	Add: Appropriate, Not Appropriate, Needs Assistance

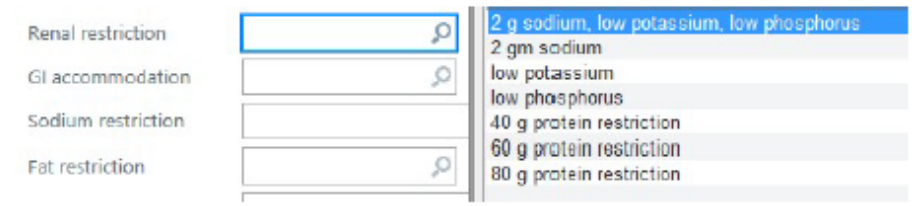
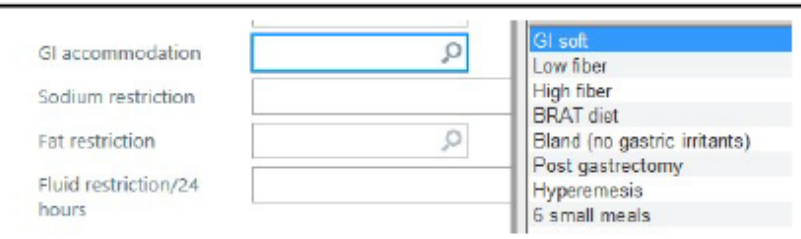
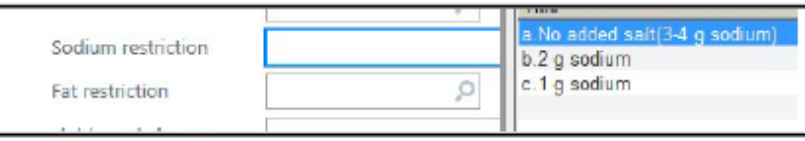
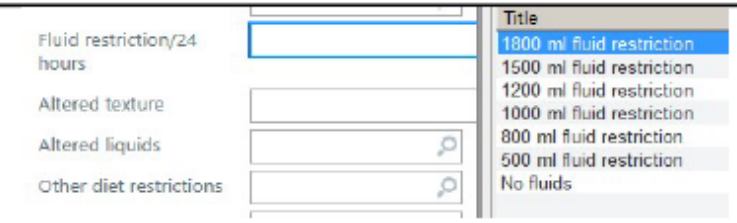
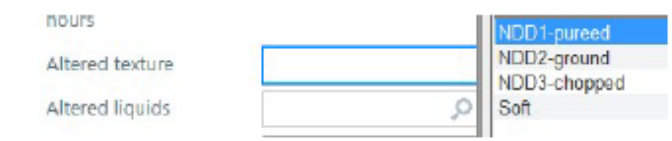


Regular	Same



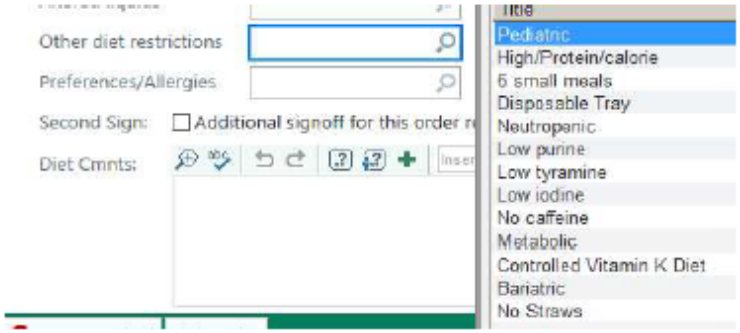
Diabetic	New List: No Concentrated Sweets 45 g Consistent Carbohydrate Diet 60 g Consistent Carbohydrate Diet 75 g Consistent Carbohydrate Diet Gestational Diabetic Diet (30 B / 45 L / 45 D / 30 HS Snack)



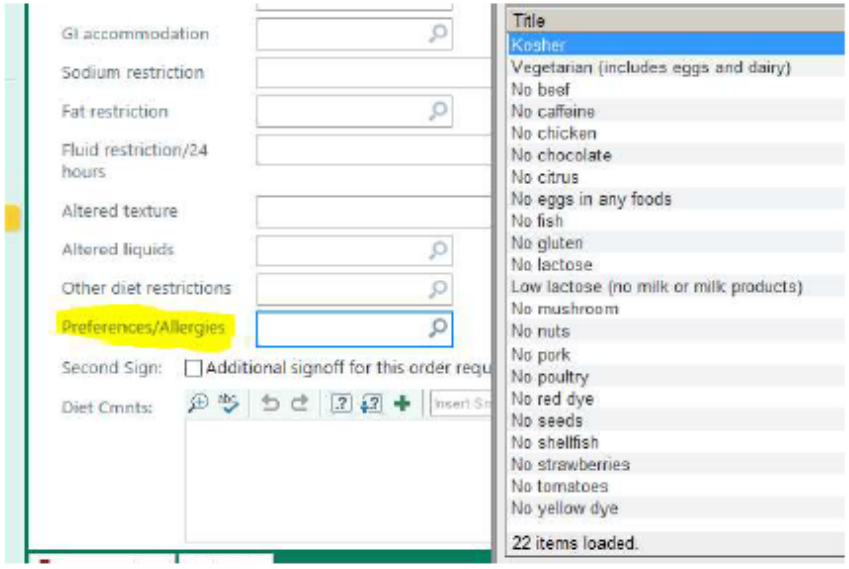
Renal	*change to 2 g sodium, 2 g potassium, 1 g phosphorus remove 40 g protein restriction, rest is the same	
GI	remove hyperemesis diet removing BRAT diet *move bariatric to the GI column	
Sodium	No Added Salt (no salt packets) 2 g Sodium 1.5 g Sodium	
Fat	Low Fat Very Low Fat (20 g/day) Minimal Fat (10 g/day) Low Cholesterol	
Fluid	Same	
Texture	Pureed-4 (Pureed) Minced and Moist-5 (Ground) Soft and Bite-Sized-6 (Chopped) Easy to Chew-7 (Soft)	

Altered Liquid	No Liquids Mildly Thick Liquids-2 (Nectar-Thick) Moderately Thick Liquids-3 (Honey-Thick) Extremely Thick Liquids-4 (Pudding-Thick) No Carbonation

Other	remove controlled vitamin K diet (hospitals don't carry high Vit K foods) add transplant diet (removing banana, grapefruit, cranberry) add Metabolic low protein diet add Cystic Fibrosis diet (High Calorie/High Protein)



Prefrences	Vegan finger foods no cold beverages no hot beverages cold foods only 911 precautions wired jaw



Appendix A

CHI Memorial

POLICY

Title: CONTRAST MEDIA ADMINISTRATION			
		Page 1 of 7	
Policy Number: PC-07335		Date Last reviewed/Revised: 10/21	Valid Until: 10/22
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia ☒CHI Memorial Ooltewah Imaging ☒ CHI Memorial Parkway Imaging *Check all that apply*			
Department(s) Affected: Imaging Services, Radiation Oncology, Pharmacy, Emergency Care Center		Review Period: Annually	

OUTCOME: To provide safe contrast media administration.

POLICY:
This policy is a joint responsibility of the All Imaging Services/Radiation Oncology locations, Emergency Care Centers, and Pharmacy departments.

A. Patients receiving IV contrast media (Gadolinium)

a. Prior to receiving IV contrast media

CONTRAST MEDIA ASSESSMENT (154403) will be completed and all the information confirmed by the patient and technologist to include a history of allergies and any past X-ray studies and/or adverse drug reactions.

The following guidelines will be followed for administration of Gadolinium Based Contrast:

Risk Factors

- Age > 60
- History of Renal Disease, including:
  - Dialysis
  - Kidney Transplant
  - Single Kidney
  - Kidney Surgery
  - History of known cancer involving the kidney(s)
- History of hypertension requiring medical therapy
- History of Diabetes mellitus

If risk factors are identified, the patient will have a creatinine/eGFR drawn and sent to Lab prior to administration of Gadolinium based contrast.

GFR > 30: Gadolinium based contrast will be calculated by weight per protocol 0.1mmol/kg (0.2ml/kg) not to exceed 20ml IV for standard MRI's. MRA's may include doses up to 40ml IV.

GFR < 30: Do not administer Gadolinium.

The patient does not need to sign informed consent except for exams performed in Georgia.
The calculated eGFR will be documented on the contrast history assessment and maintained in the patient's medical record.

b. Administration of IV contrast media and Observation of Patient (Gadolinium or Iodinated)

i. Contrast media injection will not be administered without a Radiologist, Radiation Oncologist, MHI or Emergency Care Center physician being available at time of the injection.
ii. Contrast injections may be administered by any radiologic technologist or didactically trained RN.
iii. The nurse or technologist administering the contrast will observe the patient for five minutes following the completion of the injection. If any adverse drug reaction is noted, the RN or technologist will immediately follow the appropriate management of adverse reaction guidelines for minor, intermediate, or major reactions.

c. **For EXTRAVASATION OF CONTRAST MATERIAL:**
Refer to **EXTRAVASATION OF CONTRAST MATERIAL (RAD-10105)**

NOTE: For returning patients with follow-up exams, use the same gadolinium contrast agent used in the previous "like" exam.

All CHI Memorial locations will be consistent with the current FDA recommendations as they evolve in the use of Gadolinium based contrast agents

B. **Patients receiving Iodinated Contrast Materials (ionic or non-ionic):**
a. Intravenous contrast dosage is calculated according to patient's weight (1ml/lb) up to 100 pounds, at which patients 100 pounds and over will receive a dose of 100ml.
b. All other contrast agent dosage will be determined using a standard dose chart per Radiologist/MHI physician protocol (attached).
c. These standard protocols may be altered based on patient history and Creatinine/GFR calculation if applicable.
d. Contrast dosage will be recorded on **CONTRAST MEDIA ASSESSMENT (154403)** to include type of contrast and amount given.
e. For patients **without** concomitant conditions or medications listed on the **CONTRAST MEDIA ASSESSMENT (154403)**:
i. Patients with a serum creatinine of 1.8 mg/dl or less may have IV contrast media administered.**See special consideration for CTA Stroke Protocol
ii. Patients with a serum creatinine greater than 1.8 mg/dl may only have IV contrast administered at the discretion of the Radiologist/MHI physician, Radiation Oncologist, or ED physician. Clearance to administer contrast will be documented on the contrast history form by the technologist and signed by the physician who has given the clearance.
iii. **Special Consideration for CTA Stroke Protocol**: If a patient is on hemodialysis for chronic ESRD with a serum creatinine that is > 1.8, contrast may be administered if approved by the attending neurologist.
f. **Administration of IV contrast media and Observation of Patient (Gadolinium or Iodinated)**
i. Contrast media injection will not be administered without a Radiologist, Radiation Oncologist, MHI or Emergency Care Center physician being available at time of the injection.
ii. Contrast injections may be administered by any radiologic technologist or didactically trained RN.
iii. The nurse or technologist administering the contrast will observe the patient for five minutes following the completion of the injection. If any adverse drug reaction is noted, the RN or technologist will immediately follow the appropriate management of adverse reaction guidelines for minor, intermediate, or major reactions.
g. **For EXTRAVASATION OF CONTRAST MATERIAL:**
Refer to **EXTRAVASATION OF CONTRAST MATERIAL (RAD-10105)**

C. **STANDARD DOSING:**
a. For all procedures, the contrast dosage and contrast agent will be determined using a standard dose chart per Radiologist protocol (**Refer to section I. below DOSING GUIDELINES FOR CONTRAST ADMINISTRATION)**
b. Contrast dosage will be recorded on **CONTRAST MEDIA ASSESSMENT (154403)** to include type of contrast

and amount given.

D. SPECIAL CONSIDERATIONS when using IV Contrast Media

i. The decision to use IV contrast of any kind during pregnancy is determined by the radiologist/radiation oncologist.
ii. Contrast injections for CT will require 20G intravenous access for use during procedure.
iii. For outpatient procedures, IV access will not be discontinued until the procedure is complete and the patient is determined to have no symptoms of adverse reaction.
iv. **Patients on Metformin medications receiving contrast- patients who are on Metformin medications will be advised to stop taking these medications for 48 hours post procedure as recommended by the American College of Radiology. The patient will receive form 198224 – "Patients on Metformin" upon discharge from Imaging Services. A Physician Alert letter, form 198223 will be faxed to the ordering physician for follow up with the patient.**
v. It is recommended that patients undergoing routine dialysis be scheduled within 24 hours after contrast administration. Patients experiencing acute renal failure in which urine output is < 0.3 mg/kg/h for 12 h or anuria for 12 h may have contrast exams performed without undergoing dialysis. This is at the discretion of the ordering physician.

E. CLASSIFICATION OF CONTRAST MEDIA REACTIONS are as follows:

a. Minor reactions are those which cause the patient some, but not excessive discomfort or apprehension and are of short duration and not life-threatening.
   i. These reactions include headache, light headedness and dizziness, swelling of the salivary glands, pain at injection site, and chills.
   ii. Usually no treatment is required. The patient responds to reassurance and non-specified measures or to limited medication.
b. Intermediate reactions are transient episodes of hypotension or bronchospasm, and any skin reaction that is slow to respond to treatment, rash, urticaria, diaphoresis (sweating) or edema.
c. Major reactions are those which threaten life.
   i. Severe hypotension and shock, loss of consciousness, convulsions, pulmonary edema, laryngeal edema, bronchospasm, cardiac arrhythmias, and cardiac arrest are in this category.
   ii. Treatment is urgent and mandatory.
d. Chemotoxic reactions are defined as those occurring secondary to angiographic examination of organs or regions when local or regional circulation are perfused by a concentrated solution of contrast medium for a short time. The injurious effects are related to total dose, concentration of the contrast media and its application time.
e. Gadolinium dermopathy – related reactions (i.e. dermopathy) will be reported through the ADR system.

F. MANAGEMENT OF ADVERSE REACTIONS:

Refer to ANAPHYLAXIS – REACTION INTERVENTION (MM-05449)
Refer to ADVERSE DRUG REACTION & REPORTING (MM-05424) -- All reactions to contrast media must be reported immediately as noted below, documented in the patient's medical record, recorded in IRIS as an occurrence **INCIDENT REPORTING SYSTEM (IRIS), OCCURRENCE REPORT (LD-01003)**, and reported to Pharmacy.

a. Minor reactions
   i. **Glenwood/Hixson/Georgia** campus- Immediately notify Radiologist/Radiation Oncologist or Emergency Care Center physician
   ii. **Ooltewah/MHI** all campuses- Immediately notify Radiologist/MHI physician and complete IRIS report.
b. Intermediate reactions
   i. **Glenwood/Hixson/Georgia** campus- Immediately notify Radiologist/Radiation Oncologist/ Emergency Care Center physician and/or initiate a call to the rapid response team

ii. **Ooltewah/MHI** all campuses- Immediately notify Radiologist/MHI physician

c. Major Reactions
   i. **Glenwood/Hixson/Georgia** campus- Activate Code button or Call 555 and initiate Code Blue. IRIS report will be completed.
   ii. **Ooltewah/MHI** all campuses- Call 911 Immediately notify Radiologist/MHI physician.

d. All Chemotoxic reactions and Gadolinium dermopathy - will also be reported in the IRIS system and following the process as outlined in the Adverse Drug Reporting policy. **ADVERSE DRUG REACTION & REPORTING (MM-05424)**

G. PRE-MEDICATION FOR ADVERSE REACTION PROTOCOL:

a. **Outpatients:** Should an outpatient present with indications of contrast media allergy, the exam will not be performed. The licensed professional will notify the physician overseeing the procedure to obtain a prescription for premedication for the patient and will reschedule the patient accordingly.

b. **Inpatients**: Should a procedure be ordered and the patient has a known contrast allergy, the ordering physician will be notified, and ACR guidelines for premedication should be followed accordingly.

c. **Emergent Procedures**: ACR guidelines for premedication for emergent procedures should be followed accordingly.

d. **ACR Guidelines for Premedication of Contrast Allergy** (refer to physician order/protocol)
Contrast allergy (do not give for history of shellfish allergy- only pre-medicate for KNOWN contrast allergy):

- ☐ **Inpatient:**
  Medrol 32 mg PO 12 hours (evening before procedure) and 2 hours before procedure (morning of procedure), PLUS Benadryl 50 mg IV/PO 1 hour prior to procedure
- ☐ **Outpatient**
  Medrol 32 mg PO 12 hours (evening before procedure) and 2 hours before procedure (morning of procedure), PLUS Benadryl 50 mg PO 1 hour prior to procedure
- ☐ **Emergent:**
  Solu-Medrol 40 mg IV Q 4 hours x2 doses prior to procedure (call procedure department when 2nd dose administered), PLUS Benadryl 50 mg IV/PO 1 hour prior to procedure.
  If both doses of Solu-Medrol are unable to be administered prior to the procedure, the following should be administered:
  Solu-Medrol 40 mg IV x1 PLUS Benadryl 50 mg IV x1

H. DOSING GUIDELINES FOR CONTRAST ADMINISTRATION:

Per Radiologist/MHI physician/Radiation Oncologist's protocol along with recommendations from the ACR Contrast manual, the following dosing guidelines will be followed for contrast administration:

COMPUTED TOMOGRAPHY

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
IAC	IV	100 ml	Isovue 370
Brain	IV	100 ml	Isovue 370
Sinus	IV	100 ml	Isovue 370
Facial	IV	100 ml	Isovue 370
Abdomen and/or Pelvis	IV	100ml	Isovue 370
Abdomen and/or Pelvis OP/IP	Oral	675 ml	Readicat Barium Suspension
Abdomen and/or Pelvis ER	Oral	10 ml	Gastrografin (+12 oz. liquid)
Abdomen and/or Pelvis IP	Oral	30 ml	Gastrografin (+12 oz. liquid)
Abdomen and/or Pelvis with Rectal Contrast	Rectal	30 ml	Gastrografin (+2000ml. of water)

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
Chest	IV	Weight specific	Isovue 370
Soft Tissue Neck	IV	100 ml	Isovue 370
C Spine	IV	100 ml	Isovue 370
T Spine	IV	100 ml	Isovue 370
L spine	IV	100 ml	Isovue 370
Lower Extremity	IV	100 ml	Isovue 370
Upper Extremity	IV	100 ml	Isovue 370
Chest PE	IV	Weight specific	Isovue 370
Dissection Chest Abd	IV	Weight specific	Isovue 370
AAA Abd/Pel	IV	Weight specific	Isovue 370
CTA Chest/Coronary Arteries	IV	Weight specific	Isovue 370
CTA Abdomen	IV	Weight specific	Isovue 370
CTA Pelvis	IV	Weight specific	Isovue 370
CTA Neck	IV	Weight specific	Isovue 370
CTA Head	IV	Weight specific	Isovue 370
CTA Aorta	IV	Weight specific	Isovue 370
CTA Runoff	IV	Weight specific	Isovue 370
CT Brain Perfusion	IV	40ml	Isovue 370
CTA Upper/Lower Extremity	IV	100 ml	Isovue 370

DIAGNOSTIC RADIOGRAPHY

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
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 to 2000 ml)
Upper GI	Oral	135 ml	Liquid EZ Paque or EZ HD
Upper GI 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

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
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
VCUG	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	Radiologist discretion	Isovue-M 200 or Omnipaque 300
Urethrogram	Bladder	Radiologist discretion	Isovue 300 or Cystografin
Loopogram	Intracavital	Radiologist discretion	Isovue 300 or Cystografin
Fistulagram	Intracavital	20 ml	Isovue 300 or Gastrografin

MAGNETIC RESONANCE IMAGING (MRI)

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
Abdomen	IV	*use calculation	Multihance
Abdomen- Liver	IV	Radiologist discretion	Multihance
Arthrogram-Shoulder	IV	1 ml	Multihance
Brain	IV	*use calculation	Multihance
Breast	IV	*use calculation	Multihance
Chest	IV	*use calculation	Multihance
C Spine	IV	*use calculation	Multihance
T Spine	IV	*use calculation	Multihance
L Spine	IV	*use calculation	Multihance
Lower Extremity Joint	IV	*use calculation	Multihance
Upper Extremity Joint	IV	*use calculation	Multihance
Lower Extremity	IV	*use calculation	Multihance
Upper Extremity	IV	*use calculation	Multihance
Orbit/Face/Neck	IV	*use calculation	Multihance

Pelvis	IV	*use calculation	Multihance
Pituitary	IV	*use calculation	Multihance
MRA Abdomen	IV	20 ml	Multihance
MRA Chest	IV	20 ml	Multihance
MRA Head	IV	20 ml	Multihance
Sacrum	IV	Use Calculation	Multihance
MRA Neck	IV	20 ml	Multihance
MRA Runoff	IV	40 ml	Multihance

Key Contact: Directors of Imaging Services; Radiation Oncology; Radiology Manager, CHI Memorial Georgia
Approved/Reviewed by: Medical Director of Imaging; Market Director of Imaging; Director of Pharmacy; P&T Committee
Reference(s): ACR Contrast Manual
Related Forms: Contrast Assessment Form
Date First Effective & Revision/Review dates: (3/12) (3/12) (1/15) (9/15) (9/16) (12/16) (12/18) (5/19) (8/19) (1/21) (10/21)

CHI Memorial

POLICY

Title: **ANAPHYLAXIS & ACUTE DRUG HYPERSENSITIVITY REACTION PROTOCOL**			
		Page **1** of **2**	
Policy Number: MM-05449		Date ~~Last~~ reviewed/Revised: ~~12/20~~10/21	Valid Until: ~~12/23~~10/22
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas, Pharmacy		Review Period: ~~Every 3 years~~Annually	

OUTCOME:
Standing orders to be used for immediate intervention in response to a suspected hypersensitivity or anaphylactic reaction to a medication or therapy.

DEFINITIONS & TREATMENTS:

- Mild drug reactions
  A mild hypersensitivity reaction should be suspected in patients exhibiting any of the following symptoms and treatment may be initiated as indicated below:
  - **Isolated skin reactions such as urticaria, itching, rash, or flushing**
    If after stopping the infusion the signs/symptoms do not resolve within 10 minutes or begin to progress proceed with the following and notify physician:
    Diphenhydramine IVP x 1 dose (age < 65: 50 mg, age ≥ 65: 25 mg). If no IV access may administer as IM injection.

- Moderate drug reactions
  A moderate hypersensitivity reaction should be suspected in patients exhibiting any of the following symptoms and treatment may be initiated as indicated below:
  - **Acute onset diffuse skin reactions**
    Treatment: Methylprednisolone 125 mg IVP x 1 dose
  - **Progressive urticaria, itching, rash, or flushing despite treatment with Benadryl**
    Treatment: Methylprednisolone 125 mg IVP x 1 dose
  - **Rigors**
    Treatment: Methylprednisolone 125 mg IVP x 1 dose~~Demerol (meperidine) 25 mg IVP x 1 dose~~
  - **Mild dyspnea without significant wheezing or hypoxemia**
    Treatment: Methylprednisolone 125 mg IVP x 1 dose

- Severe or possible Anaphylactic reactions
  A severe hypersensitivity or anaphylactic reaction should be suspected for any of the following symptoms. These symptoms may also be accompanied by acute skin reactions as described above.
  - **Respiratory compromise:** severe respiratory compromise with significant wheezing, airway edema and/or hypoxemia
  - **Angioedema:** diffuse and painful swelling of loose subcutaneous tissue, dorsum of hands and feet, eyelids, lips, genitalia and mucous membranes
  - **Cardiovascular compromise:** evidenced by symptomatic hypotension (SBP < 90 or 30% decrease in SBP)
    Treatment: Stop infusion immediately and call Code BLUE. Administer 0.5 mg (0.5 ml) Epinephrine 1:1000 (1mg/1ml) x 1 dose **IM** to mid-outer thigh. Epinephrine may be repeated every 5 to 10 minutes, up to 3 total doses as needed. Patient should immediately be placed on monitor after epinephrine administration. Lactated ringers 500 ml IV bolus x1 dose. Administer oxygen to keep O2 sats > 88-90%.

If no response to Epinephrine x 1, OR if symptoms worsen, repeat Epinephrine dosing as indicated above and proceed with the following:

- ✓Diphenhydramine 50 mg IV x 1 dose (if not already given)
- ✓Methylprednisolone 125 mg IV x 1 dose (if not already given)

POLICY:

Standing orders for anaphylaxis and acute drug hypersensitivity intervention may be initiated by a registered nurse in any inpatient or outpatient care area for any suspected acute medication reaction, while awaiting physician contact. Physician should be notified ASAP.

PROCEDURE:

1. Immediately stop all medications being infused for all reactions severities and follow ***Anaphylaxis & Acute Drug Hypersensitivity Protocol MCT*** **orders [3040001225].**
2. For all reaction severities all medications being infused should be immediately stopped.
   a. Mild & Moderate reactions: If treatment indicated the patient may be treated according to the above and as outlined in the ***Anaphylaxis & Acute Drug Hypersensitivity Protocol MCT.*** Orders entered by the RN should be signed with the order mode "Per protocol: cosign required". If treatment administered the patient's provider should be immediately contacted for further orders and for authentication of the standing orders – see below.
   b. Severe hypersensitivity or anaphylactic reactions: Code BLUE should be called immediately (Refer to policy *RAPID RESPONSE TEAM*) and immediate treatment should proceed as indicated above and as outlined in the ***Anaphylaxis & Acute Drug Hypersensitivity Protocol MCT***. Orders entered by the RN should be signed with the order mode "Per protocol: cosign required". The patient's provider should also be contacted for further orders and for authentication of the standing orders – see below.
3. Medications for treatment of mild, moderate, or severe reactions may be removed from the Pyxis MedStation via override function.
4. Physician must sign/authenticate the orders as soon as possible following enactment of the standing orders.
5. 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.
6. If symptoms are relieved, follow physician orders for additional medications.
7. Document medication administration appropriately in the electronic medical record.
8. Return unused items to Pyxis MedStation.

Key Contact: Pharmacy Review Team

Approved/Reviewed by: ~~Pharmacy & Therapeutics~~P&T Committee, Pharmacy Director; Chief Nursing Officer; Nursing Professional Practice Council

Reference(s):

1. MM.04.01.01
2. eCRS Clinical Key: Evidence-Based Nursing: Monographs: Anaphylaxis and Anaphylactic Shock contributed by Melanie Atkinson, RN, MSN, CCRN, 2009
3. Simons, Ardusso, Bilo, et al. World Allergy Organization Guidelines for the Assessment and Management of Anaphylaxis. WAO Journal. 2011, 4: 13-37.

Date First Effective/ Reviewed/Revised: 3/13 (8/16) (3/18) (11/19) (5/20) (12/20)(10/21)

CHI Memorial

POLICY

Title: HYPOGLYCEMIA PROTOCOL			
		Page 1 of 3	
Policy Number: PC-07013		Date ~~Last~~ reviewed/Revised: ~~8/20~~10/21	Valid Until: ~~8/23~~10/22
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas		Review Period: Annually~~Every 3 years~~	

OUTCOME: To provide prompt treatment of the patient when hypoglycemia is present.

DEFINTIONS:

a. **BG:** Blood Glucose
b. **Hypoglycemia**: a BG value ≤70 and should be considered a medical emergency.
c. **Validated Range** for Nova StatStrip is 50-599; ***any value outside of this range needs to be rechecked with a stat lab draw within the hour***.
d. **Critical Values**: Any glucose value <50 and >350. To fulfill the Joint Commission/College of American Pathologists/State of Tennessee requirements for Critical Values, you need to create a comment that is attached to the critical value result.
e. **Critical Value Comments**
   - **RN Notified** - used if test performed by a tech
   - **DR Notified** - used if test performed by an RN who will notify the doctor
   - **BY RN c MD Protocol** - used if test performed by an RN with existing MD orders for critical glucose values
f. **Questioning the Patient's Glucose Result**: If the results do not match the patient's condition, the user can do any of the following:
   - Re-stick and retest patient (use comment "Will Repeat")
   - Order a lab draw
   - Run QC on strips you are using to ensure strips have not been exposed to too much moisture

Note: *if you place the meter into the docking station before entering a comment or lay the meter down without touching the screen for 5 minutes, the meter will save the result without a comment. This is in direct violation of the state and federal rules for documenting critical values and an e-mail report to the manager will be generated.*

POLICY:

The nurse will manage the care and treatment of the patient with Hypoglycemia per protocol.

Possible causes of hypoglycemia are: not eating on time, not eating the entire meal, skipping a meal, interruption of enteral/parenteral feedings, decreased rate of IV dextrose, reduction of corticosteroids, emesis, sepsis, the "peaking" of insulin and/or inappropriate timing of short- or rapid-acting insulin in relation to meals, too much insulin in relation to food and/or activity, failure of the clinician to make adjustments to glycemic therapy based on daily BG patterns, prolonged use of SSI as monotherapy, poor communication during times of patient transfer, or an unusual amount of exercise.

PROCEDURE:

If the patient is symptomatic, do a finger stick blood glucose test with a hospital BG meter. Symptoms may include sweating, shaking, dizzy, faint, headache, hunger, pounding heart, confusion, irritability, stammering, combative or convulsing, or if the patient tells you, "I am having an insulin reaction," or "a low blood sugar". If the BG meets parameters, treat according to protocol.

Initiate Hypoglycemic Protocol MCT Order Set (3040004906~~PSO #1831~~) and notify physician.

Insulin Reaction/Hypoglycemia Protocol is as outlined:

CRITERIA FOR TREATMENT:
■ **Blood Glucose ≤ 70**.

TREATMENT:
Patients who are alert and able to tolerate PO intake:
Blood Glucose 50-70

1. Give 15 grams carbohydrate: 4 oz. fruit juice (not OJ) or 3 glucose tablets (in Pyxis).
2. Recheck BG in 15 minutes and repeat treatment if BG < 80.
3. After 2nd treatment, recheck BG in 15 minutes and repeat treatment if BG remains < 80. If BG fails to increase to > 80 after repeat treatment, treat again and call MD for further orders.
4. For hypoglycemic episodes between 8:00 PM and 6:00 AM: after initial treatment has increased BG to > 80, give 8 oz. of skim or low fat milk and either six saltine crackers or 3 graham crackers.

Blood Glucose ≤ 50

1. Give 30 grams carbohydrate: 8 oz. fruit juice (not OJ) or 6 glucose tablets (in Pyxis).
2. Get stat lab draw due to blood glucose being outside the validated range.
3. Enter critical values comment in Nova StatStrip meter.
4. Recheck BG in 15 minutes and repeat treatment if BG < 80.
5. After 2nd treatment, recheck BG in 15 minutes and repeat treatment if BG remains < 80. If BG fails to increase to > 80 after repeat treatment, treat again and call MD for further orders.
6. Once BG > 80, recheck BG in 1 hour then resume point-of-care BG as previously ordered.
7. For hypoglycemic episodes between 8:00 PM and 6:00 AM: after initial treatment has increased BG to > 80, give 8 oz. of skim or low fat milk and either six saltine crackers or 3 graham crackers.

Patients who are NOT alert or NPO:
With no IV access:

1. Administer Glucagon 1 mg IM x 1 dose – ***obtain IV access ASAP***.
2. If BG < 50, get stat lab draw due to blood glucose being outside the validated range.
3. If BG < 50, enter critical values comment in Nova StatStrip meter.
4. Recheck BG in 15 minutes and if BG < 80 re-treat using D50 as outlined below (if IV access now available). If IV access not yet available, repeat Glucagon 1 mg IM x 1 additional dose and obtain IV access.
5. After 2nd treatment, check BG in 15 minutes and administer D50 as outlined below and call MD for further orders.
6. Once BG > 80, recheck BG in 1 hour then resume point-of-care BG as previously ordered.

With IV access:
Blood Glucose 50-70

1. Administer 25 ml (1/2 amp) D50 – 12.5 gm IVP x 1 dose.
2. Recheck BG in 15 minutes and repeat treatment if BG < 80.
3. After 2nd treatment, check BG in 15 minutes and repeat treatment if BG remains < 80. If BG fails to respond to repeat treatment, treat again and call MD for further orders (dextrose infusions, etc.).

Blood Glucose < 50

1. Administer 50 ml (1 amp) D50 – 25 gm IVP x 1 dose.
2. Get stat lab draw due to blood glucose being outside the validated range.
3. Enter critical values comment in Nova StatStrip meter.
4. Recheck BG in 15 minutes and repeat treatment if BG < 80.
5. After 2nd treatment, check BG in 15 minutes and repeat treatment if BG remains < 80. If BG fails to respond to repeat treatment, treat again and call MD for further orders (dextrose infusions, etc.).
6. Once BG > 80, recheck BG in 1 hour then resume point-of-care BG as previously ordered.

DOCUMENTATION:
Document all hypoglycemic episodes including treatment and physician contact in the "Notes" section and in "Flowsheets" in Daily Care/Safety under Nutrition/Hypoglycemia Management in EPIC, the Electronic Health Record (EHR) Plan of Care.

Key Contact: Diabetes Educator
Approved/Reviewed by: P&T Committee; Nursing Professional Practice Council; CNO.
Reference(s):
~~Physician Standing Order # PSO 1831~~Order Set Hypoglycemia Protocol MCT (3040004906)
American Diabetes Association. Diabetes Care 2020 Jan; 43 (Supplement 1): S193-S202
American Association of Clinical Endocrinologists and American Diabetes Association. Consensus Statement on Inpatient Glycemic Control 2009.
Joint Commission Standard: Provision of Care Chapter (PC) PC 01.01.01
Date First Effective/Revisions: 5/09, 12/13, 7/15, 4/17, 5/20, 8/20, 10/21

CHI Memorial

POLICY

Title: NARCAN (NALOXONE) OPIOID REVERSAL PROTOCOL			
		Page 1 of 2	
Policy Number: PC-07373		Date Last reviewed/Revised: ~~5/21~~10/21	Valid Until: ~~5/24~~10/22
Department(s) Affected: All Clinical Areas		Review Period: ~~every 3 years~~Annually	

OUTCOME:
Standing orders to be used for immediate intervention in response to a suspected narcotic overdose.

DEFINITIONS & TREATMENTS:

- When to suspect a narcotic overdose with unknown narcotic exposure:
  - History of narcotic overdose according to bystanders
  - Paraphernalia
  - Medical/pertinent history consistent with narcotic use
  - Pinpoint pupils
- Signs and symptoms of narcotic overdose
  - Unresponsive or only responsive to painful stimuli
  - Shallow, slow, or absent respirations
  - Cyanosis
  - Slow, erratic, or absent pulse
  - Constricted/pinpoint pupils
  - Hypotension
  - Weakness
- Treatment
  - *Goal:* Not normal level of consciousness, but ADEQUATE VENTILATION.
  - ***EXCEPTION:*** **Must have MD order prior to reversal of patients on Hospice/palliative care**.
  - *Inpatient with* **RECENT** *narcotic administration by RN/LPN:*
    - Narcan 0.4 mg IV (or IM if no IV access)
    - If there is no effect or response in 2-3 minutes after administration, repeat same dose x2 if needed.
  - *Inpatient/Outpatient/Visitor with* ***UNKNOWN*** *narcotic exposure:*
    - Narcan 2 mg IM/IV (do NOT delay administration to obtain IV access!)
    - If there is no effect or response in 2-3 minutes after administration, repeat same dose x2 if needed.

POLICY:
Standing orders for narcotic overdose may be initiated by a registered nurse in any inpatient or outpatient care area for any suspected narcotic overdose while awaiting physician contact. Physician should be notified ASAP. Use clinical judgment to call a Rapid Response at any time.

PROCEDURE:

1. Assess for known or unknown narcotic exposure and follow **Narcan (Naloxone) Opioid Reversal Protocol MCT ~~(PSO#2461[3040004919])~~.**
   - ~~If unknown narcotic exposure, apply PPE before making contact with the patient~~
2. Perform primary survey (ABCs)
   A. If patient is unresponsive and not breathing:
      - Call a CODE BLUE
      - Administer Narcan per protocol

- Narcan may be removed from the Pyxis Med Station via override function or from ~~Rapid Response Team (RRT) Medication~~Intubation Kit.
- Physician must sign/authenticate the orders as soon as possible following enactment of the standing orders.

B. If RR < 10 **AND** vigorous stimulation needed to arouse **OR** unable to arouse patient (POSS = 4):

- Administer Narcan per protocol
  - Narcan may be removed from the Pyxis Med Station via override function/ Obtain from ~~RRT Medication~~Intubation Kit.
  - Physician must sign/authenticate the orders as soon as possible following enactment of the standing orders.
- Apply cardiac monitor and pulse oximetry.
- Provide oxygen 100% non-rebreather mask if intubation is not indicated
- Call RRT if unresponsive to 1-2 doses of Narcan or if patient condition worsens
- Document medication administration appropriately in the medical record
- Return unused items to Pyxis Med Station/~~RRT Medication~~Intubation Kit

POST-NARCAN ADMINISTRATION:

1. Monitor vital signs closely
   a. Every 15 min x4
   b. Every 30 min x 2
   c. Every hour x 2
2. Administer oxygen to keep sats > 88-90%
3. Notify MD of all actions taken and have him/her sign/authenticate the Narcan (Naloxone) Opioid Reversal Protocol MCT~~Narcan Protocol Orderset~~.

Key Contact: Clinical Educator Critical Care
Approved/Reviewed by: Pharmacy Team; P&T Committee; Nursing Professional Practice Council; CNO
Date First Effective & (Revision/Review dates): 3/18 (5/21) (10/21)