Pharmacy & Therapeutics Committee Meeting

SCN Board Room + Zoom

November 9, 2023 7:00 a.m.

Next Meeting Date: <u>TBD 2024</u>

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: September 14, 2023 CALLED TO ORDER: 7:02 a.m.
LOCATION: SCN Boardroom or Zoom ADJOURNED: 8:01 a.m.

Voting Member Attendance:				Non-Voting Member Attendance:		Guests:
X	**Nathan Chamberlain, MD- Chairman**	X	**Matthew Kodsi, MD- Quality**	X	**Karen Babb, PharmD- Manager**	**Claire Hiott, Pharmacy Resident**
X	**Mark Anderson, MD- Infectious Disease**	X	**Aditya Mandawat, MD- Cardiology**		Jamie Barrie, PharmD- Manager, HX	**Asher Melton, Pharmacy Resident**
	Justin Blinn, MD- Anesthesiology	X	**Daniel Marsh, PharmD- Director of Pharmacy**	X	**Kenneth Dyer, PharmD- Operations Manager**	**Cricket Patterson, Pharmacy Resident**
	David Dodson, MD- Hospitalist	X	**Chad Paxson, MD- Intensivist**	X	**Rodney Elliott- Purchasing**	**Raegan Willoughby, Pharmacy Resident**
	Karen Frank, RN- Quality		James Wahl, MD- Hospitalist, GA		Lori Hammon, RN- Quality	**Deb McKaig, Pharmacy Administrative Coordinator**
	Sherry Fusco, RN- CNO	X	**Richard Yap, MD- Hospitalist**		Shannon Harris, RN- Infection Prevention	**Jarrett Kilgore, Student pharmacist**
	F. Lee Hamilton, MD- Hospitalist				Kevin Hopkins, RT- Director of Resp Therapy	**Hailey Dobson, Student pharmacist**
				X	**Rachel Kile, PharmD- Clinical Manager**	
					Carey Smith, RPh- Manager, GA	
					Ingrid Wright, Clinical Dietician	

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 2023 minutes were approved as submitted.	Approved	Complete
CommonSpirit Health System P&T Committee	**July 2023 Decision Brief:** The medication decisions that were approved at the CommonSpirit Health System P&T committee meeting were reviewed. All new system formulary medications or changes were either consistent with existing CHI Memorial formulary decisions or are described in the "Formulary Decisions & Therapeutic Interchanges" section of the minutes below, or will be reviewed at an upcoming P&T committee meeting, with the exception of the following: a. Restriction of guaifenesin w/ codeine antitussive liquid: Recent recommendation that antitussive products with codeine be restricted to adult use only per FDA recommendation. Rachel reported that a utilization report for this calendar year found only one order for this medication.	Approved	Complete

Formulary Decisions & Therapeutic Interchanges	**A. Bevacizumab-maly (Alymsys):** Alymsys is a new biosimilar for the reference product, Avastin. It is a vascular endothelial growth factor inhibitor indicated for the treatment of metastatic colorectal cancer in combination with other chemotherapy agents. Per the CHI Memorial Biosimilar policy, new biosimilars that have been FDA approved for the same indications as the reference product (RP) will be automatically added to hospital formulary if the RP is currently approved as a formulary agent. Any formulary restrictions currently in place for the RP will be applied to the biosimilar medication. **B. Drug shortage update**: Nystatin powder 15 gram bottles is currently a critical shortage item. On September 8, 2023 the P&T Committee chairman, CMO, and Hospitalist Medical Director emergently approved the automatic interchange by pharmacists of nystatin to miconazole powder at the same dosing frequency. The recommendation was made to formally approve the pharmacist emergent automatic interchange for orders of nystatin powder to miconazole powder during times of nystatin powder shortage. **C. Medications for COVID-19:** The FDA fully approved remdesivir (Veklury) for use in patients with severe renal impairment, including those receiving hemodialysis based on a Phase 1 and Phase III RED TIME trials which included hospitalized patients with severe renal impairment and HD patients. These patients received doses with no renal adjustment and no new safety signals were identified. The recommendation to remove the requirement for renal testing prior to initiating remdesivir and removal of eGFR <30 ml/minute precaution was approved.	Approved Approved Approved	Complete Complete Complete
Protocols & Orders	A. **Heparin Drip Order set:** Our nursing staff have been questioning the requirement to wait for lab results before initiating a heparin drip based on the following order on the Heparin Drip Order MCT order set: *"Notify physician before initiating protocol if baseline aPTT is GREATER than 50 or INR is GREATER than 2, or platelets are LESS than 100,000".* Physician leadership recommended the following update to the order: "Notify physician before starting protocol if patient has results within the last 24 hours that show aPTT GREATER than 50, INR GREATER than 2 or platelets LESS than 100,000. Otherwise start protocol and notify physician if baseline labs show any of these values." These changes will clarify that it is appropriate to begin heparin infusion prior to baseline lab results. It also verifies that the provider is aware of significant values already present and provides instruction for nursing on action if significant baseline laboratory values return. The changes have been updated in Epic. B. **Methocarbamol Hard Limit in EHR:** An IRIS report was submitted due to an active order for IV methocarbamol every 8 hours remaining on a patient's chart for over 1 week. It is recommended that max dose is 3 g/day for no more than 3 days with a 48 hour washout period due to accumulation of polyethylene glycol. It was recommended to grant approval for pharmacists to: a. Automatically discontinue active orders for IV methocarbamol once the order is active for more than 3 consecutive days **OR** b. If the original order is for longer than 3 days, pharmacists may limit the order to 3 days. Providers may re-order after a 48 hour washout period.	Informational Approved	Complete Complete
Medication Use	**A. Patient Controlled Analgesia (PCA) orders MUE:** Nurses brought questions regarding PCA orders to the Medication Safety Committee concerning the dose of PCAs for patients who are elderly or may be particularly sensitive to opiates (opiate naïve). The results of an MUE were presented at the Medication Safety Committee and the recommendation from that committee was to get P&T Committee input regarding suggested recommendations. Based on the results of the MUE, the following recommendations/conclusions were made by the Medication Safety Committee: a. Unclear if order selection was intentional, or a "favorite" on post-op order set	Approved	Incomplete

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b. Should the PCA order set specify to discontinue all other PRN opiates at same time as PCA ordered?
c. Should order set specify to change the order to the “high risk” dosing panel if the patient meets such criteria and no exclusions are met? Exclusions might include: providers who do not order a PCA directly from order set (“custom” orders) or hospice, palliative care and/or end of life orders from critical care.
d. Change the order of the medication panels in the set to place “high risk” order at top rather than the standard dose
Discussion followed with the decision to discuss this with heavy users of the order set and surgeons who would be most impacted by changes to the order panels. Recommendations will be shared for review and discussion at Med Exec.
B. Sedative/Hypnotic & Patient Falls MUE: At a prior P&T Committee meeting, the Sedative/Hypnotics for Sleep policy was reviewed. A MUE was performed from January to March of 2023 and 56 patients aged 65 or older were identified with documented fall incidents. The medications cross referenced in the MUE with the fall list are listed in the P&T packet. Approximately 9% of patients that fell received a potentially inappropriate medication around bedtime 24 hours before documented fall. Due to the results of the MUE, there was an evaluation of safer alternative sleep medications compared to current formulary medications. It was also postulated to consider hospitalist education, review of the current sedative/hypnotic sleep policy with a focus on sleep safety, or potential guidelines for prioritizing appropriate medication selection for sleep and increased fall monitoring/precautions with addition of medications to the MAR. Physician discussion followed with recommendations for non-pharmacologic options for sleep. Dr. Paxson suggested restricting BZDs for the purpose of sleep, regardless of age, but rather based on presence of fall risks. Dr. Kodsi recommended a step-wise list for nurses to use when administering sleep medications. It was recommended to:
a. Add Eszopiclone (Lunesta) 1 and 2 mg tablets to formulary with the same ordering restrictions as other sedative/hypnotic agents per policy.
b. Approve a sedative/hypnotic automatic pharmacist therapeutic interchange as follows, in addition to the currently approved interchanges:
<u>Sedative Hypnotic Therapeutic Interchange</u>
<table>
<tr><th>Medication Ordered</th><th>Dose Ordered</th><th>Formulary Medication</th><th>Frequency</th></tr>
<tr><td>Zolpidem CR (Ambien CR)</td><td>6.25 mg or 12.5mg</td><td>Zolpidem (Ambien) 5mg</td><td rowspan="12">As ordered</td></tr>
<tr><td>Ramelteon (Rozerem)</td><td>8mg</td><td>Melatonin 3 mg</td></tr>
<tr><td rowspan="5">Zaleplon (Sonata)</td><td rowspan="3">5mg</td><td>Eszopiclone (Lunesta) 1 mg</td></tr>
<tr><td>OR</td></tr>
<tr><td>Zolpidem (Ambien) 5 mg</td></tr>
<tr><td rowspan="3">10mg</td><td>Eszopiclone (Lunesta) 2 mg</td></tr>
<tr><td>OR</td></tr>
<tr><td>Zolpidem (Ambien) 5 mg</td></tr>
<tr><td rowspan="5">Suvorexant (Belsomra)</td><td rowspan="3">10mg</td><td>Eszopiclone (Lunesta) 1 mg</td></tr>
<tr><td>OR</td></tr>
<tr><td>Zolpidem (Ambien) 5mg</td></tr>
<tr><td rowspan="3">20mg</td><td>Eszopiclone (Lunesta) 2 mg</td></tr>
<tr><td>OR</td></tr>
<tr><td>Zolpidem (Ambien) 5 mg</td></tr>
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Lastly, Dr. Mandawat will reach out to a colleague at UCLA to inquire about their sleep program and a subcommittee will convene to work towards development of an enhanced safe sleep policy that includes non-pharmacologic and pharmacologic guidance.
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<td>Policies</td>
<td>A. Biosimilar Medications: The Biosimilar Medications-Formulary Management policy was reviewed and approved with no edits required.</td>
<td>Approved</td>
<td>Complete</td>
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	B. Look-Alike Sound-Alike Policy: Addition of pentobarbital to LASA drug list due to recent error that reached the patient. No patient harm resulted. Discussed with neurology and decision was made to keep pentobarbital in stock due to expansion of neurology services.	Approved	Complete
Subcommittee Meeting Minutes	**A. Antimicrobial Stewardship August 2023:** **a. Beta-lactam allergy clarification and delabeling project report:** Pharmacy-led beta-lactam allergy clarification protocol led to 167 interventions during 1 month period, with most common intervention being allergy clarification by medication history technicians. The committee is planning to present to outpatient physicians groups to encourage penicillin test dose challenges in patients with low-risk allergies. **b. Pharmacist intervention on discharge antibiotic therapy for CAP:** In January 2023, a new CAP pharmacist evaluation document was created and implemented through education and workflow changes with the goal of optimizing antibiotic therapy with a focus on reducing duration of therapy at discharge. A decentralized pharmacist reviewed CAP patients and made recommendations encouraging providers to switch to an appropriate agent, route, dose and duration of therapy. i. The median duration of total antibiotics & discharge antibiotics decreased by one day in the post-intervention group. ii. Majority of the discharge antibiotics were deemed appropriate, although most appropriate in post-intervention (91.7% and 97.3%, respectively). iii. 40.5% of patients in the post-intervention group had pharmacist interventions and 100% of interventions were accepted. **c. UA/urine culture criteria update in EPIC**: CSH will be adding indications to all urine culture orders. All UAs and urine cultures will live in a panel. The committee voted to remove UA with reflex to culture order from the following order sets: MCT ED nursing protocols quick list, MCT IP Cardiology admission, MCR IP Gen Common Labs, MCT IP Neu Stroke Intracranial hemorrhage (intraparenchymal), MCT IP CC ECMO, MCT IP Gen Diabetic ketoacidosis (DKA), MCT IP Neu Stroke non TPA & TIA, MCT IP Pat preoperative testing, MCT IP Ren Peritoneal dialysis) **d. Rebyota**: This is a fecal microbiota rectal instillation approved for use in November 2022. It is indicated for prevention of recurrent C. difficile infection within 72 hours after treatment with oral vancomycin or fidaxomicin. Evidence for this product is based on the PUNCH CD3 study that demonstrated a treatment success at 8 weeks of 71.4% for Rebyota and 62.4% for placebo. The CSH P&T committee has restricted it to outpatient setting subsequent to payer approval due to cost and other factors. There will be discussion with outpatient infusion administrators and GI to formulate a final plan for use of this product. **e. VOWST:** This product is a fecal transplant oral capsule that was approved for use in April 2023, although it is not available for purchase currently. It is indicated for prevention of recurrent C diff infection within 48-96h after treatment with standard drugs such as oral vancomycin or fidaxomicin. Evidence for this product is based on the ECOSPOR III study which demonstrated C.difficile infection recurrence rate at 8 weeks was 12% with VOWST and 40% with placebo. Due to cost and other factors, this product is non-formulary. **f. Other topics**: Discussed focus area for antimicrobial stewardship for cellulitis and aspiration pneumonia. AUC-based vancomycin dosing system implementation was also discussed. **g. Next meeting discussion:** Xacduro and Rezzayo		

There being no further business, the meeting was adjourned at 8:01 a.m. The next P&T meeting is **November 9, 2023.**

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

Approved by,
Nathan Chamberlain, MD, Chairman

CSH SYSTEM PHARMACY AND THERAPEUTICS COUNCIL DECISION BRIEF

September 2023 Decisions

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

Medication Name	Medication Used For	Formulary Decision			Comments/Restrictions/Therapeutic Interchange	Time to implementation
		Formulary Unrestricted	Formulary Restricted	NonFormulary		
nirsevimab-alip	RSV infection prevention in infants		BEYFORTUS		Restriction Criteria: Outpatient: Use per CDC/ACIP recommendations (payer coverage/prior authorization should be confirmed) Inpatient: Use per CDC/ACIP recommendations and one of the following: 1. State vaccination program eligible: May be given during hospitalization if available/authorized for inpatient administration via state vaccination program (eligibility and requirements vary by state) 2. Infants with birth hospitalizations exceeding 7 days : nirsevimab may be given shortly before or promptly following discharge 3. Inpatient administration prior to discharge may be considered at provider discretion if prompt administration following discharge not likely or feasible AAP Nirsevimab Administration Guide (Sept 23) Nirsevimab - CommonSpirit Health Site of Care Flowchart	Within 90 days of System P&T Committee approval
perfluorohexyloctane	Dry eye disease			MIEBO	Link to therapeutic interchange	Within 90 days of System P&T Committee approval

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		Formulary Unrestricted	Formulary Restricted	NonFormulary		
mosunetuzumab-axgb	Follicular lymphoma		LUNSUMIO		Restriction Criteria: Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
porfimer	Esophageal cancer, NSCLC, high-grade dysplasia in Barrett's esophagus		PHOTOFRIN		Restriction Criteria: Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
pneumococcal 20-valent conjugate vaccine	Prevention of pneumococcal infection		PREVNAR 20		Restriction Criteria: Outpatient use (adult and pediatric): unrestricted Inpatient use: • Patients 65 years or older with underlying medical conditions or other risk factors* and cannot wait until after discharge to be vaccinated who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown • Patients where continuation of care is not likely (e.g. homeless) or where routine pneumococcal screening is required per state law *Risk factors include: alcoholism; chronic heart, liver, or lung disease; chronic renal failure; cigarette smoking; cochlear implant; congenital or acquired asplenia; cerebrospinal fluid leak; diabetes mellitus; generalized malignancy; HIV; Hodgkin disease; immunodeficiency; iatrogenic immunosuppression; leukemia, lymphoma, or multiple myeloma; nephrotic syndrome; solid organ transplant; sickle cell disease; or other hemoglobinopathies	Within 90 days of System P&T Committee approval

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rezafungin	Candidemia and invasive candidiasis			REZZAYO		Within 60 days of System P&T Committee approval
pegcetacoplan	age-related macular degeneration		SYFOVRE		Restriction Criteria: Outpatient setting for FDA-approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.	Within 90 days of System P&T Committee approval
quizartinib	Acute myeloid leukemia			VANFLYTA		Within 60 days of System P&T Committee approval
sulbactam / durlobactam	hospital-acquired and ventilator-acquired bacterial pneumonia caused by carbapenem-resistant *Acinetobacter baumannii-calcoaceticus* complex (CRAB)		XACDURO		Restriction Criteria: Prescribed by ID specialist only (where available) and diagnosis must be infection due to confirmed carbapenem-resistant Acinetobacter baumannii-calcoaceticus complex	Within 90 days of System P&T Committee approval
belantamab mafodotin-blmf	Refractory multiple myeloma			BLENREP	Link to AHFS multi class anti-neoplastic data	Within 60 days of System P&T Committee approval
doxylamine	Nausea and vomiting prevention	UNISOM			Link to AHFS multi class antihistamine data	Within 90 days of System P&T Committee approval
prochlorperazine injection	Nausea and vomiting prevention	PROCHLORPERAZINE, COMPAZINE			Link to AHFS multi class antihistamine data	Within 90 days of System P&T Committee approval

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paricalcitol	Secondary hyperparathyroidism	ZEMPLAR			Link to AHFS multi class vitamin data	Within 90 days of System P&T Committee approval
respiratory syncytial virus (RSV) vaccines	Prevention of RSV in infants through maternal vaccination		ABRYSVO		Restriction Criteria: Outpatient setting only (in accordance with ACIP recommendations for maternal use)	Within 90 days of System P&T Committee approval
	Prevention of RSV in older adults		AREXVY, ABRYSVO		Restriction Criteria: Outpatient use for FDA-approved indications only in populations and settings in which reimbursement is offered/available* or payer-approved off-label indications subsequent to insurance approval or prior authorization. *reimbursement for Medicare beneficiaries is limited to the part D benefit and vaccination should be deferred to community pharmacies unless clinic locations are equipped/able to bill Medicare part D	Within 90 days of System P&T Committee approval
etranacogene dezaparvovec-drlb	Hemophilia B			HEMGENIX		Within 60 days of System P&T Committee approval
delandistrogene moxeparvovec-rokl	Duchenne muscular dystrophy			ELEVIDYS		Within 60 days of System P&T Committee approval
valoctocogene roxaparvovec-rvox	Hemophilia A			ROCTAVIAN		Within 60 days of System P&T Committee approval
autologous	Repair of single or			MACI		Within 60 days

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cultured chondrocytes/ collagen	multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adult					of System P&T Committee approval
Azficel-T	Improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults			LAVIV		Within 60 days of System P&T Committee approval
Allogeneic Cultured Keratinocytes and Fibroblasts	Topical application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults			GINTUIT		Within 60 days of System P&T Committee approval
voretigene neparvovec-rzyl	retinal dystrophy			LUXTURNA		Within 60 days of System P&T Committee approval
onasemnogene abeparvovec-xioi	pediatric spinal muscular atrophy			ZOLGENSMA		Within 60 days of System P&T Committee approval
thymus tissue-agdc	pediatric patients with congenital athymia			RETHYMIC		Within 60 days of System P&T Committee approval
omidubicel-onlv	allogeneic hematopoietic cell transplantation			OMISIRGE		Within 60 days of System P&T Committee approval
donislecel-jujn	Diabetes mellitus,			LANTIDRA		Within 60 days

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	type 1, treatment					of System P&T Committee approval
elivaldogene autotemcel	Cerebral adrenoleukodystrophy			SKYSONA		Within 60 days of System P&T Committee approval
betibeglogene autotemcel	Beta thalassemia			ZYNTEGLO		Within 60 days of System P&T Committee approval
keratinocytes, fibroblasts, collagen-dsat	the treatment of adult patients with thermal burns containing intact dermal elements (remaining deep skin layers) for which surgical intervention is clinically indicated (deep partial thickness burns)			STRATAGRAFT		Within 60 days of System P&T Committee approval
beremagene geperpavec-svdt	Dystrophic epidermolysis bullosa			VYJUVEK		Within 60 days of System P&T Committee approval
tisagenlecleucel	Acute lymphoblastic leukemia, relapsed or refractory Diffuse large B-cell lymphoma, relapsed or refractory Follicular lymphoma,		KYMRIAH		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent	Within 90 days of System P&T Committee approval

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	relapsed or refractory				to insurance approval or prior authorization where other therapy options are limited.	
sipuleucel-T	Metastatic prostate cancer		PROVENGE		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval
talimogene laherparepvec	Unresectable melanoma		IMLYGIC		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval
ciltacabtagene autoleucel	Multple myeloma, relapsed or refractory		CARVYKTI		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval

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idecabtagene vicleucel	Multple myeloma, relapsed or refractory		ABECMA		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval
axicabtagene ciloleucel	Follicular lymphoma, relapsed or refractory and Large B-cell lymphoma, relapsed or refractory		YESCARTA		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval
brexucabtagene autoleucel	Acute lymphoblastic leukemia, B-cell precursor, relapsed or refractory and mantle cell lymphoma, relapsed or refractory		TECARTUS		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval

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lisocabtagene maraleucel	Large B-cell lymphoma, relapsed or refractory		BREYANZI		Restriction Criteria: Outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited. *CAR-T Centers for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization where other therapy options are limited.	Within 90 days of System P&T Committee approval
anacaulase-bcdb	the removal of eschar after a thermal burn incident		NEXOBRID		Restriction Criteria: • burn surgeon in burn centers • adult patients with deep partial or full thickness thermal burn EHR/HOS guidance • provide nursing training on application • provide patient with adequate pain management	Within 90 days of System P&T Committee approval

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lecanemab-irmb	Alzheimer's disease		LEQEMBI		Restriction Criteria: Outpatient setting for FDA-approved indications or payor-approved off-label indications subsequent to insurance approval or prior authorization **Medicare National Coverage Determination:** (must meet ALL of the below, in addition to any label requirements specified by the FDA) a) be enrolled in Medicare Part B b) be diagnosed with mild cognitive impairment or early dementia caused by Alzheimer's disease c) have a qualified physician participating in a registry with an appropriate clinical team and follow-up care (Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease CED Study Registry)* * Note: it is the ordering provider's responsibility to enroll patients in the registry **Clinical Considerations & Monitoring Requirements:** • Presence of amyloid beta pathology should be confirmed prior to initiating therapy (PET or lumbar puncture). • Patient presents with mild cognitive impairment or mild dementia stage of disease confirmed by a mental status scale (clinical dementia rating - CDR, mini-mental examination status -MMSE, Montreal cognitive assessment - MoCA). • ApoE genotyping should be performed prior to initiation to inform the risk of developing ARIA. Risk of ARIA is highest in ApoE ε4 homozygotes compared to heterozygotes and	Within 90 days of System P&T Committee approval

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					noncarriers. Therapy should likely be avoided if the patient is ApoE ε4/ε4. ● MRI monitoring available for pre-treatment assessment of ARIA and ongoing MRI monitoring for ARIA as required by package labeling*: o Brain MRI prior to initiation (within 1 year) o quantification of microhemorrhages: > 4 are associated with increased risk of ARIA o Brain MRI prior to 5th, 7th, 14th infusions and periodically as appropriate in the setting of ARIA. * Patients with contraindications to brain MRI (pacemaker, etc.) should not receive lecanemab ● Concomitant Antithrombotic & Anticoagulant Therapy o Antithrombotics (Aspirin or other antiplatelet): in clinical trials the use of antithrombotic medications did not increase the risk of ARIA o Anticoagulants: caution should be exercised when considering the use of lecanemab in patients on concomitant anticoagulant therapy due to a potential increased risk of intracerebral hemorrhage. ● Prescribing clinicians or their staff shall submit at first baseline treatment via the dedicated CMS CED data submission portal and every six	

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					months for up to 24 months (five total assessments). **Billing and Reimbursement:** ● Prior authorization approval for commercial insurers is required before lecanemab is procured. ● A new permanent J-code for lecanemab is now available (J0174) ● Billing Medicare requires information described on page 2 of this CMS document: o Note: some unique coding/billing requirements do apply such as the use of a "registry trial number" and the use of a "Q" modifier - detail outlined per the below link ● CMS National Patient Registry for New Within 90 days of System P&T Committee approval Alzheimer's Drugs	

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COVID - 19 vaccines	COVID-19 infection prevention	COMIRNATY, SPIKEVAX				Within 90 days of System P&T Committee approval
bexagliflozin	Diabetes mellitus, type 2			BRENZAVVY	Link to therapeutic interchange	Within 90 days of System P&T Committee approval
ertugliflozin pidolate	Diabetes mellitus, type 2			STEGLATRO	Link to therapeutic interchange	Within 90 days of System P&T Committee approval
dapagliflozin	Diabetes mellitus, type 2 and heart failure	FARXIGA				Within 90 days of System P&T Committee approval
empagliflozin	Diabetes mellitus, type 2 and heart failure	JARDIANCE				Within 90 days of System P&T Committee approval
canagliflozin	Diabetes mellitus, type 2			INVOKANA	Link to therapeutic interchange	Within 90 days of System P&T Committee approval
sotagliflozin	Diabetes mellitus, type 2			INPEFA	Link to therapeutic interchange	Within 90 days of System P&T Committee approval

THERAPEUTIC INTERCHANGES

Perfluorohexyloctane ophthalmic solution (Meibo)	
Ordered	**Provided**
Perfluorohexyloctane (Miebo) Instill 1 drop into the affected eye(s) 4 times daily	Polyvinyl alcohol (artificial tears) 1.4% ophthalmic solution at same dose and frequency as ordered OR most cost-effective artificial tear product available same dose and frequency as ordered

SGLT2 Inhibitors	
Ordered	**Provided**
Bexagliflozin 20 mg	Empagliflozin 10 mg
Canagliflozin 100 mg	Empagliflozin 10 mg
Canagliflozin 300 mg	Empagliflozin 25 mg
Ertugliflozin 5 mg	Empagliflozin 10 mg
Ertugliflozin 15 mg	Empagliflozin 25 mg
Sotagliflozin 200 mg	Empagliflozin 10 mg

FORMULARY UPDATE

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

GENERIC NAME: Empagliflozin

PROPRIETARY NAME: Jardiance®

BACKGROUND/RATIONALE:
Sodium-glucose co-transporter-2 inhibitors (SGLT2i) are oral agents initially prescribed for their efficacy in diabetes mellitus patients as an adjunct therapy. However, over the years, its cardioprotective and renoprotective benefits in various disease states like chronic kidney disease and heart failure (HF) have made this drug class a key component of comprehensive disease management. Bexagliflozin (Inpefa), canagliflozin (Invokana), dapagliflozin (Farxiga), empagliflozin (Jardiance) and ertugliflozin (Steglatro) are the five available SGLT2i. Sotagliflozin is a newer agent approved for HF and has affinity for both SGLT 1 and 2 inhibitors. Sotagliflozin has no data in patients without diabetes. Bexagliflozin did not show any significant difference in Major Adverse Cardiovascular Events (MACE) when compared with placebo. Canagliflozin showed significant differences in MACE but has increased cost with use compared to the other SGLT2i. SGLT2i are included in the 2022 AHA/ACC/HFSA Guideline for the Management of HF (dapagliflozin and empagliflozin as SGLT2i of choice). Guideline-directed medical therapy (GDMT) for HF with reduced ejection fraction (HFrEF) now includes 4 medication classes that include SGLT2i.

The only SGLT2i on the CHI Memorial formulary is empagliflozin. The CommonSpirit Health System P&T Committee recently approved dapagliflozin to system formulary, in addition to empagliflozin, as it now has the same FDA indication as empagliflozin for HF.

CURRENT CHI MEMORIAL RESTRICTION CRITERIA FOR EMPAGLIFLOZIN**:**

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:
    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

PHARMACOECONOMICS/COST:

Product	Cost per tablet
Jardiance (empagliflozin) 10 mg or 25 mg tablet	$13.18
Farxiga (dapagliflozin) 5 mg tablet	$14.14
Farxiga (dapagliflozin) 10 mg tablet	$12.41

RECOMMENDATION/DISCUSSION:
Based on GDMT use of empagliflozin in HF, it is recommended to revise the current use restrictions 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 must meet the following criteria for use:
    a. eGFR is >= 25 and renal function is stable or improving (patients with eGFR <25 mL/min have not been evaluated)
    b. Patient does not have recurrent UTIs
    c. Patient does not have history of, or at high risk for, DKA
    d. Patient does not have hypovolemia
    e. Patient does not have severe PAD, foot ulcerations, or at risk of amputation

It is also recommended that dapagliflozin (Farxiga) remain non-formulary at this time in order to maintain lower inventory costs and simplification of the SGLT2i available on formulary.

FORMULARY REVIEW

GENERIC NAME: Inclisiran

PROPRIETARY NAME: *Leqvio®*

INDICATIONS:

FDA Approved
Heterozygous familial hypercholesterolemia ● Adjunct to diet and maximally tolerated statin therapy in patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) Clinical atherosclerotic cardiovascular disease (atherosclerosis) ● Adjunct to diet and maximally tolerated statin therapy in patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

THERAPEUTIC CATEGORY: Antilipemic - Small interfering ribonucleic acid (siRNA) agent that prevents proprotein convertase subtilisin/kexin type 9 (PCSK9) production in the liver

SIMILAR DRUGS:

- PCSK9 Inhibitors – Alirocumab (Praluent) and evolocumab (Repatha)
    - Human monoclonal IgG1 antibody that binds to and inhibits PCSK9 binding to low-density lipoprotein receptors (LDLR)

PHARMACOKINETICS:

	Inclisiran
Absorption	● Cmax: 509 ng/mL ● Time to peak: ~4 hours ● Mean AUC: 7980 ng*h/mL
Distribution	● Volume of distribution: ~500 L ● Protein binding: 87%
Metabolism	● Metabolized primarily by nucleases to shorter nucleotides of varying length
Elimination	● Half-life elimination ~9 hours ● Renal elimination: ~16%

SPECIAL POPULATIONS:

	Inclisiran
Pregnancy	Discontinue inclisiran when pregnancy is recognized. There are no available data on the use of inclisiran in pregnant patients to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Treatment of hyperlipidemia is not generally necessary during pregnancy and the lipid lowering effects of inclisiran may cause fetal harm.
Lactation	There is no information on the presence of inclisiran in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, inclisiran was present in the milk of lactating rats in all dose groups, however, there was no evidence of systemic absorption in the suckling rat neonates. Oligonucleotide-based products typically have poor oral bioavailability; therefore, it is considered unlikely that low levels of inclisiran present in milk will adversely impact an infant's development during lactation.
Pediatrics	Not studied
Geriatrics	No overall differences in safety or effectiveness were observed between age ranges in the 1833 patients treated with inclisiran in clinical studies.
Hepatic Impairment	Approximately 1.1 to 2.1-fold increase in inclisiran Cmax and 1.3 to 2.0-fold increase in AUC reported in patients with mild and moderate hepatic impairment. Reductions in LDL-C were similar with normal hepatic function and mild hepatic impairment, but were less in those with moderate hepatic impairment. Inclisiran has not been studied in severe hepatic impairment.
Renal Impairment	Approximately 2.3 to 3.3-fold increase in inclisiran Cmax and 1.6 to 2.3-fold increase in AUC reported in patients with mild, moderate or severe renal impairment. Reductions in LDL-C were similar across all groups based on renal function.

CLINICAL STUDIES:

ORION-10 LDL-C Reduction in Patients with Clinical Atherosclerotic Cardiovascular Disease	
METHODS	
Study Design	● Multicenter, double-blind, randomized, placebo-controlled conducted in the United States
Study Funding	● Funded by the Medicines Company – Designed trial protocol along with authors and the steering committee (with subsequent review and approval by regulators) and selected participating sites
Patient Enrollment Inclusion	● Ages ≥18 years ● LDL cholesterol levels at screening ≥70 mg per deciliter ● History of ASCVD ● Maximum tolerated or intolerance to statin therapy ● On a stable dose of lipid-lowering therapy for ≥30 days before screening with no planned medication or dose changes ● eGFR >30 mL/min/1.73 m2
Patient Enrollment Exclusion	● Treatment with monoclonal antibodies directed towards PCSK9 within the past 90 days ● Major adverse cardiovascular event within the past 3 months ● Any uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study ● Cardiac arrhythmia within past 3 months that is not controlled by medication/ablation ● New York Heart Association (NYHA) class IV heart failure or last known left ventricular ejection fraction <25% ● Uncontrolled severe hypertension ● Active liver disease ● Life expectancy less than 2 years
Baseline Characteristics	● Mean age: Inclisiran – 66.4 years, Placebo – 65.7 years ● Male sex: Inclisiran – 68.5%, Placebo – 70.3% ● White race: Inclisiran – 83.6%, Placebo – 87.8% ● Percentage with diabetes: 42% ● Percentage of patients on stable doses of statin treatment: 89.2% ● Percentage of patients using ezetimibe: 9.9% ● **Mean (±SD) LDL cholesterol level at baseline: 104.7±38.3 mg/dL**
Treatment Plan	● Screened 2329 patients with 1561 undergoing randomization ● Randomized 1:1 to inclisiran 284 mg or placebo administered as a 1.5 ml subcutaneous injection under blinded conditions for four injections (day 1, 90, 270, and 450) ● Patients attended clinic on days 30, 150, 330, and 510 for follow-up and laboratory assessments. The end-of-trial visit was conducted on day 540.
RESULTS	
Primary Endpoint	● **Percentage change in LDL cholesterol level** at day 510 o Inclisiran: -52.3%, Placebo: 1.0% o Between-group difference of −52.3% (95% CI, −55.7 to −48.8; P<0.001) ● **Time-adjusted change in LDL cholesterol** level after day 90 and up to day 540 as compared with baseline o Inclisiran: -51.3%, Placebo: 2.5% o Between-group difference of −53.8% (95% CI, −56.2 to −51.3; P<0.001)
Secondary Endpoint	● Absolute change in LDL cholesterol level at day 510 o Inclisiran: -56.2 mg/dL, Placebo: -2.1 mg/dL o Between-group difference of −54.1 mg/dL (95% CI, −57.4 to −50.9 mg/dL; P<0.001) ● Time-adjusted absolute change in LDL cholesterol level from day 90 to day 540 o Inclisiran: -53.7 mg/dL, Placebo: -0.4 mg/dL o Difference of −53.3 mg per deciliter (95% CI, −55.8 to −50.8 mg/dL; P<0.001) ● Percentage change in PCSK9 levels from baseline at day 510 o Inclisiran: -69.8%, Placebo: 13.5% o Between-group difference of −83.3% (95% CI, −89.3 to −77.3; P<0.001) ● Inclisiran resulted in improvement in other key secondary end points at day 510 as compared with placebo, including lower levels of total cholesterol, non-HDL cholesterol, and apolipoprotein B (P<0.001 for all three comparisons)
Adverse Events	● Total adverse events o Inclisiran: 574/781 patients (73.5%), Placebo: 582/778 (74.8%)

	● Serious adverse events o Inclisiran: 175/781 patients (22.4%), Placebo: 205/778 (26.3%) o All cause death - Inclisiran: 12/781 (1.5%), Placebo: 11/778 (1.4%) ● Injection-site adverse events o Inclisiran 20/781 (2.7%), Placebo 7/778 (0.9%) ● AEs reported in ≥ 5% of patients that occurred more frequently in the inclisiran group than the placebo group o Diabetes Mellitus- Inclisiran (15%), Placebo (14%) o Bronchitis- Inclisiran (6%), Placebo (4%) o Dyspnea- Inclisiran (5%), Placebo (4%)
Limitations	● High degree of involvement from the sponsor ● Study was not designed or powered to analyze patient-centered outcomes ● Low proportion of non-white patients enrolled
ORION-11 LDL-C Reduction in Patients with Clinical Atherosclerotic Cardiovascular Disease	
METHODS	
Study Design	● Multicenter, double-blind, randomized, placebo-controlled conducted in Europe and South Africa (trial protocol nearly identical to ORION-10)
Study Funding	● Funded by the Medicines Company – Designed trial protocol along with authors and the steering committee (with subsequent review and approval by regulators) and selected participating countries and sites
Patient Enrollment Inclusion	● Ages ≥18 years ● LDL cholesterol levels at screening ≥70 mg per deciliter ● History of ASCVD *or an ASCVD risk equivalent (type 2 diabetes, familial hypercholesterolemia, or a 10-year risk of a cardiovascular event of ≥20%)* **o Only difference in trial protocol between ORION-10 and ORION-11** ● Maximum tolerated or intolerance to statin therapy ● On a stable dose of lipid-lowering therapy for ≥30 days before screening with no planned medication or dose changes ● eGFR >30 mL/min/1.73 m2
Patient Enrollment Exclusion	● Treatment with monoclonal antibodies directed towards PCSK9 within the past 90 days ● Major adverse cardiovascular event within the past 3 months ● Any uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study ● Cardiac arrhythmia within past 3 months that is not controlled by medication/ablation ● New York Heart Association (NYHA) class IV heart failure or last known left ventricular ejection fraction <25% ● Uncontrolled severe hypertension ● Active liver disease ● Life expectancy less than 2 years
Baseline Characteristics	● Mean age: 64.8 years ● Male sex: Inclisiran – 71.5%, Placebo – 72.0% ● White race: Inclisiran – 97.7%, Placebo – 98.6% ● Patients with a history of ASCVD: 87.6% ● Patients with ASCVD risk-equivalents: 12.4% ● **Mean baseline LDL-C: 112 mg/dl** ● Percentage of patients on statin treatment: 96.2% ● Percentage of patients on ezetimibe: 7.1%
Treatment Plan	● Screened 2381 patients with 1617 undergoing randomization ● Randomized 1:1 to inclisiran 284 mg or placebo administered as a 1.5 ml subcutaneous injection under blinded conditions for four injections (day 1, 90, 270, and 450) ● Patients attended clinic on days 30, 150, 330, and 510 for follow-up and laboratory assessments. The end-of-trial visit was conducted on day 540.
RESULTS	
Primary Endpoint	● **Percentage change in LDL cholesterol level** at day 510 was o Inclisiran: -45.8%, Placebo: 4.0% o Between-group difference of −49.9% (95% CI, −53.1 to −46.6; P<0.001) ● **Time-adjusted change in LDL cholesterol** level after day 90 and up to day 540 as compared with baseline

	o Inclisiran: -45.8%, Placebo: 3.4% o Between-group difference of −49.2% (95% CI, −51.6 to −46.8; P<0.001)
Secondary Endpoint	● Absolute change in LDL cholesterol level at day 510 o Inclisiran: -50.9 mg/dL, Placebo: 1.0 mg/dL o Between-group difference of −51.9 mg/dL (95% CI, −55.0 to −48.7 mg/dL; P<0.001) ● Time-adjusted absolute change in LDL cholesterol level from day 90 to day 540 o Inclisiran: -48.6 mg/dL, Placebo: 0.3 mg/dL o Difference of −48.9 mg/dL (95% CI, −51.4 to −46.5 mg/dL; P<0.001) ● Percentage change in PCSK9 levels from baseline at day 510 o Inclisiran: −63.6%, Placebo: 15.6% o Between-group difference of −79.3% (95% CI, −82.0 to −76.6; P<0.001) ● Inclisiran resulted in improvement in other key secondary end points at day 510 as compared with placebo, including lower levels of total cholesterol, non-HDL cholesterol, and apolipoprotein B (P<0.001 for all three comparisons)
Adverse Events	● Total adverse events o Inclisiran: 671/811 patients (82.7%), Placebo: 655 of 804 (81.5%) ● Serious adverse events o Inclisiran: 181/811 patients (22.3%), Placebo: 181/804 (22.5%) o All cause death - Inclisiran: 14/811 (1.7%), Placebo: 15/804 (1.9%) ● Injection-site adverse events o Inclisiran 38/811 (4.7%), Placebo 4/804 (0.5%) ● AEs reported in ≥ 5% of patients that occurred more frequently in the inclisiran group than the placebo group o Upper respiratory tract infection- Inclisiran: 6.4%, Placebo: 6.1% o Arthralgia- Inclisiran: 5.8%, Placebo: 4.0%
Limitations	● High degree of involvement from the sponsor ● Study was not designed or powered to analyze patient-centered outcomes ● Low proportion of non-white patients enrolled
Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia (HeFH) (ORION-9)	
METHODS	
Study Design	● Multicenter, double-blind, randomized, placebo-controlled
Study Funding	● Funded by the Medicines Company - Designed trial protocol along the steering committee
Patient Enrollment Inclusion	● Age ≥18 years ● History of HeFH ● Maximum tolerated or intolerance to statin therapy ● On a stable dose of lipid-lowering therapy for ≥30 days before screening with no planned medication or dose changes ● Stable low-fat diet ● Serum LDL-C ≥2.6 mmol/L (≥100 mg/dL) at screening ● Fasting triglyceride <4.52 mmol/L (<400 mg/dL) at screening ● eGFR >30 mL/min
Patient Enrollment Exclusion	● Major adverse cardiovascular event within the past 3 months ● Any uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study ● Cardiac arrhythmia within past 3 months that is not controlled by medication/ablation ● New York Heart Association (NYHA) class IV heart failure or last known left ventricular ejection fraction <25% ● Uncontrolled severe hypertension ● Active liver disease or known history of alcohol and/or drug abuse in the past 5 years ● Life expectancy less than 2 years
Baseline Characteristics	● Mean age: 56 years ● Male sex: 47% ● White race: 94% ● Preexisting coronary heart disease: 25% ● History of diabetes: 10%. ● **Mean baseline LDL: 153.1±54.0 mg/dL** ● Statin use: 90% (75% receiving high-intensity statins)

	● Ezetimibe use: 52.9%
Treatment Plan	● Screened 617 patients with 482 undergoing randomization ● Randomized in a 1:1 ratio to receive inclisiran 284 mg or placebo, administered as a 1.5 ml subcutaneous injection on days 1, 90, 270, and 450. ● Patients attended clinic on days 30, 150, 330, and 510 for follow-up and laboratory assessments. The end-of-trial visit was conducted on day 540.
RESULTS	
Primary Endpoint	● **Percent change from baseline in LDL cholesterol** at day 510 o Inclisiran: -39.7%, Placebo: 8.2% o Between-group difference of −47.9% (95% CI, −53.5 to −42.3; P<0.001) ● **Time-adjusted percent change from baseline in the LDL cholesterol level** between day 90 and day 540 o Inclisiran: -38.1%, Placebo: 6.2% o Between-group difference of −44.3% (95% CI, −48.5 to −40.1; P<0.001)
Secondary Endpoint	● Mean absolute change in LDL-C at Day 510 o Inclisiran: -59.0 mg/dL, Placebo: 9.9 mg/dL o Between-group difference −68.9 mg/dL (95% CI, −77.1 to −60.7; P<0.001) ● Time-adjusted absolute reduction in LDL-C from baseline between Day 90 and day 540 o Inclisiran: −56.9 mg/dL, Placebo: 5.8 mg/dL o Between-group difference of −62.6 mg/dL (P<0.001)
Adverse Events	● Total adverse events o Inclisiran: 185/241 (76.8%), Placebo: 172/240 (71.7%) ● Serious adverse events o Inclisiran: 18/241 patients (7.5%), Placebo: 33/240 (13.8%) o All cause death - Inclisiran: 1/241 (0.4%), Placebo: 1/240 (0.4%) ● Injection-site adverse events o Inclisiran 41/241 (17.0%), Placebo 4/240 (1.7%) ● AEs reported in ≥ 5% of patients that occurred more frequently in the inclisiran group than the placebo group o Nasopharyngitis- Inclisiran: 11.6%, Placebo: 8.3% o Back pain- Inclisiran: 7.1%, Placebo: 4.2%
Limitations	● High degree of involvement from the sponsor ● Study was not designed or powered to analyze patient-centered outcomes ● Low proportion of non-white patients enrolled

COMPARATIVE EFFICACY:
The most current 2018 American College of Cardiology (ACC) and American Heart Association (AHA) guidelines on the management of cholesterol, high-intensity or maximally tolerated statin therapy is recommended as first line treatment for the reduction of ASCVD risk. If LDL-C is still >70 mg/dL in patients on maximally tolerated statins, the addition of ezetimibe is recommended. If LDL-C is still elevated, PCSK9 inhibitors, such as alirocumab or evolocumab, are then recommended in addition to maximally tolerated statin and ezetimibe. Inclisiran (Leqvio) targets PCSK9 that can be added to maximally tolerated statin therapy to help decrease LDL-C for treatment of HeFH or ASCVD risk.

Inclisiran works similarly to alirocumab (Praluent) and evolocumab (Repatha) to reduce cholesterol by targeting PCSK9. However, Inclisiran does so in a novel manner, by degrading the mRNA molecules used to translate genetic instructions into proteins during PCSK9 production, while Repatha and Praluent are monoclonal antibodies that inhibit PCSK9 activity. In all of inclisiran's phase three trials, inclisiran added to statin therapy significantly reduced LDL cholesterol compared to placebo by approximately 50% over an 18 month study period. This is similar to the efficacy shown by other PCSK9 targeting therapies. In their phase three studies, alirocumab and evolocumab reduced serum LDL concentrations from baseline by 44-61% and 50-60% respectively compared with placebo after 18 months of therapy. All three medications were shown to have similar rates of adverse reactions, although mild to moderate injection site reactions were more common with inclisiran use (8.2%), and nasopharyngitis was more common with alirocumab (11.3%) and evolocumab (4.0%) use.

The benefit that inclisiran provides over these similar medications is its twice-yearly injection schedule, while alirocumab and evolocumab are injected every two weeks or monthly. However, unlike alirocumab and evolocumab that can be dispensed by outpatient pharmacies for patients to self inject, inclisiran must be administered by a healthcare professional which may be less convenient and provide additional billing considerations.

Inclisiran's phase three trials were not powered or designed to evaluate patient-centered cardiovascular outcomes. Alirocumab and evolocumab have both been proven to significantly reduce the risk of major adverse cardiovascular events and are associated with decreased mortality. **The ongoing ORION-4 study is currently investigating this knowledge gap, and is examining the association between lower cholesterol levels with improved cardiovascular outcomes in patients on inclisiran.**

WARNING AND PRECAUTIONS:
-Pregnancy - Discontinue inclisiran when pregnancy is recognized. Treatment of hyperlipidemia is not generally necessary during pregnancy and the lipid lowering effects of inclisiran may cause fetal harm.
-Breastfeeding - The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for inclisiran and any potential adverse effects on the breastfed infant from inclisiran or from the underlying maternal condition.

CONTRAINDICATIONS: None

ADVERSE REACTIONS:
Occurring in Greater Than or Equal to 3% of inclisiran-treated Patients and More Frequently than with Placebo

Adverse Reactions	Intervention Group (N=1833)	Placebo (N=1822)
Injection site reaction	8.2%	1.8%
Arthralgia	5.0%	4.0%
Urinary tract infection	4.4%	3.6%
Diarrhea	3.9%	3.5%
Bronchitis	4.3%	2.7%
Pain in extremity	3.3%	2.6%
Dyspnea	3.2%	2.6%

CLINICALLY SIGNIFICANT DRUG INTERACTIONS: None known

DOSING AND ADMINISTRATION:
Adult Dosing/Indication and Administration

- Heterozygous familial hypercholesterolemia and Clinical atherosclerotic cardiovascular disease
  - **o** 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months thereafter
- Missed dose
  - o If a planned dose is missed by less than 3 months, administer inclisiran and maintain dosing according to the patient's original schedule.
  - o If a planned dose is missed by more than 3 months, restart with a new dosing schedule - administer inclisiran initially, again at 3 months, and then every 6 months.
- Administration
  - o Inclisiran should be administered by a healthcare professional. Inject inclisiran subcutaneously into the abdomen, upper arm, or thigh. Do not inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infections.

RECOMMENDED MONITORING:

- Serum lipid panel
  - o Assess LDL-C when clinically indicated. These LDL-lowering effect of inclisiran may be measured as early as 30 days after initiation and anytime thereafter without regard to timing of the dose.

PHARMACOECONOMICS/COST:

Product (Drug, Strength, Form)	Price
Leqvio (inclisiran) 284 mg/1.5 mL prefilled syringe	$3,298.44 per syringe

Product (Drug, Strength, Form)	Cost/Dose	Cost/Year
Leqvio (Inclisiran) 284 mg/1.5 mL prefilled syringe- *administered by HCP*	$3,298.44	$9,652.50 (Y1) $6,596.88 (Y2 and beyond)

Medication specific billing codes: J-code: J1306 (effective 7/1/22)

CONCLUSION & RECOMMENDATION:
The CommonSpirit Health System P&T committee evaluated inclisiran in the spring of 2022 and voted it as non-formulary at the time until a permanent billing code (J-code) and clinical outcomes data were available. A permanent billing code was assigned on July 1st, 2022. The system P&T will be re-reviewing Leqvio this month with the recommendation to add to formulary with restrictions the to the outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization. The CHI Memorial P&T Committee reviewed Leqvio for formulary inclusion last fall, and aligned with the system decision at that time (non-formulary). Outcomes data is still pending. A financial analysis of drug reimbursement by payer mix determined that CHI Memorial would not incur a loss by adding this medication to formulary. The Chattanooga Heart Institute currently prescribes Leqvio for approximately 70 patients who are being treated at two non-Memorial infusion centers.

It is now recommended to add Leqvio to formulary in alignment with the CommonSpirit Health system P&T recommendation for restricted use: the outpatient setting for FDA approved indications or payer-approved off-label indications subsequent to insurance approval or prior authorization.

FAILURE, MODE AND EFFECTS ANALYSIS (FMEA)

Medication Management Step	Identified Risk	Steps for Prevention
Selection		
Therapeutic interchange?	No	NA
Special Ordering Requirements?	No	NA
Storage		
LASA* separation of stock?	No	NA
Special storage (e.g. refrigeration, protect from light, controlled substance)?	No	NA
Pharmacist/Technician Education?	No	NA
Ordering & Prescribing		
Restriction to particular specialty, indication, or particular patient population?	No	NA
Dosing Issues (e.g. renal, hepatic dosage adjustment, max dose warnings)?	No	NA
Drug Interactions?	No	NA
Pregnancy?	Yes	Inclisiran should not be used in pregnant females
Absolute Contraindications?	No	NA
Requires Order Set, Protocol, concomitant therapy with another drug?	No	NA
LASA* nomenclature issues?	No	NA
Prescriber education?	No	NA
Processing, Preparing, & Dispensing		
High-risk drug double check?	No	NA
Drug Interaction check in place?	No	NA
LASA* computer warnings?	No	NA
Administration Notes for MAR (e.g. handling precautions, surrounding food or other drugs)?	No	NA
Packaging/Labeling (e.g. prepacking)?	No	NA
Dispensing (e.g. auxiliary labeling, light protection, refrigeration)?	No	NA
Documentation required (e.g. double check, worksheet)?	No	NA
Pharmacist/Technician Education?	No	NA
Administration		
Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, or other administration information?	No	NA
Special delivery system (e.g. pump)?	No	NA

Medication Management Step	Identified Risk	Steps for Prevention
Documentation required? (e. g. double check)	Yes	Medication injection documentation
Nurse education?	Yes	Inclisiran should only be administered by a healthcare professional
Monitoring		
Interactions, adverse effects, efficacy, changes in renal function, or similar?	No	NA
Follow-up laboratory tests?	Yes	Lipid panel
Education?	No	NA

FORMULARY UPDATE

THERAPEUTIC CLASS: Antidote; Phenothiazine Derivative

GENERIC NAME: Methylene blue

PROPRIETARY NAME: ProvayBlue®

BACKGROUND/RATIONALE:

Methylene blue is an oxidation-reduction agent that is FDA indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia. However, this agent is most commonly used as a diagnostic aid for various purposes including sentinel lymph node mapping in breast cancer surgery and chromoendoscopic procedures (eg, esophageal, gastric, colon). Other off-label indications include but are not limited to vasoplegia syndrome associated with cardiac surgery, shock related to beta-blocker or calcium channel blocker overdose, ifosfamide-induced encephalopathy, etc.

In 2016 methylene blue transitioned to a branded product (ProvayBlue) available as a 0.5% concentration whereas prior to this branded approval only a 1% concentrated product was available for use/purchase. However, in February 2022 a generic version of methylene blue (1% concentration) again became available for purchase at a discounted price compared to ProvayBlue. A full conversion to the methylene blue 1% product would result in approximately $26K in annualized savings at CHI Memorial and it is felt that this conversion should result in minimal clinical and operational disruptions. In the event that a less dilute version of methylene blue is needed the 1% concentration may be further diluted as deemed clinically necessary. This product change was approved by the CommonSpirit System P&T Committee.

PHARMACOECONOMICS/COST:

ProvayBlue 0.5% 10 ml ampule (50 mg/10 ml) Drug expense by purchase history Sept 2022 through Sept 2023

Campus	Total # ampules purchased	Total drug expense
Glenwood Main Pharmacy	175	$32,747.78
Glenwood Surgery Pharmacy	195	$36,462.30
Hixson Pharmacy	75	$13,901.88
Total (13 mos: 9/22-9/23)	**445**	**$83,111.96**

Product	Cost per unit (Nov 2023)
ProvayBlue 0.5% 10 ml ampule (50 mg/10 ml)	$192.43
Methylene Blue 1% 10ml vial (100 mg/10 ml)	$138

Anticipated annual cost savings by converting to methylene blue 1% 10ml vial (100 mg/10 ml) (est 410 vials/12 months)	**$26,425.80**

RECOMMENDATION/DISCUSSION:

It is recommended to adopt the system P&T Committee decision and convert our formulary product to the methylene blue 1% 10 ml vial (100 mg/10 ml) without restrictions for use. ProvayBlue 0.5% 10 ml ampule should be non-formulary and any orders for it would be automatically converted to the 1% concentration product. In the event that a less dilute version of methylene blue is needed the 1% concentration may be further diluted as deemed clinically necessary.

FORMULARY UPDATE

THERAPEUTIC CLASS: Analgesic, Topical; Local Anesthetic

GENERIC NAME: Benzocaine 20%

PROPRIETARY NAME: HurriCaine One®

BACKGROUND/RATIONALE:

Benzocaine 20% (HurriCaine) topical anesthetic spray products are used for mucosal membrane application prior to various procedures including intubation and laryngoscopy. Methemoglobinemia has been reported following topical use of high concentrations of benzocaine spray applied to the mouth and mucous membranes. Use of multiple sprays of benzocaine 20% are not recommended. In 2012, CHI Memorial removed all benzocaine containing sprays from formulary due to these safety risks and lack of metered/unit dosed products on the market. Recently, ENT physicians have requested availability of topical benzocaine for select emergent procedures in the ED and/or OR.

Benzocaine 20% is now available as a unit dose product which may reduce risk of excessive benzocaine 20% mucosal membrane application, provide a more easily disposable option than the larger 2 ounce spray can with extension tube, and limit possible infection concerns with using a multi-dose canister for multiple patients. The HurriCaine One unit dosed products (available as a 25 pack and 2 pack) are approved to the CommonSpirit Health System formulary per the system P&T Committee.

PHARMACOECONOMICS/COST:

Product (Drug, Strength, Form)	Cost
Hurricaine Spray (Benzocaine 20%) 2 oz with extension tubes (~117 doses)	$39.68 **($0.34/dose)**
Hurricaine One (Benzocaine 20%) 0.5 ml single use (25 pack)	$253.23 **($10.13 each)**
Hurricaine One (Benzocaine 20%) 0.5 ml single use (2 pack)	$21.60 **($10.80 each)**

RECOMMENDATION/DISCUSSION:
The following actions are recommended:

- Add Hurricaine One (benzocaine 20% oral anesthetic) unit dose products to formulary with the following restrictions for use:
    - Restrict ordering to ENT providers only
    - Dispense only 1 dose at a time
- Benzocaine 20% oral/topical anesthetic 2 oz spray with extension tubes should remain non-formulary

FORMULARY UPDATE

THERAPEUTIC CLASS: Ophthalmic corticosteroid; anti-inflammatory

GENERIC NAME: Dexamethasone 0.1% ophthalmic suspension

PROPRIETARY NAME: Maxidex®

BACKGROUND/RATIONALE:

The below therapeutic interchange table (approved by the CSH System P&T Committee) was previously approved at the December 2022 CHI Memorial P&T Committee meeting. The bottom eye drop, Maxidex, was inadvertently omitted at that time.

Therapeutic Interchanges

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

PHARMACOECONOMICS/COST:

Product (Drug, Strength, Form)	Cost
MAXIDEX SUSP (dexamethasone) 0.1% DT 5 ML	$72.45
DEXAMETH OPH SOLUTION 0.1% 5 ML	$49.93

RECOMMENDATION/DISCUSSION:
It is recommended to add Maxidex to the above therapeutic interchange table and automatically convert all orders to the generic dexamethasone 0.1% solution.

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

November 2023

[See Appendix A for Policies]

Protocol	**Key contact(s)**	**Action Required 2023**
MCT RIS Contrasts Order Set/ Contrast Media Administration Policy	Director of Imaging Services Dr. Rowlett	Order sets and policies are up to date. No medication edits are required.
Anaphylaxis & Acute Drug Hypersensitivity Protocol	Pharmacy Review Team	
Hypoglycemia Protocol	Diabetes education, Pharmacy Review Team	
Narcan (Naloxone) Opioid Reversal Protocol	Pharmacy Review Team; Clinical educator critical care	
Respiratory Distress Protocol	Pulmonary management team	
Bradycardia Management Protocol	Clinical educator critical care	

Medication Loss in Small Volume Intermittent Infusions

Situation

In 2020, ISMP published a safety alert warning hospital pharmacists of an issue regarding hidden medication loss when using a primary administration set for small volume intermittent infusions. Due to the small volume infused, medication from these infusions can remain in the tubing as residual volume and may result in patients receiving incomplete doses or unintentional bolus doses of medications. Best practice recommends these small volume intermittent infusions to be administered via a secondary administration set to ensure that carrier fluid from the primary administration set is infused after the intermittent infusion to completely flush residual drug from the tubing.

Background

Our institution utilizes tubing that is specific for our particular infusion pumps (ICU Medical Plum360), since it contains a cassette. Primary infusion sets hold a minimum of 13 mL of medication in the tubing. This would mean that at least 13-26% of a dose could be lost to residual volume for 50 and 100 mL infusions, respectively, if the bag was run dry. The secondary infusion sets hold up to 7 mL of medication in the tubing. However, secondary infusions could be completely infused with lines flushed for 0 mL of residual volume.

Assessment

Bedside nurses at our institution have specifically reported seeing these small volume intermittent infusions occasionally being run without a primary carrier fluid, as there is not always one ordered. Preliminary data was pulled on 8/28/23 for IV pumps running Zosyn 100 mL infusions during a 2 hour window. One page of the report generated 25 separate infusions from various clinical care areas in the hospital. This report shows if the infusion was programmed to be run as a primary administration (channel A) or as a secondary administration (channel B). Of the 25 individual infusions on the report, 10 were programmed incorrectly to run on channel A and 15 were programmed correctly to run on channel B. This means that 40% of these patients potentially experienced hidden medication loss.

Recommendation

For all small-volume anti-infectives:

- Approve a workflow change and add to the Medication Administration & Monitoring policy to allow nurses to place an order for a default maintenance fluid of normal saline to run as the primary infusion, if no maintenance IV fluid is already ordered.
- Add default Admin Instructions in EHR: "Infuse as piggyback. Nurse to place order for sodium chloride 0.9% (NS) infusion at X ml/hr to run as primary infusion, if no IV fluid already ordered on MAR. Infuse at least 15 ml post-piggyback to flush tubing. Stop IVF when infusion is complete."
    - The rate will be the same as the infusion rate for the small volume anti-infective.
- Add clinical data category (CDC) alerts on the Pyxis dispensing cabinet. This CDC alert will pop up to remind nurses that these select infusions are to be administered as a secondary infusion.
    - CDC will read "I will program as a PIGGYBACK on the IV pump."
- Smart pump vendors recommend a software update to MedNet SW15.20 which will include 2 additional features within the IV pumps.
    - Post piggyback flush, which will allow 5 to 30 mL of the carrier fluid to infuse at the secondary infusion rate to flush the line after the secondary infusion is complete.
    - Clinical advisories, or “pop up” alerts on the IV pumps to specify that these medications should be programmed as a secondary infusion.

Sliding Scale Insulin for NPO & Associated-Hyperglycemia

Situation:
Levels 1-3 of sliding scale insulin for patients who are NPO/bedtime have the same scaling throughout, despite the purpose of giving higher doses of rapid acting insulin by escalating levels to those who are more insulin resistant. Dr. Mull reported higher rates of hypoglycemia in patients specifically on levels 2 and 3 due to this and recommended changes to the sliding scales.

Background:
A chart review was completed to confirm if blood glucose was or was not effectively being lowered in patients in which level 1, 2, or 3 was ordered. Four weeks of data were assessed; it included only orders with documented administrations by the nurse with an ordered q4 or q6 frequency. Administrations analyzed were patients who were NPO with no parenteral or enteral feeding (excluded). Each insulin administration was then analyzed to determine if the subsequent FSBG reading was greater than 179 mg/dL.

Insulin Administrations in NPO Patients					
SSI Level	**Doses Given**	**# of subsequent BG > 179 mg/dL**	**Median Time between Admin and BG (minutes)**	**Average Next BG Reading (mg/dL)**	**Average change in BG (mg/dL)**
1	8	6 (75%)	236	249	-1.25
2	53	39 (66%)	272	218	-27.1
3	6	5 (83%)	226	302	-15.5

Assessment:
The majority of documented administrations were from level 2; 66% of FSBG levels following insulin administration remained greater than 179 mg/dL. Among all three levels, subsequent FSBG readings were greater than 179 mg/dL despite adherence to the orders. The average next FSBG reading after insulin was administered was also greater than 200 mg/dL for all three levels.

Some limitations in this analysis include large variances in the time between administration of insulin and the following FSBG level, as well as the smaller sample size for level 1 and 3 order sets. It is difficult to make direct comparisons between the three levels due to the sample size.

Recommendation:
It is recommended to modify the current scales for NPO/bedtime insulin doses to increase the amount of insulin ordered (see scales below).

Level 1 If BG < 70 mg/dL, initiate hypoglycemia protocol

BG (mg/dL)	Units	Current Bedtime/NPO Units	**no change**
71-139	0	0	
140-175	+1	0	
176-200	+2	1	
201-225	+3	2	
226-275	+4	3	
276-325	+5	4	
326-375	+6	5	
> 375	Give same amt as above and notify MD.		

Level 2 If BG < 70 mg/dL, initiate hypoglycemia protocol

BG (mg/dL)	Units	Current Bedtime/NPO Units	**Updated Bedtime/NPO Units**
71-139	0	0	**0**
140-175	+2	0	**1**
176-200	+4	1	**2**
201-225	+6	2	**3**
226-275	+8	3	**4**
276-325	+10	4	**6**
326-375	+12	5	**8**
> 375	Give same amt as above and notify MD.		

Level 3 If BG < 70 mg/dL, initiate hypoglycemia protocol

BG (mg/dL)	Units	Current Bedtime/NPO Units	**Updated Bedtime/NPO Units**
71-139	0	0	**0**
140-175	+4	0	**2**
176-200	+6	1	**4**
201-225	+8	2	**6**
226-275	+10	3	**8**
276-325	+12	4	**10**
326-375	+14	5	**12**
> 375	Give same amt as above and notify MD.		

Enteral Nutrition Quick Reference Guide

Enteral Formula Selection: Consult dietitian to help determine appropriate formula and goal rate. The TF order set can be found in Epic by searching "Enteral Nutrition Adult".

Adult Tube Feeding Guidelines (ASPEN Recommendations)

1. Gastric Residuals—it is suggested:

- Patients are monitored daily for tolerance of enteral nutrition and inappropriate cessation of TF should be avoided.
- For ICUs where GRVs are used, holding tube feeding for GRVs <500 mL in absence of signs of intolerance should be avoided.

2. Flushes

- 30 mL of water every 4 hours during continuous feeding
- Before and after intermittent feeds

3. Hang time

- Ready to hang (RTH) prefilled enteral feeding containers can hang safely up to 48 hours. Use only one feeding set per RTH container.
- Open systems can hang for up to 12 hours.

4. Head of Bed (HOB)

- Keep HOB elevated 30-45 degrees during feeding unless contraindicated.

5. Bowel Sounds

- In the ICU patient, neither the presence or absence of bowel sounds nor evidence of passage of flatus and stool is required to initiate tube feeding.

Tube Feeding/Medication Interactions

Consult Pharmacy to evaluate PO medications for liquid substitutions.

Dilantin (phenytoin) and Coumadin (warfarin): hold feeding 1 hour before and 1 hour after administration.

Cipro, Levaquin, Avelox (fluoroquinolone): hold feeding 1 hour before and 2 hours after administration.

Tube Feeding Clogged

First attempt to flush with water, if unsuccessful, order pancrelipase tablet crushed with 325 mg sodium bicarbonate.

Oral Supplements

Product Name	Ensure Clear	Ensure High Protein	Ensure Enlive	Ensure Compact	Ensure Plant-Based Protein
Category	Clear Liquid	High Protein	Standard	Fluid Restriction	Plant-Based
Nutrient Values Per	8 fl oz	8 fl oz	8 fl oz	4 fl oz	11 fl oz
Calories	240	160	350	220	180
Total Carbohydrate (g)	52	19	44	32	13
Dietary Fiber (g)	0	<1	3	0	5
Protein (g)	8	16	20	9	20
Total Fat (g)	0	2	11	6	6
Potassium (mg)	NL	470	560	330	470
Phosphorus (mg)	188	310	375	190	500
Allergens	Milk	Milk and Soy	Milk and Soy	Milk and Soy	NA
Suitable for	Halal (Apple Only), Kosher, GF, LF	Halal, Kosher, GF, LF	Halal (Except Van.), Kosher, GF, LF	Halal, Kosher, GF, LF	Halal (Van only), Kosher, GF, LF, Dairy Free
Flavors	Apple, Mixed Berry	Chocolate, Vanilla	Chocolate, Strawberry, Vanilla	Chocolate, Vanilla	Chocolate, Vanilla

Oral Supplements

Product Name	Glucerna Therapeutic Shake	Nepro with CARBSTEADY	Magic Cup	Gelatein Plus	Gelatein 20
Category	Diabetes	Renal (dialysis)	High calorie, Dysphagia	Clear Liquid	Clear Liquid
Nutrient Values Per	8 fl oz	8 fl oz	4 oz	4 oz	4 oz
Calories	220	420	290	160	80
Total Carbohydrate (g)	26	38	38	20	<1 g
Dietary Fiber (g)	4	6	0	2	<1 g
Protein (g)	10	19	9	20	20
Total Fat (g)	9	23	11	0	0
Potassium (mg)	376	225	190	110	120
Phosphorus (mg)	250	170	190	0	0
Allergens	Milk and Soy	Milk and Soy	Milk	Milk	Milk
Suitable for	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	GF	LF	LF
Flavors	Chocolate, Strawberry, Vanilla	Butter Pecan, Vanilla	Vanilla, Chocolate	Cherry	Orange

NA = Not applicable
NL = Not listed on corporate website
GF = Gluten Free
LF = Lactose Free

CHI Memorial

Imagine better health.℠

Medical Nutrition Formulary

2023

Ordering Information

- Products listed in this formulary are readily available. It may take several days for non-formulary items that are requested to be procured.
- Tube feeding formulas are stocked on all floors, they are restocked on Mondays and Fridays. If stock is needed in between these dates, call the diet office at 423-495-8368.

Nutrition Assessment

- A Registered Dietitian (RD) is available for consultation to assist with enteral feeding recommendation. Referrals should be made by consulting RD through Epic.
- A nutrition assessment is completed by an RD on all patients receiving enteral or parenteral nutrition.
- The nutrition assessment will include the calories, protein, and fluid needs of the patient that are supplied by the enteral nutrition formula.
- The RD will manage the tube feeding when consult "Registered Dietitian to manage TF" is ordered. The RD will continue to manage the tube feeding unless the physician changes the order.

CHI MEMORIAL HOSPITAL - ENTERAL NUTRITION FORMULARY

	Standard Formulas					Specialty Formulas						
Product Name	Osmolite 1.5 Cal	Promote	TwoCal HN	Jevity 1.2 Cal	Jevity 1.5 Cal	Glucerna 1.2 Cal	Nepro with CARBSTEADY	Vital AF 1.2 Cal	Vital 1.5 Cal	Vital High Protein	Pivot 1.5 Cal	Kate Farms 1.4 Standard
Category	Concentrated Calories	High Protein	Calorie and Protein Dense	Added Fiber	Added Fiber	Diabetes	Renal (Dialysis)	Peptide-Based, High Protein	Peptide-Based	Peptide-Based, High Protein	Immune Support	Plant Based
Cal per mL	1.5	1	2	1.2	1.5	1.2	1.8	1.2	1.5	1	1.5	1.4
Nutrient Values Per	1 L	1 L	1 L	1 L	1 L	1 L	1 L	1 L	1 L	1 L	1 L	1 L
Protein (g)	62.7	63	83.5	55.5	63.8	60	81	75	67.5	87.3	93.8	62
Protein Source	Sodium and calcium caseinates, Soy protein isolates	Sodium caseinate, Soy protein isolate	Milk protein concentrate, Sodium caseinate, Calcium caseinate	Sodium and calcium caseinates, Soy protein isolates	Sodium and calcium caseinates, Soy protein isolates	Sodium caseinate, Soy protein isolate, Milk protein concentrate	Calcium, magnesium and sodium caseinates, Milk protein isolates	Whey protein hydrolysate, Hydrolyzed sodium caseinate	Whey protein hydrolysate, Hydrolyzed sodium caseinate	Whey protein hydrolysate, Hydrolyzed sodium caseinate	Hydrolyzed sodium caseinate, Whey protein hydrolysate, L-arginine	Organic pea protein
Total Fat (g)	49.1	26	90.5	39.3	49.8	60	96	53.9	57.1	23.2	51	58
Fat Source	High-oleic safflower, canola, and MCT oils	safflower, MCTs, and soy oils	Canola oil, Corn oil	Canola oil, Corn oil, MCTs	Canola oil, Corn oil, MCTs	High-oleic safflower oil, Canola oil	High-oleic safflower oil, Canola oil	MCT/marine oil structured lipid, MCTs, Canola oil, Soy oil	Canola/MCT structured lipid, Canola oil, MCTs	MCTs, Marine oil, Corn oil	Structured lipid (MCT/marine oil), Soy oil and canola oil	Organic: MCT oil, high linoleic sunflower oil, flaxseed oil
Total Carbohydrate (g)	203.6	130	218.6	169.4	215.7	114.5	160	110.6	187	111	172.4	157
Carbohydrate Source	Corn maltodextrin	Corn maltodextrin, sugar	Corn syrup solids, Corn maltodextrin, Sugar, scFOS	Corn maltodextrin, Corn syrup solids, scFOS, Soy fiber, Oat fiber	Corn maltodextrin, Corn syrup solids, scFOS, Soy fiber, Oat fiber	Corn maltodextrin, Isomaltulose, Fructose, Sucromalt, Soluble corn fiber, soy fiber, oat fiber, scFOS, Glycerin	Corn syrup solids, Sugar, Soluble corn fiber, Glycerin, scFOS	Corn maltodextrin, scFOS	Corn maltodextrin, Sugar, scFOS	Corn maltodextrin, Sugar	Corn syrup solids, scFOS	Organic: brown rice syrup solids, agave syrup, pea starch
Osmolality (mOsm/kg H20)	525	405	710	450	525	720	745	459	671	419	660	455
Dietary Fiber (g)	0	0	5	17	21	16.1	25	5.1	6	0	7.5	9
Sodium (mg)	1330	993	844	1067	1330	1110	1050	1266	1139	1400	1475	1077
Potassium (mg)	2180	2667	2110	2390	2180	2020	949	1645	2194	1400	1983	2231
Calcium (mg)	1300	1533	1371	1200	1300	800	1050	1046	1300	869	1013	1077
Magnesium (mg)	420	280	414	370	420	320	169	337	422	281	421	431
Phosphorus (mg)	1250	833	1321	1200	1250	800	717	1004	1251	835	969	923
Vitamin K (mcg)	170	90	169	123	170	100	80	141	148	165	126	123
Water (mL)	762	839	700	807	760	805	727	811	764	836	750	720
mLs to meet 100% of RDIs	1000	1500	948	1250	1000	1250	944	1250	1000	1500	1300	1000
Allergens	Milk, Soy	Milk, Soy	Milk, Soy	Milk, Soy	Milk, Soy	Milk, Soy	Milk, Soy	Milk	Milk	Milk	Milk, Soy	NA
Suitable for	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	Halal, Kosher, GF, LF	GF, LF	GF, LF	GF, LF	Halal, GF, LF	Kosher, GF, LF, Dairy Free, Organic

NA = Not applicable
NL = Not listed on corporate website
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LF = Lactose Free

Specialized Formula Needs

Critical Care/Obese/Lipid-based sedation (ex. Propofol) —> Vital High Protein

Peptide-based/GI intolerance/Diarrhea —> Vital AF 1.2 / Vital 1.5

Surgery/Trauma/Wounds —> Pivot 1.5

Renal Insufficiency —> Nepro with CARBSTEADY

Diabetes / Hyperglycemia —> Glucerna 1.2

Tube Feeding Initiation Protocol

Continuous Feedings: Unless otherwise ordered, feedings will start at 30 mL/hr and advance by 10 mL every 4 hours until goal is reached.

Bolus/Intermittent Feedings: All bolus or intermittent feedings will be administered through the feeding pump to maintain closed system feeding. Each prescribed dose will be administered by using the pump's intermittent feeding function and programming the ordered volume.

Modular Supplements

Product Name	Banatrol Plus with Bimuno Prebiotic	Beneprotein	ProSource NoCarb Liquid Protein	Juven (Flavored)	Juven (Unflavored)
Category	Diarrhea	Protein	Protein	Wound Healing	Wound Healing
Nutrient Values Per	1 pkt (10.75g)	1 pkt (7g)	1 fl oz (30mL)	1 pkt (27.5g)	1 pkt (23g)
Calories	40	25	60	90	80
Total Carbohydrate (g)	10	0	0	8.4	4.2
Dietary Fiber (g)	2	0	0	0	0
Protein (g)	0	6	15	2.5	2.5
Total Fat (g)	0	0	0	0	0
Potassium (mg)	125	0	14	NA	NA
Phosphorus (mg)	9	NL	49	NA	NA
Allergens	Milk	Milk, Soy	Milk	Phenylalanine	NA
Suitable for	GF	GF, LF, Kosher	GF, IF	GF, LF, Kosher	GF, LF, Kosher
Flavors	Banana	Unflavored	Neutral	Orange	Unflavored

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CHI Memorial

POLICY

Title: PENICILLIN ALLERGY SKIN TESTING			
		Page 1 of 5	
Policy Number: MM-05448		Date Last reviewed/Revised: 11/23	Valid Until: 11/26
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	

OUTCOME:
Use of PRE-PEN and an appropriate dilution of benzyl penicillin (Penicillin G) to identify patients who have an IgE-mediated penicillin allergy at risk for immediate-type reactions to penicillins. Antibiotic skin testing can improve antibiotic utilization leading to improved efficacy, reduced microbial resistance, decreased collateral damage, and reduced cost.

POLICY:
Only 10-20% of patients reporting a history of penicillin allergy are truly allergic when assessed by skin testing. Patients reporting an allergic reaction to antibiotics have fewer treatment options. It is reported that using PRE-PEN and an appropriate dilution of benzylpenicillin (Penicillin G) identifies up to 97% of patients who have an IgE-mediated penicillin allergy.

__**This test will only be available Mon-Fri from 8AM to 4PM. Ordering is restricted to infectious disease physicians only.**__

Testing will be completed in **two steps** and a **third optional** test if ordered:

1. Scratch/Prick test
2. Intradermal Skin Test - **only if the scratch/prick test is negative**.
3. **Oral Penicillin** challenge **(OPTIONAL) per physician order** if both the Scratch/Prick and Intradermal tests are negative. *This step is considered as optional since these tests are rarely positive after negative skin testing.*

Inclusion Criteria:

a. Patient is ≥18 years old.
b. Patient reports having a Type I hypersensitivity reaction to penicillin >5 years ago.
c. Penicillin or a β-lactam antibiotic is the drug of choice for treatment in this patient.
d. Patient consents to this procedure.

Exclusion Criteria:

a. Patient reports an immediate reaction (within 1 hour) to the antibiotic within the last 5 years.
b. Patient is pregnant.
c. Patient has taken histamine antagonists in the past 24 hours.
d. Patient has a history of dermatographism.
e. Patient reports a hypersensitivity reaction other than a Type I reaction (hemolytic anemia, interstitial nephritis, Stevens-Johnson syndrome, etc.)
f. Patient has an intolerance to the antibiotic (e.g. stomach upset), not a true allergy.
g. Patient has severe immunosuppression, not including Diabetes or corticosteroid use.

DEFINITIONS:

1. PRE-PEN®: A skin test antigen reagent indicated for the assessment of sensitization to penicillin (benzylpenicillin or penicillin G) in patients suspected to have clinical penicillin hypersensitivity. The release of chemical mediators produces an immediate wheal and flare reaction at a skin test site.
2. IgE Mediated Reaction: An IgE-mediated immediate type hypersensitivity reaction that includes the clinical features of anaphylaxis, angioedema, bronchospasm, and/or urticaria.

3. Penicillins: Medications belonging to the penicillin medication class including extended spectrum and penicillinase resistant penicillins. Examples include penicillin G, penicillin V, piperacillin, ticarcillin, nafcillin, cloxacillin, dicloxacillin and oxacillin.
4. Aminopenicillins: Semisynthetic penicillins such as amoxicillin and ampicillin. *Patients may be selectively allergic to aminopenicillins but are able to tolerate penicillins as defined above.*
5. Credentialed IV Team Nurse: Nurse that has received the appropriate training and has been signed-off as competent by employer using the "Pre-Pen Competency Checklist".
6. Antimicrobial Stewardship Pharmacist (ASP): A pharmacist trained on antimicrobial stewardship and Pre-Pen testing that is available Mon-Fri from 8AM-4PM and can be reached on Ext. 7536.

PERSONNEL:

A. Physician Responsibilities:

1. **Ordering is restricted to infectious disease physicians only.**
2. Completes a medication/allergy history
3. Have the informed consent discussion with patient and/or patient's representative
   Refer to Policy INFORMED CONSENT (RI-03212)
4. Order: "Penicillin allergy skin testing - if patient meets exclusion/inclusion criteria" (Test will only be available Mon-Fri from 8AM to 4PM.)
5. Makes therapy changes based on test results.

B. Pharmacist Responsibilities:

1. Receives Pre-Pen order and Antimicrobial Stewardship Pharmacist (ASP) will ensure patient meets appropriate inclusion/exclusion criteria.
2. Dispenses the penicillin allergy skin testing kit.
3. Pharmacy shall supply the following supplies for the skin test:
   a. Skin test syringes for intradermal testing (.5-1.0cc syringe, 26-28g needle)
   b. scratch/prick puncture device: Duotip-Test II skin test applicator
   c. Alcohol swabs
   d. 0.9% Sodium chloride PF (negative control)
   e. Histamine base 0.1 mg/ml (positive control)
   f. PRE-PEN® ampule (benzylpenicilloyl polylysine injection USP)
   g. Pen G (diluted to a strength of 10,000 Units/ml) reconstituted within 24 hours
   h. Ruler
4. Upon receiving report from the IV Team nurse, a pharmacist will electronically update the patient's allergies to reflect the testing results and notify the ordering physician.

C. Trained IV Team Nurse Responsibilities:

1. Review medication/allergy history and confirm patient meets exclusion/inclusion criteria. Confirm physician order is present for "Penicillin Allergy Skin Testing"
2. After the physician has completed the informed consent discussion with the patient or patient representative,
   a. The nurse may provide the patient with the completed consent form: INFORMED CONSENT FOR TREATMENT OR PROCEDURE (130106), and ask the patient if any questions
   b. Obtain patient or representative signature(s) on the form.
      Refer to Policy INFORMED CONSENT (RI-03212)
3. Requests kit from pharmacy when ready to perform test.
4. Gather other supplies such as ink pen for skin marker and timer or watch.
5. Provide patient with FORM-PENICILLIN ALLERGY SKIN TESTING PATIENT HANDOUT (198189) regarding the Pre-Pen test and results.
6. Performs penicillin allergy skin testing procedure steps as ordered and noted below.
7. **ADVERSE REACTIONS:**
   a. Occasionally patients may develop an intense local inflammatory response at the skin test site.
   b. **Rarely, patients will develop a systemic allergic reaction**, manifested by generalized erythema, pruritus, angioedema, urticaria, dyspnea, hypotension, and anaphylaxis.

c. If reaction occurs, follows appropriate interventions per **ANAPHYLAXIS - REACTION INTERVENTION (MM-05449)** policy, ***Allergic Reaction/Anaphylaxis*** orders, notify physician and call the Rapid Response Team.

8. Administer **Oral Penicillin** challenge (optional Step 3) **only if ordered by physician** and both the Scratch/Prick and Intradermal tests are negative.
9. Notify the patient's primary nurse when test has been completed.
10. Document using **FORM-PENICILLIN ALLERGY SKIN TESTING RESULTS (198190)**, enter the results of the testing
11. Report results and any adverse reaction of allergy testing to **Antimicrobial Stewardship Pharmacist (ASP) Ext. 7536**
12. Scan **FORM-PENICILLIN ALLERGY SKIN TESTING RESULTS (198190)** to pharmacy. Fax documentation form to caregiver and/or primary care physician (*if applicable*)
13. Place the completed **FORM-PENICILLIN ALLERGY SKIN TESTING RESULTS (198190)** under the Progress notes tab in the patient's chart.

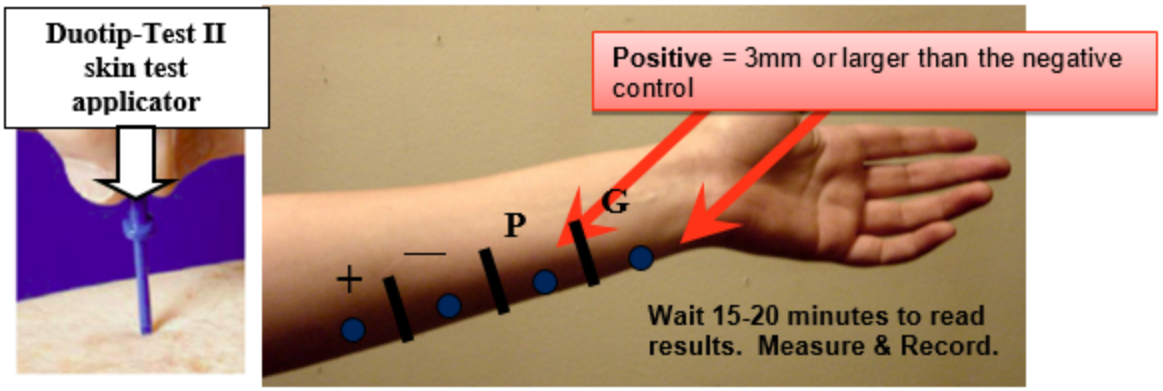
D. Patient's Primary Nurse Responsibilities:

1. Receive report of results and response to test from the IV Team nurse
2. Monitor the patient's vital signs every 15 minutes for the first hour when the initial dose of penicillin is given.
3. Continue to monitor the patient for any clinical signs or symptoms of an adverse drug reaction as long as the patient is receiving penicillin treatment.
4. Any signs of a reaction should be reported to the ordering physician.

PROCEDURE:

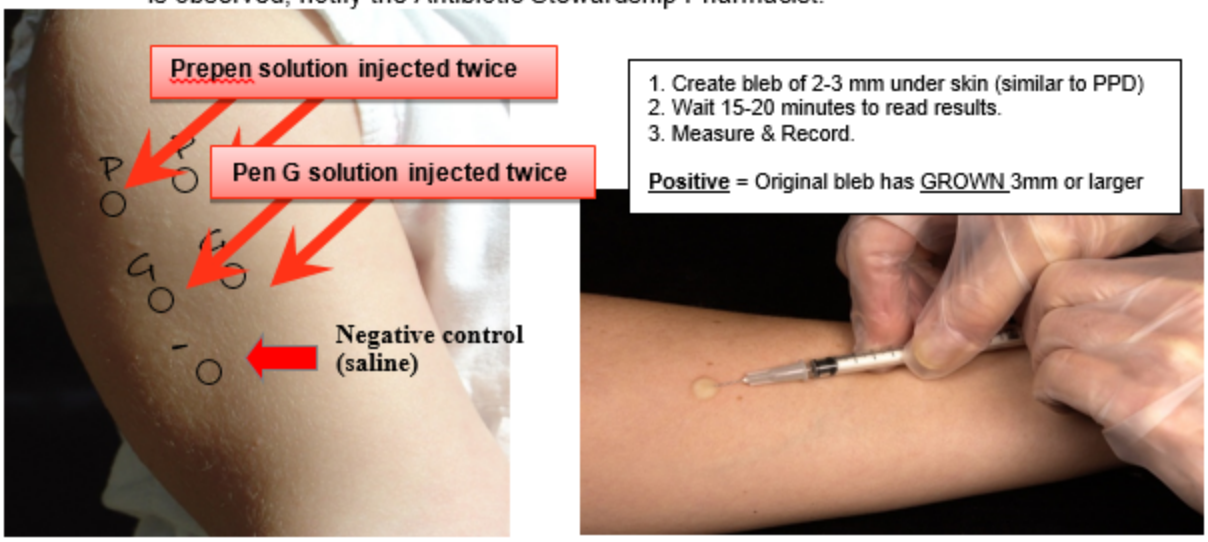
STEP 1 SCRATCH/PRICK TESTING:

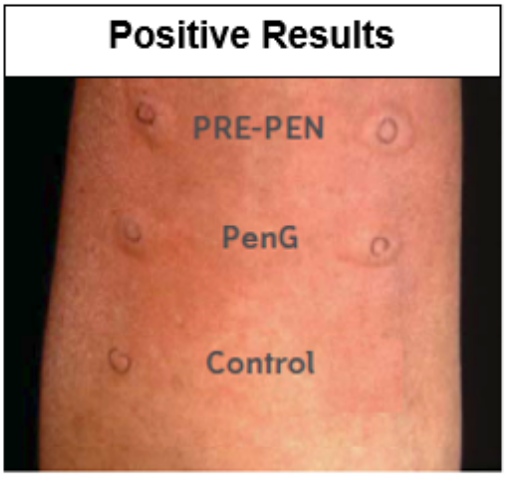
1. Sequential tests, spaced about 1 inch apart shall be made on either the volar surface of the forearm or the lateral aspect of the upper arm. Clean designated area with an alcohol swab.
2. Using an ink pen, draw 3 vertical lines about 1 inch apart on the designated testing area of the arm.
3. Draw up 0.1 ml of the 4 solutions (Pre-pen, diluted Penicillin G, histamine positive control, and saline negative control) in 4 separate allergy syringes.
4. Apply a small drop of each solution to the separate pre-marked sites on the testing arm (see illustration below)
5. The histamine test site should be the most proximal site, followed down the arm by saline, Pre-Pen, and Pen G
6. Puncture the epidermis using a twisting motion at each drop site using the Duotip-Test II applicator, using a new Duotip-Test II applicator for each agent. Do not draw blood.
7. Read the test in 15-20 minutes and document:
    a. Test is **negative**: change in diameter of wheal is <3 mm than that observed with the negative control. **Proceed to intradermal test.**
    b. Test is **positive**: change in diameter of wheal is >3 mm that that observed with the negative control. As soon as a positive response is observed, the solution should be wiped off the skin. **Do not proceed to intradermal test.**
    c. The positive control (histamine skin test) should be positive to ensure the results are not falsely negative.
    d. The negative control (saline skin test) should be negative. If a wheal >2-3mm develops after 20 min, repeat prick skin test. Upon re-testing, if control still creates a wheal >2-3mm after 20 min, discontinue test and notify the Antimicrobial Stewardship Pharmacist. This may indicate the presence of a skin condition known as dermatographism.



STEP 2 INTRADERMAL TEST: (complete only if the scratch/prick test in STEP 1 is negative)
Select 5 sites on either the volar surface of the forearm or the lateral aspect of the upper arm for intradermal testing. These sites should be on the opposite arm as the prick test, if possible.

1. **Intradermal Injection:** refer to **eCRS skill** Medication Administration: Intradermal Injections
2. Using a 26-30 gauge, short bevel needle, **intradermally inject** 0.02 ml of Pre-Pen solution **twice** (separate at least 2 cm apart). (Note: You will use the same syringe/needle filled with Pre-Pen to make both intradermal injections.
3. Mark the margins of the initial blebs with an ink pen.
4. Using separate needles and syringes, **intradermally inject** diluted Pen G (0.02ml = 200 units PCN) **twice** (separate at least 2 cm apart) and 0.02 ml of saline (separate at least 5 cm apart from other sites). (Note: you will use the same syringe/needle filled with diluted Pen G and saline to make both intradermal injections.
5. **Read in 20 minutes and document:**
   a. Test is **negative**: there is no increase in the original bleb and no greater reaction than the negative control site.
   b. Test is **positive**: bleb or wheal increases >2 mm from its original size or is >2 mm larger than the negative controls. Patient is NOT to receive penicillin.
   c. If the negative control (saline) site exhibits a wheal >2-3 cm, repeat the test. If the same reaction is observed, notify the Antibiotic Stewardship Pharmacist.





Key Contact: IV Team, Pharmacy
Approved/Reviewed by: Infection Prevention Medical Staff, Pharmacy Director, Nursing Professional Practice Council,
Reference(s): Vendor: ALK
http://www.prepen.com/physician-tools Training Video for Hospitals
Pre-Pen® package insert
eCRS skill Medication Administration: Intradermal Injections
Policy ANAPHYLAXIS - REACTION INTERVENTION (MM-05449)
Policy INFORMED CONSENT (RI-03212)
Related Forms: FORM: INFORMED CONSENT FOR TREATMENT OR PROCEDURE (130106)
FORM-PENICILLIN ALLERGY SKIN TESTING PATIENT HANDOUT (198189)
FORM-PENICILLIN ALLERGY SKIN TESTING RESULTS (198190)
FORM-PENICILLIN ALLERGY SKIN TESTING FLOW SHEET (198191)
Date First Effective & (Revision/Review dates): 6/13, (3/17) (1/21) (11/23)

CHI Memorial

POLICY

Title: PHARMACY & THERAPEUTICS COMMITTEE			
		Page **1** of **4**	
Policy Number: PHRM-0624		Date Last reviewed/Revised: 11/23	Valid Until: 11/26
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: Pharmacy		Review Period: Every 3 years	

PURPOSE:
The Pharmacy and Therapeutics (P&T) Committee establishes and maintains CHI Memorial, CHI Memorial Hixson, and CHI Memorial Georgia medication formularies and assists in the formulation of policies-procedures regarding the evaluation, selection, procurement, distribution, safety procedures, and other matters relating to the safe use of medications. The Committee assists in the formulation of programs designed to meet the needs of the professional staffs for complete current knowledge on matters and practices related to medications. CHI Memorial Georgia will maintain a sub-committee to review quality improvement and Georgia specific issues related to this practice site. Formulary decisions will be made as a CHI Memorial system and communicated to the appropriate leadership at each facility.

POLICY/PROCEDURE:

Committee Membership & Structure:
Authority – The P&T Committee members consist of the Director of Pharmacy, Pharmacy Clinical Manager, Chief Medical Officer (or designee), physician representatives from selected disciplines of medicine, hospital administration, nursing, education and selected ancillary departments.

Chairperson – A physician member of the committee appointed by the CMO and/or Chief of Staff. Chairmanship shall be for a 2-year term but can be extended for an additional term(s) upon approval by CMO and/or Chief of Staff.

Physician Membership – Physician members shall be appointed by the CMO or Chief of Staff, in collaboration with the chairperson, to assure broad representation sufficient to meet the committee's needs regarding the committee's functions and purposes.

Reporting Structure – The Committee reports to the Medical Executive Committee (MEC) on matters that affect all disciplines of medical staff.

Voting Members – The voting members of the committee consist of the following members: physicians (including Chief Medical Officer), Director of Pharmacy, Chief Nursing Officer, and the Vice President of Quality (or designee).

Quorum – A quorum shall consist of at least 3 physician members (or their proxy), the Director of Pharmacy (or designee), and at least one member of hospital leadership (Chief Nursing Officer, Chief Medical Officer, or Vice President of Quality).

Meeting Frequency – The P&T Committee will meet a minimum of five times per year at a date and time convenient for the majority of its members. Ad-hoc Committee meetings occur on an agenda driven basis at a mutually convenient time and place for those attending. The Ad-hoc Committee(s) reports findings and recommendations to the P&T Committee.

Committee Functions:
The Committee functions may include, but are not limited to:

- Formulary Management: Works in collaboration with the medical staff to evaluate, determine therapeutic use, and select drugs for inclusion in the CHI Memorial formulary by evaluating relevant clinical data and evidence-based medicine. Provides final approval of CHI Memorial drug formulary that is maintained to meet the needs of patients treated within CHI Memorial facilities. Additionally, provides recommendations to the national CommonSpirit Health Pharmacy & Therapeutics Committee. Ongoing formulary maintenance will also be conducted via medication class reviews to ensure ideal, evidence-based formulary selections are in place.

- Policy Management: Works in collaboration with the medical staff to review polices related to the use and evaluation of pharmaceutical, therapeutic, and related therapies in an effort to standardize clinical practice and to avoid unintended consequences.

- Medication Use Evaluations: Reviews evaluations of medication use for formulary medications and reviews data for the purpose of optimizing medication utilization and/or patient safety on an as needed basis. These reviews shall be conducted for the purpose of optimizing safety, efficacy, best practices, and/or cost.

- Patient Safety: Investigates and oversees ~~all~~ medication related safety concerns in collaboration with the Medication Safety Committee for opportunities to optimize or improve medication related therapies. This may include but is not limited to reviews of reported adverse drug reactions related to inpatient or outpatient drug administrations.

- Staff Education: Plans and establishes suitable educational programs for the medical staff on pertinent matters relating to drugs and their use regarding safe and effective best practices for use of medications.

- Communication: Ensures bi-directional communication with the CHI Memorial medical staffs/committees and the CommonSpirit Health Pharmacy & Therapeutics Committee~~national CHI Pharmacy & Therapeutics Committee~~.

Formulary Requests – Formulary requests will be requested via a Formulary Addition Request Form for drugs in which the physician would like to be considered for formulary (see Appendix A). The requestor must also submit a Disclosure Statement with the Formulary Addition Request Form (see Appendix B). The Pharmacy Department Clinical Lead (or designee) will receive and assign the request to be presented at the most appropriate P&T Committee meeting. The requestor (or designee) must be present at the assigned Committee meeting. Once assigned to a Committee agenda, a formulary evaluation will be conducted by assigned members. The evaluation shall include, but not be limited to, monograph production with a literature evaluation, a Safety and Efficacy Evaluation and an Operational/Safety addendum as necessary.

Key Contact: Pharmacy Review Team, Clinical Pharmacy Manager
Approved/Reviewed by: Director of Pharmacy, Chief Medical Officer
Attachments: FORMULARY ADDITION REQUEST FORM (Appendix A)
DISCLOSURE STATEMENT (Appendix B)
Date First Effective/Revisions: 10/20/88, 5/09, (1/10) (1/13) (7/15) (11/18) (11/19) (11/22)(11/23)

POLICY

Title: SEDATIVES / HYPNOTICS FOR SLEEP			
Page 1 of 2			
Policy Number: MM-05410		Date ~~Last~~ reviewed/Revised: ~~2/22~~11/23	Valid Until: 11~~2/25~~26
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:
Sedatives/hypnotics for sleep in hospitalized patients will be used safely and in an effort to reduce the risk of fall and injury, especially in the elderly population of patients.

POLICY:

1. No sedative/hypnotic will be administered for sleep to any patient 65 or greater. **Exceptions are limited to the following:**
    a. Receiving as a home medication (note items 4.b, 5.b, 6)
2. All sleep medications must have a written order by physician.
3. All sleep medication included on physician order sets must have a check box (☐) for physician to individually designate appropriateness for medication (must not be pre-checked).
4. Zolpidem (Ambien®)
    a. The **maximum** Zolpidem (Ambien ®) dose is **5 mg** for any patient. This dose may not be repeated.
    b. Patients currently receiving as a home medication any dose greater than 5 mg will only be provided 5 mg maximum dosage.
5. Diphenhydramine (Benadryl®)
    a. **Only** patients currently receiving diphenhydramine as a home medication may continue to receive this medication as a sedative/hypnotic. Patients who do not take diphenhydramine as a home sedative/hypnotic will not be allowed to receive this medication as a sedative/hypnotic.
    b. The maximum Diphenhydramine (Benadryl®) dose is 25 mg for any patient. This dose may not be repeated. Patients currently receiving as a home medication any dose greater than 25 mg will only be provided 25 mg maximum dosage.
6. Approved formulary therapeutic substitutions are listed below and will be automatically interchanged as outlined:

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

Temazepam (Restoril®) 7.5 mg	Zolpidem (Ambien®) 5 mg
Temazepam (Restoril®) 15 mg or 30 mg	Temazepam (Restoril®) 15 mg
Zolpidem CR (Ambien CR®) 6.25 mg or 12.5 mg	Zolpidem (Ambien®) –5 mg
Suvorexant (Belsomra) 10 mg	Eszopiclone (Lunesta®) 1 mg OR Zolpidem (Ambien®) 5 mg
Suvorexant (Belsomra) 20 mg	Eszopiclone (Lunesta®) 2 mg OR Zolpidem (Ambien®) 5 mg

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

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

Joint Commission Standard: Medication Management (MM)

Date First Effective/Revisions: 9/10, (1/12), (4/13) (2/16)(1/19) (2/22) (11/23)

Appendix A

POLICY

Title: CONTRAST MEDIA ADMINISTRATION			
Page **1** of **8**			
Policy Number: PC-07335		Date Last reviewed/Revised: 11/22	Valid Until: 11/23
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.

Patients receiving MultiHance (Gadobenate dimeglumine), a group II gadolinium-based-contrast-agent (GBCA), no longer need to have a GFR assessment prior to imaging.

Patients receiving Eovist (Gadoxetate disodium), a group III GBCA, will continue to need to be assessed for renal failure and risks of renal failure.

The following guidelines will be followed for administration of Eovist:

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 Eovistt.

GFR > 30: Eovist contrast will be calculated by weight per protocol 0.1mmol/kg (0.2ml/kg) not to exceed 20ml IV for standard MRI's. .

GFR < 30: Do not administer Eovist. In consultation with the radiologist, the exam needs to be converted to a MultiHance post-contrast exam, or a non-contrast exam.

The patient does not need to sign informed consent except for exams performed in Georgia. If there is a calculated eGFR, it 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.
vi. When using a contrast warmer, Contrast warmer will be checked and temperature logged daily (Form#198542). To ensure a ready supply of contrast media at body temperature (98.6 F / 37C) the contrast warmer will be stocked prior to AM exams. At or before noon ,12 PM the inventory will be evaluated and additional product added as needed for afternoon exams. Added product will be stocked behind any already prepared media to create a "first in, first out" process and allow newly added product time to reach appropriate temperature. Contrast should be stored in a locked cabinet between 68 F 20 C and 77 F 25 C away from light when not in the warmer.

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/Parkway** 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)

When treating a contrast reaction in the outpatient setting, the following guidelines may be utilized as suggested by the American College of Radiology. These guidelines are for reference purposes only and are not intended to substitute for the judgment and expertise of a physician or other user.

HIVES/DIFFUSE ERYTHEMA

1. Observation; monitor vitals q 15 min. Preserve IV access.
2. If associated with hypotension or respiratory distress then considered Anaphylaxis:

A. O2 6-10 L/min by face mask
B. IVF 0.9% NS wide open; elevate legs > 60°
C. Epinephrine 0.3 mL of 1mg/mL IM (or auto-injector) OR Epinephrine 1 mL of 1mg/10ML (0.1 mg/mL) IV with slow flush or IV fluids
D. Call 911 or CODE BLUE

3. If ONLY skin findings but severe or progressive may consider Benadryl 50 mg PO, IM, IV but may cause or worsen hypotension.

HYPOTENSION WITH TACHYCARDIA (ANAPHYLAXIS)

1. Preserve IV access, monitor vitals q 15m
2. O2 6-10 L/min by face mask
3. Elevate legs > 60°
4. IVF 0.9% NS wide open
5. Epinephrine 0.3 mL of 1mg/mL IM (or auto-injector) OR Epinephrine 1 mL of 1mg/10mL (0.1 mg/mL) IV with slow flush or IV fluids
6. Call 911 or CODE BLUE

HYPOTENSION WITH BRADYCARDIA

1. Preserve IV access; monitor vitals
2. O2 6-10 L/min by face mask
3. Elevate legs > 60°

4. IVF 0.9% NS wide open
5. Atropine 0.6-1 mg IV if refractory
6. Consider calling 911 or CODE BLUE

LARYNGEAL EDEMA (INSPIRATORY STRIDOR)

1. Preserve IV access, monitor vitals
2. O2 6-10 L/ min by face mask
3. Epinephrine 0.3 mL of 1mg/ mL IM (or auto-injector) OR Epinephrine 1 mL of 1mg/10mL (0.1 mg/mL) IV with slow flush or IV fluids
4. Call 911 or CODE BLUE

BRONCHOSPASM (EXPIRATORY WHEEZE)

1. Preserve IV access, monitor vitals
2. O2 6-10 L/min by face mask
3. Beta-2 agonist inhaler 2 puffs; repeat x 3
4. If not responding or severe, then use Epinephrine 0.3 mL of 1mg/ mL IM (or auto-injector) OR Epinephrine 1 mL of 1mg/10mL (0.1 mg/mL) IV with slow flush or IV fluids
5. Call 911 or CODE BLUE

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)
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

BODY PART	METHOD OF ADMINISTRATION	AMOUNT	PRODUCT
			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
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
Myelogram Thoracic	Intrathecal	10 ml	Isovue-M 200
Myelogram Lumbar	Intrathecal	10 ml	Isovue-M 200
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
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) (11/22)

POLICY

Title: **ANAPHYLAXIS & ACUTE DRUG HYPERSENSITIVITY REACTION PROTOCOL**			
		Page **1** of **2**	
Policy Number: MM-05449		Date Last reviewed/Revised: 11/22	Valid Until: 11/23
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia ***Check all that apply***			
Department(s) Affected: All Clinical Areas, Pharmacy		Review Period: 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
  - **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: 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) (11/22)

POLICY

Title: HYPOGLYCEMIA PROTOCOL			
		Page 1 of 3	
Policy Number: PC-07013		Date Last reviewed/Revised: 11/22	Valid Until: 11/23
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas		Review Period: Annually	

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

DEFINITIONS:

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) 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 Orange Juice) 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 Orange Juice) 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):
Order Set Hypoglycemia Protocol MCT (3040004906)
American Diabetes Association. Diabetes Care 2023 Jan; 46 (Supplement 1): S267-S278
American Association of Clinical Endocrinologists and American Diabetes Association. Consensus Statement on Inpatient Glycemic Control 2009.
Center for Disease Control and Prevention. (2022, December 30). "Diabetes and Kidney Disease: What to Eat?" https://www.cdc.gov/diabetes/managing/eat-well/what-to-eat.html
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, 11/22, 5/23

POLICY

Title: NARCAN (NALOXONE) OPIOID REVERSAL PROTOCOL			
		Page **1** of **2**	
Policy Number: PC-07373		Date Last reviewed/Revised: 11/22	Valid Until: 11/23
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: All Clinical Areas		Review Period: Annually	

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

EXCEPTIONS:
Patients on Hospice/palliative care must have an MD order to prior to reversal

DEFINITIONS & TREATMENTS:

- When to suspect a narcotic overdose with unknown narcotic exposure:
  - History of narcotic overdose according to bystanders
  - Drug paraphernalia present
  - Medical/pertinent history consistent with narcotic use
- 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
  - The goal of treatment is to achieve ADEQUATE VENTILATION, not necessarily a normal level of consciousness
  - *Inpatient with* **RECENT** *narcotic administration by RN/LPN:*
    - Narcan (naloxone) 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 (naloxone) 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 [3040004919].**
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 an 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 or from an 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/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 them sign/authenticate the Narcan (Naloxone) Opioid Reversal Protocol MCT orders.

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) (11/21) (11/22)

POLICY

Title: RESPIRATORY DISTRESS PROTOCOL - PULMONARY SERVICES			
		Page 1 of 1	
Policy Number: PUL-01928		Date Last reviewed/Revised: 8/22	Valid Until: 10/23
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia *Check all that apply*			
Department(s) Affected: Pulmonary Services		Review Period: every year	

OUTCOME: To open and maintain obstructed airways.

PERSONNEL: Registered Respiratory Therapists.

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

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

RESPIRATORY DISTRESS PROTOCOL:

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

Key Contact: Pulmonary Management Team
Approved/Reviewed by: Pulmonary Medical Director; P&T Committee
Date First Effective & Revision/Review dates: 1/12 (4/15) (1/16) (11/18) (04/19) (2/21) (2/22) (8/22)

POLICY

Title: **BRADYCARDIA MANAGEMENT PROTOCOL**			
		Page **1** of **1**	
Policy Number: PC-07408		Date Last reviewed/Revised: 11/22	Valid Until: 11/23
Campus: ☒ CHI Memorial Glenwood ☒ CHI Memorial Hixson ☒ CHI Memorial Georgia ***Check all that apply***			
Department(s) Affected: All Departments		Review Period: Annually	

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

DEFINITIONS:
- Bradycardia: heart rate (HR) less than 60 beats per minute (bpm)
- Symptomatic bradycardia: HR < 40 AND one of the following: Systolic blood pressure ≤80, altered mental status, signs of shock, ischemic chest discomfort, OR acute heart failure

PERSONNEL: Medications to only be ordered by ACLS certified nurses

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

PROCEDURE & TREATMENTS:
All RNs:
1. Maintain patent airway- assist breathing as necessary
2. Maintain oxygen SpO2 ≥ 92%
3. Contact Primary MD and call a RRT
4. Connect patient to crash cart with pacing pads and leads
5. Ensure IV access
6. Obtain 12 Lead EKG

ACLS Certified RN:
7. Identify heart rate is < 40 bpm
8. Identify patient is symptomatic: SBP ≤ 80, altered mental status, signs of shock, ischemic chest discomfort, or acute heart failure
9. If HR < 40 and patient is symptomatic, administer Atropine 1 mg IVP. May repeat every 3-5 minutes to a max dose of 3 mg.
10. Atropine may be removed from the Pyxis Med Station via override function.
11. Physician must sign/authenticate the orders as soon as possible following enactment of the standing orders.
12. If at any time the patient's symptoms deteriorate and the patient experiences respiratory or cardiovascular compromise a CODE BLUE should be called for additional support.
13. Document medication administration appropriately in the electronic medical record.
14. Return unused items to Pyxis Med Station

Key Contact: Clinical Educator Critical Care
Approved/Reviewed by: Pharmacy & Therapeutics Committee, Pharmacy Director; Code Blue Committee; NPPC, Chief Nursing Officer
Related Forms: AHA ACLS Guidelines, AHA Bradycardia Protocol
Date First Effective & Revision/Review dates: 2/22, 11/22