Pharmacy & Therapeutics Committee Meeting
Private Dining Room
December 13, 2012 7:00 a.m.

Agenda Items	Individual Responsible
1. Call to Order	Richard Pesce, MD
2. Approval of October, 2012 Minutes	Richard Pesce, MD

Next Meeting will be February 14, 2013 at 7:00am in the Private Dining Room

CATHOLIC HEALTH INITIATIVES
Memorial Health Care System

PHARMACY AND THERAPEUTICS COMMITTEE

DATE: October 11, 2012 CALLED TO ORDER: 7:00 A.M.
LOCATION: Private Dining Room ADJOURNED: 8:03 A.M.

Members Present:		**Members Absent**:		**Guest**:
Richard Pesce, M.D.	Karen Babb, RPh	Nathan Chamberlain, M.D.	Gwen Davis, RN	John Jantz, RPh, resident
Mark Anderson, M.D.	Diona Brown, RN,C.N.O.	John L. Gwin, Jr., M.D.	Scott Madaris, RN	Daniel Marsh, RPh
David Dodson, M.D.	Vickie Burger, Lab	Tarek Kadrie, M.D	Robert Mynatt, M.D.	
Gale Fellowes, M.D.	Patrick Ellis, RPh	Susan Izell, RN	Patrick Hagan, Finance.	
Michael Stipanov, M.D	Beverly Slate, Supply Chain	William Oellerich, M.D.	Deb Moore, RN, COO	
	Hannah Walker, RN	Elvie Smith, RN	Nan Payne, RN	
	Jackie Jackson, RN,COO	Melissa Roden, RN	Don Jones, RPh	
	Brian Jones, RD, LDN			
	Cindy Brooks, RN			
	Sandy Vredeveld, RPh			
	Lila Heet, RPh			

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 28, 2012 minutes were approved as submitted.		Complete
Formulary	The following medication were reviewed: 1. **Lepirudin (Refludan®)** – Used in the management of HIT. Due to a recent cost increase, lepirudin will be therapeutically interchanged to **argatroban**. A very limited supply of Refludan will be on hand for patients with severe hepatic impairment who are not suitable candidates for argatroban therapy. 2. **Roflumilast (Daliresp®)** – Used in the treatment of COPD. 3. **Denosumab (Prolia®) –** Used in the treatment of osteoporosis. Its use will be limited to only outpatients that are not candidates for **Reclast®** therapy (CrCl < 35 ml/min). 4. **Aclidinium bromide (Tudorza®, Pressair®) –**Used in the treatment of COPD. All new orders will be substituted to a therapeutically equivalent dose of **Spiriva®.** 5. **IVIG (Octagam®)** – Used in treatment of immunodeficiencies. Annual savings of $500,000. 6. **Sulphan Blue** – Used to facilitate sentinel node biopsy. Annual savings is $14,896. Will be utilized instead of isosulfan blue. 7. **TobraDex®--** Used in the treatment for eye infections. All orders will be substituted to a therapeutically equivalent dose of **Pred-G®.** Annual savings is $4,600. 8. **Current Formulary** – annual formulary review completed by committee.	1-2. Approved. 3. Restricted use only (per criteria) 4. Denied 5-8. Approved	Complete Complete Complete Complete
Medication Safety	1. **Safe Use of Opioids in hospitals**. The Joint Commission published article was discussed by members of the committee. It was recommended to share the information with the members of Ortho CQI for their input. A group including nursing, pharmacy and the chief of staff is currently reviewing the content for recommendations and subsequent plan of action. A sub group will also be formed to evaluate the feasibility of utilizing capnography for patients at high risk of respiratory depression and/or over-sedation secondary to opioid use. 2. **Ondansetron (Zofran®) --** FDA warns of abnormal heart rhythms associated with single 32mg doses of ondansetron**.** IV doses will now be limited to a maximum single dose of 16mg per dose. 3. **Topical Benzocaine sprays –** Due to continued reports to the FDA of methemoglobinemia, all benzocaine containing sprays will be removed from formulary.	1. Information 2. Approved 3. Approved	Pending Complete Complete

AGENDA ITEM	FINDINGS OR CONCLUSION	ACTION, RESPONSIBILITY	STATUS
MUE	1. **Chlorothiazide (Diuril®) –** An MUE was conducted to identify the types of prescribers with highest utilization, provide information about current expenditures, and determine the usual indications surrounding its use. Due to the findings, pharmacy will begin to monitor for discontinuation in patients receiving this drug greater than 24-36 hours when clinically appropriate. Stability testing for a longer expiration date is currently underway as well to minimize wastage. 2. **IV Acetaminophen (Ofirmev®) –**A retrospective study reviewed 300 patients to determine if this drug affected a patient's perceived pain scores or opioid usage post-orthopedic surgery. Results showed no significant reduction in pain scores, opioid consumption in PACU, or 24 hour opioid consumption. Recommendation was made to remove from formulary. Dr. Pesce to follow-up with the remaining specialty that continues to utilize this medication.	1. Information 2. Do not add to formulary	Complete Pending
Policy and Procedure	1. **Sedatives/Hypnotics For Sleep –** This policy was amended to allow the use of diphenhydramine (Benadryl®) for sleep if a patient takes it at home. Maximum dose will be limited to 25mg. 2. **Restricted antimicrobials –** List was reviewed. 3. **Anticoagulation Management –** This policy was amended to expand the time frame for a baseline INR required prior to initiating warfarin. INRs within 72 hours will be allowed instead of 24 hours. 4. **Alteplase (Cathflo®) –** All alteplase orders for catheter occlusion will be converted from 2mg/ml to 1mg/1ml. This offers a potential annual savings of $24,695.	1-4. Approved	Pending
Pharmacy Dashboard	July-August 2012 compared to May-June 2012 • Documented Clinical Interventions (CIs) increased by 2.4% • Major Adverse Drug Events Prevented by pharmacists increased by 138% • Pharmacokinetic consults increased 10% • TPN pts per 1000 Adj Pt Days increased by 45% • 1 central line infections in TPN pts • Coumadin consults increased by 7.9% • Antimicrobial Stewardship Clinical Interventions increased by 11.2% • Chemotherapy doses increased by 8.2%	Information	Complete
Nutrition Support Team	1. **Clear Liquid Diet –** Diabetic patients receiving a clear liquid diet will receive 200 grams of carbohydrates spread equally throughout the day. 2. **Vital HN –** Peptide-based, elemental, low-residue tube feeding. All orders for Vital HN will be substituted to Vital 1.5.	1. Approved 2. Denied	Complete Complete

There being no further business, the meeting was adjourned at 8:03 A.M. The next P&T meeting is December 13, 2012.

Respectfully submitted,
Sandy Vredeveld, D.Ph. Director of Pharmacy
Patrick Ellis, Pharm.D. Pharmacy Clinical Coordinator

Approved by,
Richard Pesce, M.D. Chairman

FORMULARY UPDATE

REMICADE® (INFLIXIMAB)

BACKGROUND:
Infliximab is a monoclonal antibody approved for the treatment of various inflammatory disorders such as Crohn's disease, ulcerative colitis, rheumatoid arthritis, and ankylosing spondylitis. Infliximab neutralizes the biological activity of the cytokine TNFalpha thereby reducing the infiltration of inflammatory cells and TNFalpha production in inflamed areas of the intestines, joints, etc.

Since infliximab's original FDA approval, it has been on formulary for outpatient use for the above mentioned indications without restrictions. Based on a recent analysis, 153 patients have been treated with infliximab in our outpatient infusion center over the past year. Only 71 patients (46%) of these patients have received a dose within the previous 3 months. Additionally, 34 of these patients (22%) received their first dose of infliximab at the infusion center within the last 3 months.

FINANCIAL ANALYSIS
Previous 12 month purchases: $1,959,902.21
A detailed contribution margin analysis was performed by the finance department and it was determined that the profit/loss for infliximab therapy varied by payer but the overall contribution margin was essentially a "break-even" when the cost was compared to actual reimbursement. Infliximab currently represents the 2nd highest overall drug expenditure at Memorial Healthcare System.

RECOMMENDATION & CONCLUSION
Based on the above, it is recommended to implement the below adjustments to the use of infliximab in the outpatient infusion center:

- MHCS will no longer accept NEW infliximab orders UNLESS prior treatment with Humira or other TNF-Antagonist agents has been made and it has been documented that the patient does not tolerate the alternate agents.
- This will not impact any patients currently treated in the infusion center. (current patients defined as: patients treated within the previous 8 months)

It is not the intent to remove infliximab from formulary but only to designate this as an agent to be used AFTER failure with other TNF antagonist agents. If patients have had documented failure with other agents then these patients can be scheduled without restrictions to receive their infliximab therapy at MHCS. This recommendation has been discussed with various prescribers of infliximab and also with members of Memorial's leadership team and the service line director of the infusion center. Annual savings estimated at approximately $400,000.

FORMULARY REVIEW

GENERIC NAME: Bupivacaine Liposomal

PROPRIETARY NAME: Exparel (Pacira)

INDICATIONS: Exparel is a liposome injection of bupivicaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia.

CLINICAL PHARMACOLOGY: Local anesthetics block the generation and the conduction of nerve impulses presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers.

PHARMACOKINETICS: Local infiltration of EXPAREL results in significant systemic plasma levels of bupivacaine which can persist for 96 hours. The rate of systemic absorption of bupivacaine is dependent upon the total dose of drug administered, the route of administration, and the vascularity of the administration site.

ADVERSE REACTIONS: Nausea, Constipation, and Vomiting were reported in greater than or equal to 10% of the patients.

DRUG INTERACTIONS: Do not admix with lidocaine or other nonbupivacaine-based local anestheics. This can result in a rapid increase in free (unencapsulated) bupivacaine, which may adversely affect safety and/or efficacy.

DOSING: Is intended for single-dose administration only. The recommended dose is based on the surgical site and the volume required to cover that area:

Surgery	**Dose of EXPAREL**	**Volume of EXPAREL**
Bunionectomy	106 mg	8 mL (undiluted)
Hemorrhoidectomy	266 mg	20 mL (diluted)

PRODUCT AVAILABILITY and STORAGE: This medication was approved by the U.S. FDA on October 28, 2011. It is available in 20ml single use vials at 13.3mg/ml. The vials should be stored in the refrigerator (2-8 degrees C) in the original carton to protect from light. The vials may be held at a controlled room temperature of 20-25 degrees C for up to one month in sealed, unopened vials. Vials should not be re-refrigerated. Do not freeze.

CONTRAINDICATIONS: Do not use in obstetrical paracervical block anesthesia.

WARNINGS AND PRECAUTIONS: Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection. It is metabolized by the liver, so use with caution in patients with hepatic disease. It is substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Other formulations of bupivacaine should not be administered within 96 hours following administration of Exparel.

STUDY RESULTS: One hundred eighty-nine patients were randomly assigned and treated; 186 completed the study. Pain intensity scores were significantly lower in the bupivacaine extended-release group in comparison with the group receiving placebo (141.8 vs 202.5, $P< 0001$). More patients in the bupivacaine extended-release group remained opioid free from 12 hours (59%) to 72 hours (28%) after surgery compared with patients receiving placebo (14% and 10%; $P<.0008$ through 72 h). The mean total amount of opioids consumed through 72 hours was 22.3 mg and 29.1 mg in the bupivacaine extended-release and placebo groups ($P<.0006$). The median time to first opioid use was 14.3 hours in the bupivacaine extended release group vs 1.2 hours in the placebo group ($P<.0001$). A greater proportion of patients in the bupivacaine extended-release group were satisfied with their postsurgical analgesia (95% vs 73%, $P<.0007$) than in the placebo group.

Liposomal bupivacaine has not been evaluated for, and therefore is not recommended for epidural, intrathecal, regional nerve block or intra-articular use.

CONCLUSION: Based on the study results above, Exparel demonstrated a statistically significant reduction in pain through 72 hours, decreased opioid requirements, delayed time to first opioid use, and improved patient satisfaction compared with placebo after hemorrhoidectomy.

COST: $285/20 ml

RECOMMENDATION: Do not add bupivacaine liposome (Exparel) to the formulary given its high cost and undefined efficacy and safety profile. This recommendation may be reviewed at a latter time when bupivacaine liposome is more widely available and studies have been conducted to show its efficacy in postsurgical analgesia.

Failure Mode and Effects Analysis

Liposomal bupivacaine

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
• Therapeutic interchange?	No	
• Special Ordering Requirements?	No	
Storage		
• LASA* – separation of stock?	Yes	Both are a milky white liquid that when prepared in syringes look VERY similar.
• Special storage – refrigeration, protect from light, controlled substance, etc.?	Yes	Refrigeration required
Ordering & Prescribing		
• Restriction to particular specialty, indication, or particular patient population?	No	
• Are calculations required to obtain the dose?	No	
• Will the drug be limited to the critical care units?	No	
• Dosing Issues – i.e. renal, hepatic dosage adjustment, max dose warnings	No	
• Significant drug interactions?	No	
• Significant side effect profile?	No	
• Pregnancy?	No	
• Black box warning?	No	
• Requires Order Set, Protocol, concomitant therapy with another drug?	No	
• LASA* – nomenclature issues?	No	
• Prescriber education?	Yes	
Processing, Preparing, & Dispensing		
• High-risk Drug double check?	No	
• Drug Interaction check in place?	No	
• LASA* – labeling/packaging?	Yes	See above comments
• Administration Notes for MAR – handling precautions, surrounding food or other drugs, etc.?	No	
• Dispensing – auxiliary labeling, light protection, refrigeration, etc.?	Yes	Short shelf-life at room temperature
• Documentation required? (i.e. double check, worksheet, etc.)	No	
• Pharmacist/Technician Education?	No	
Administration		
• Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, etc.?	No	
• Does the physician need to be present to administer the drug or monitor the patients	No	
• Special delivery system – i.e. pump, etc.?	Yes	
• Documentation required? (i.e. double check, etc.)	No	
• Nurse education?	No	
Monitoring		
• Interactions, adverse effects, efficacy, changes in renal function, etc.?	No	
• Narrow therapeutic index?	No	
• Follow-up laboratory tests?	No	
• Education?	No	

* LASA=Look-alike, sound-alike

FORMULARY REVIEW

GENERIC NAME: TAFLUPROST

PROPRIETARY NAME: *Zioptan* (Merck)

INDICATIONS: Tafluprost is approved for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

CLINICAL PHARMACOLOGY: Tafluprost belongs to a group of drugs classified as selective FP prostanoidreceptor agonists. The pharmacologic activity of tafluprost is hypothesized to be comparable with other prostaglandin analogues.[5] Tafluprost is a fluorinated analogue of prostaglandin F2alpha. Corneal esterases rapidly convert tafluprost into its active metabolite, tafluprost acid, and subsequently penetrate into the anterior chamber of the eye. Studies have indicated that tafluprost has potent and selective agonistic activity of the human prostanoid FP receptor, with minimal activity at other receptors. Tafluprost lowers IOP by stimulating the increase of aqueous humor outflow through the uveoscleral passage.

PHARMACOKINETICS: Tafluprost is a 16-phenoxy analogue of prostaglandin F2alpha, with a 15,15-difluoro substitution. This 2 fluorine atom substitution at the carbon 15 position differs from the hydroxyl groups that are present in latanoprost, travoprost, and bimatoprost. The major metabolic pathway of the other prostaglandin analogues is via 15-hydroxy-dehydrogenase. Tafluprost is not metabolized through this pathway; instead, it undergoes beta-oxidation of the alpha-chain of prostaglandin skeleton. The systemic bioavailability and absorption of tafluprost is minimal, with plasma concentrations of the active metabolite low at all time points.

COMPARATIVE EFFICACY & SAFETY: Tafluprost has been shown to be non-inferior to comparator prostaglandin agonists in temrs of efficacy and patient tolerability. Tafluprost had a similar adverse reaction profile to latanoprost in clinical trials, and reported adverse reactions were classified as predominantly mild to moderate in severity. Tafluprost has no apparent advantage in terms of efficacy, tolerability, or adverse reactions. Tafluprost is currently the only ophthalmic prostaglandin agonist in a preservative-free formulation.

ADVERSE REACTIONS: The most common ocular adverse reaction associated with tafluprost therapy is conjunctival hyperemia (4% to 20%).

DRUG INTERACTIONS: No drug-drug interactions are anticipated in humans because of the low systemic concentrations of tafluprost following ocular administration. In clinical studies, tafluprost was used concomitantly with timolol without evidence of any problems.

DOSING: Instill 1 drop into the affected eye(s) once daily in the evening.

COST:
Tafluprost - $92.90
Latnoprost - $10.09
Bimatoprost - $92.98
Travoprost - $85.09

CONCLUSION: Tafluprost has no apparent advantage in terms of efficacy, tolerability, or adverse reactions. **Due to similar efficacy and a significant cost advantage associated with the use of latanoprost, it is recommended to add tafluprost to the already existing therapeutic interchange for the prostaglandin antagonists. Orders for tafluprost will be automatically interchanged to the therapeutically equivalent dose of latanoprost as outlined below.**

Drug	Equivalent Dosage
Bimatoprost	1 drop in the affected eye(s) once daily
Latanoprost	1 drop in the affected eye(s) once daily
Tafluprost	1 drop in the affected eye(s) once daily
Travoprost	1 drop in the affected eye(s) once daily

Failure Mode and Effects Analysis

Tafluprost

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
• Therapeutic interchange?	Yes	Automatic therapeutic interchange as mentioned above.
• Special Ordering Requirements?	No	
Storage		
• LASA* – separation of stock?	No	
• Special storage – refrigeration, protect from light, controlled substance, etc.?	No	
Ordering & Prescribing		
• Restriction to particular specialty, indication, or particular patient population?	No	
• Are calculations required to obtain the dose?	No	
• Will the drug be limited to the critical care units?	No	
• Dosing Issues – i.e. renal, hepatic dosage adjustment, max dose warnings	No	
• Significant drug interactions?	No	
• Significant side effect profile?	No	
• Pregnancy?	No	
• Black box warning?	No	
• Requires Order Set, Protocol, concomitant therapy with another drug?	No	
• LASA* – nomenclature issues?	No	
• Prescriber education?	No	
Processing, Preparing, & Dispensing		
• High-risk Drug double check?	No	
• Drug Interaction check in place?	No	
• LASA* – labeling/packaging?	No	
• Administration Notes for MAR – handling precautions, surrounding food or other drugs, etc.?	No	
• Dispensing – auxiliary labeling, light protection, refrigeration, etc.?	No	
• Documentation required? (i.e. double check, worksheet, etc.)	No	
• Pharmacist/Technician Education?	Yes	Pharmacists will be educated regarding interchange details.
Administration		
• Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, etc.?	No	
• Does the physician need to be present to administer the drug or monitor the patients	No	
• Special delivery system – i.e. pump, etc.?	No	
• Documentation required? (i.e. double check, etc.)	No	
• Nurse education?	No	
Monitoring		
• Interactions, adverse effects, efficacy, changes in renal function, etc.?	No	
• Narrow therapeutic index?	No	
• Follow-up laboratory tests?	No	
• Education?	No	

* LASA=Look-alike, sound-alike

FORMULARY REVIEW

GENERIC NAME: MIRABEGRON

PROPRIETARY NAME: *Myrbetriq* (Astellas Pharma)

INDICATIONS: Mirabegron is approved by the Food and Drug Administration for treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

CLINICAL PHARMACOLOGY: Mirabegron is a potent and selective beta-3 adrenoceptor agonist. It activates the beta-3 adrenoceptor on the detrusor muscle of the bladder, resulting in increased bladder filling and storage of urine without suppressing the amplitude of bladder contractions during micturition.

PHARMACOKINETICS: Mirabegron tablets use an oral controlled-absorption system formulation. This is a modified-release, film-coated tablet. This dosage form slows the rate of absorption compared with immediate-release tablets, attenuates the effects of high-fat meals, and reduces the fluctuation in plasma concentrations. Peak plasma concentrations (C_{max}) occur 3 to 4 hours after oral administration. Food decreases the absorption of mirabegron, but the labeling states mirabegron can be taken with or without food. Its effective half-life is approximately 19 hours, and the terminal half-life is approximately 50 hours. Changes in renal function can increase C_{max} and area under the curve (AUC). Changes in hepatic function also influence the pharmacokinetic parameters of mirabegron.

ADVERSE REACTIONS: The most common adverse reactions reported with mirabegron included headache, nasopharyngitis, urinary tract infection, and hypertension.

DRUG INTERACTIONS: Mirabegron is metabolized by CYP3A4 isozymes, and its elimination can be influenced by the presence of CYP3A4 inhibitors and inducers. There is no apparent difference in mirabegron exposure between CYP2D6 poor metabolizers and extensive metabolizers. Mirabegron is also a moderate inhibitor of the CYP2D6 isozyme. However, caution is advised when mirabegron is coadministered with medication significantly metabolized by CYP2D6 with a narrow therapeutic index (eg, thioridazine, flecainide, propafenone).

DOSING: The recommended initial dosage is 25 mg once daily with or without food. The tablets should be swallowed whole with water and not chewed, divided, or crushed. Reassess after 8 weeks to determine if an increase in dose is necessary; if so, the dosage can be increased to 50 mg once daily. The maximum recommended dosage for patients with severe renal impairment or moderate hepatic impairment is 25 mg once daily. Mirabegron is not recommended for patients with end-stage renal disease or severe hepatic impairment.

COST: All strengths (25 mg &50 mg) - $6.66 per dose

PRODUCT AVAILABILITY: The Reproductive Health Drugs Advisory Committee recommended approval (yes: 7, no: 4, abstain: 1) of mirabegron for the treatment of OAB in April 2012. It was approved for use in Japan in 2011 and the United States in June 2012. *Myrbetriq* is available as a 25 and 50 mg film-coated, extended-release tablet.

DRUG SAFETY/REMS: No REMS is required for mirabegron.

CONCLUSION: Mirabegron is the first beta-3 adrenoceptor agonist intended for the treatment of OAB. Most drugs approved for the treatment of OAB are anticholinergic agents. Mirabegron may be useful for patients who are unable to tolerate the side effects associated with anticholinergic agents or patients for whom anticholinergic-induced mydriasis may increase intraocular pressure (eg, uncontrolled narrow-angle glaucoma). **Due to the unique mechanism of action of mirabegron and the lack of any other agents with this specific pharmacologic activity, it is recommended to add mirabegron to formulary without restrictions. As newer agents in this drug class are approved a therapeutic interchange will be considered to limit the number of similar agents to formulary.**

Failure Mode and Effects Analysis

Mirabegron

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
• Therapeutic interchange?	No	
• Special Ordering Requirements?		
Storage		
• LASA* – separation of stock?	No	
• Special storage – refrigeration, protect from light, controlled substance, etc.?	No	
Ordering & Prescribing		
• Restriction to particular specialty, indication, or particular patient population?	No	
• Are calculations required to obtain the dose?	No	
• Will the drug be limited to the critical care units?	No	
• Dosing Issues – i.e. renal, hepatic dosage adjustment, max dose warnings	No	
• Significant drug interactions?	No	
• Significant side effect profile?	No	
• Pregnancy?	No	
• Black box warning?	No	
• Requires Order Set, Protocol, concomitant therapy with another drug?	No	
• LASA* – nomenclature issues?	No	
• Prescriber education?	No	
Processing, Preparing, & Dispensing		
• High-risk Drug double check?	No	
• Drug Interaction check in place?	No	
• LASA* – labeling/packaging?	No	
• Administration Notes for MAR – handling precautions, surrounding food or other drugs, etc.?	No	
• Dispensing – auxiliary labeling, light protection, refrigeration, etc.?	No	
• Documentation required? (i.e. double check, worksheet, etc.)	No	
• Pharmacist/Technician Education?	No	
Administration		
• Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, etc.?	No	
• Does the physician need to be present to administer the drug or monitor the patients	No	
• Special delivery system – i.e. pump, etc.?	No	
• Documentation required? (i.e. double check, etc.)	No	
• Nurse education?	No	
Monitoring		
• Interactions, adverse effects, efficacy, changes in renal function, etc.?	No	
• Narrow therapeutic index?	No	
• Follow-up laboratory tests?	No	
• Education?	No	

* LASA=Look-alike, sound-alike

FORMULARY REVIEW

GENERIC NAME: ROMIPLOSTIM

PROPRIETARY NAME: *Nplate* (Amgen)

INDICATIONS: Romiplostim is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Romiplostim should only be used in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Romiplostim should not be used to normalize platelet counts.

CLINICAL PHARMACOLOGY: Romiplostim is a recombinant thrombopoiesis-stimulating Fc-peptide fusion protein produced via a genetically modified *Escherichia coli.* The Fc component extends the half-life of the molecule in the circulation. The peptide portion binds to and activates the human thrombopoietin receptor, Mpl.

PHARMACOKINETICS: Romiplostim concentrations are dependent on dose and baseline platelet count. Romiplostim clearance increases as a result of romiplostim-induced increases in platelet count and thrombopoietin receptor capacity. Peak romiplostim concentrations appear to occur between 7 and 50 hours (median, 14 hours) after subcutaneous administration. The half-life ranges from 1 to 34 days (median, 3.5 days).

ADVERSE REACTIONS: The most common adverse reactions observed during romiplostim therapy have included arthralgia, dizziness, headache, insomnia, myalgia, extremity pain, abdominal pain, shoulder pain, dyspepsia, and paresthesia. Most other adverse reactions, except headache and transient worsening of thrombocytopenia, appeared to be related to the underlying disease. Serious adverse reactions related to romiplostim have included severe headache, elevated serum lactic dehydrogenase, elevated bone marrow reticulin, reticulin fibrosis, thrombosis, bleeding, unacceptably high platelet count, and thrombocytopenia.

DRUG INTERACTIONS: Drug interactions have not been reported; formal drug interaction studies were not performed.

DOSING: The initial dose is 1 mcg/kg subcutaneously once weekly. Actual body weight at initiation of therapy should be used for the initial dose and dosage adjustments. A syringe with 0.01 mL graduations should be used to administer romiplostim because of the very small volumes administered. The dose may be adjusted weekly by increments of 1 mcg/kg to achieve and maintain a platelet count of 50×10^9/L or more as necessary to reduce bleeding risk.

PRODUCT AVAILABILITY and STORAGE: Romiplostim received Food and Drug Administration approval in August 2008. Romiplostim is supplied as 250 and 500 mcg single-use vials containing sterile, preservative-free lyophilized powder requiring reconstitution with preservative-free sterile water for injection. Each 250 mcg vial contains romiplostim 375 mcg; each 500 mcg vial contains romiplostim 625 mcg. Vials should be stored in their carton to protect from light and refrigerated (2° to 8°C; 36° to 46°F).

COST

Romiplostim 250 mcg vial - $1,165 Romiplostim 500 mcg vial - $2,330

CONCLUSION: Romiplostim is a unique thrombopoiesis-stimulating agent for use in patients with thrombocytopenia and chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Its use has been associated with a reduced incidence of bleeding and a reduction in the need for administration of immunoglobulin and corticosteroids. It is recommended to approve for formulary addition for the above mentioned FDA approved indication and ordering restricted to Hematology specialists only.

Failure Mode and Effects Analysis

Romiplostim

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
• Therapeutic interchange?	No	
• Special Ordering Requirements?	Yes	Only available from specialty wholesaler.
Storage		
• LASA* – separation of stock?	No	
• Special storage – refrigeration, protect from light, controlled substance, etc.?	Yes	Refrigeration required
Ordering & Prescribing		
• Restriction to particular specialty, indication, or particular patient population?	Yes	Hematology
• Are calculations required to obtain the dose?	Yes	Weight based dosing (see above)
• Will the drug be limited to the critical care units?	No	
• Dosing Issues – i.e. renal, hepatic dosage adjustment, max dose warnings	No	
• Significant drug interactions?	No	
• Significant side effect profile?	No	
• Pregnancy?	No	
• Black box warning?	No	
• Requires Order Set, Protocol, concomitant therapy with another drug?	No	
• LASA* – nomenclature issues?	No	
• Prescriber education?	No	
Processing, Preparing, & Dispensing		
• High-risk Drug double check?	No	
• LASA* – labeling/packaging?	No	
• Administration Notes for MAR – handling precautions, surrounding food or other drugs, etc.?	No	
• Dispensing – auxiliary labeling, light protection, refrigeration, etc.?	No	
• Documentation required? (i.e. double check, worksheet, etc.)	No	
• Pharmacist/Technician Education?	No	
Administration		
• Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, etc.?	No	
• Does the physician need to be present to administer the drug or monitor the patients	No	
• Special delivery system – i.e. pump, etc.?	No	
• Documentation required? (i.e. double check, etc.)	No	
• Nurse education?		
Monitoring		
• Interactions, adverse effects, efficacy, changes in renal function, etc.?	No	
• Narrow therapeutic index?	No	
• Follow-up laboratory tests?	No	
• Education?	No	

* LASA=Look-alike, sound-alike

FORMULARY REVIEW

STADOL NASAL SPRAY® (BUTORPHANOL)

CLINICAL PHARMACOLOGY: Butorphanol is a schedule IV controlled substance that is an opiate agonist-antagonist that is currently available on formulary as both the injectable and nasal spray dosing formulations.

DISCUSSION & RECOMMENDATION: Butorphanol nasal spray has been on formulary for an extensive period of time although the overall use of this agent continues to drop each year with an annual use of approximately 6 total doses per year. Since this is a multi dose container of a controlled substance, safely securing this between doses is of extreme importance although due to the complexity of our medication distribution systems, the safe storage and timely delivery of this medication dosage form is difficult at best. Due the relatively low use and the difficulties in securely storing this medication it is recommended to remove this agent from formulary. A multitude of other narcotics including injectable butorphanol are available for use as viable alternatives.

FORMULARY REVIEW

GENERIC NAME: PENICILLOYL POLYLYSINE INJECTION

PROPRIETARY NAME: *PRE-PEN* (ALK)

CLINICAL PHARMACOLOGY: Pre-Pen is a skin test antigen reagent that reacts specifically with benzylpenicilloyl IgE antibodies initiating the release of chemical mediators which produce an immediate wheal and flare reaction at a skin test site. All individuals exhibiting a positive skin test to Pre-Pen possess IgE against the benzylpenicilloyl structural group which is the major antigenic determinant in penicllin allergic individuals. A negative skin test is associated with an incidence of immediate allergic reactions of less than 5% after the administration of therapeutic penicillin, whereas the incidence may be more than 50% in a history positive patient with a positive skin test to Pre-Pen. The Pre-Pen product (benzylpenicilloyl polylysine) is the major determinant of an IgE mediated penicillin allergy. It is recommended to also skin test with a minor determinant (diluted penicillin G) which will allow improve identification of up to 97% of patients with IgE mediated penicillin allergy.

INDICATIONS: Pre-Pen is indicated for the assessment of sensitization to penicllin (benzylpenicillin or penicillin G) in patients suspected to have clinical penicillin hypersensitivity.

ADVERSE REACTIONS: Occasionally, patients may develop an intense local inflammatory response at the skin test site. Rarely, patients will develop a systemic allergic reaction, manifested by generalized erythema, pruritis, angioedema, urticaria, dyspnea, hypotension, and anaphylaxis.

CONTRAINDICATIONS: Contraindicated in patients who have exhibited either a systemic or marked local reaction to previous penicillin administration. Patients known to be extremely hypersensitive to penicillin should not be skin tested.

DOSING/ADMINISTRATION: Pre-pen is administered as a series of prick/puncture tests followed by intradermal tests of Pre-Pen (major determinant), diluted penicllin G (minor determinant) and a diluent control. The initial prick tests are monitored for 15-20 minutes and then the results determined prior to proceeding with the intradermal testing. If no reaction is observed following the prick testing, intradermal testing will be performed and monitored for 15-20 minutes and then the final determination is made regarding positive or negative skin testing results.

PRODUCT AVAILABILITY & COST:
0.25 ml single dose ampule (1 ampule per test): $73.82

CONCLUSION & RECOMMENDATION:
Allergy to penicillins and related antibiotics is the most commonly reported drug allergy in the United States. Estimates show that of the patients who claim a penicillin allergy approximately only 10% are generally found to have a true penicillin allergy. Clinical situations are often encountered at MHCS when patients are ideal candidates for therapy with a penicllin or other beta-lactam antimicrobial but must be avoided due to the presence of a penicillin allergy per their history often without details on the type of reaction. This can result in the utilization of suboptimal therapies and often more expensive therapies. Pre-Pen allergy testing would be useful for a small subset of patients in which therapy with a beta-lactam would be preferred and result in more optimal antimicrobial therapy. It is recommended to approve Pre-Pen for formulary addition. A policy and procedure is currently in development to clearly outline the testing procedure and interpretation of the results. This product will not be used until the policy/procedure has been developed and education has been provided to a small subset of the IV team who at this point is anticipated to be the designated providers of the Pre-Pen testing. Initially, the ordering of Pre-Pen will be limited to the infectious disease specialists until more experience is gained with the use of this product.

Failure Mode and Effects Analysis

Penicilloyl polylysine

Medication Management Step	Identified Risk	Steps for Prevention
Selection & Procurement		
• Therapeutic interchange?	No	
• Special Ordering Requirements?	No	
Storage		
• LASA* – separation of stock?	No	
• Special storage – refrigeration, protect from light, controlled substance, etc.?	No	
Ordering & Prescribing		
• Restriction to particular specialty, indication, or particular patient population?	Yes	Initially will be restricted to ID
• Are calculations required to obtain the dose?	No	
• Will the drug be limited to the critical care units?	No	
• Dosing Issues – i.e. renal, hepatic dosage adjustment, max dose warnings	No	
• Significant drug interactions?	No	
• Significant side effect profile?	No	
• Pregnancy?	No	
• Black box warning?	No	
• Requires Order Set, Protocol, concomitant therapy with another drug?	Yes	Protocol in development
• LASA* – nomenclature issues?	No	
• Prescriber education?	No	
Processing, Preparing, & Dispensing		
• High-risk Drug double check?	No	
• LASA* – labeling/packaging?	No	
• Administration Notes for MAR – handling precautions, surrounding food or other drugs, etc.?	No	
• Dispensing – auxiliary labeling, light protection, refrigeration, etc.?	No	
• Documentation required? (i.e. double check, worksheet, etc.)	No	
• Pharmacist/Technician Education?	Yes	Education will be provided for pharmacy and nursing.
Administration		
• Handling precautions, high-risk double check, administration with/without food, interactions, incompatibilities, etc.?	No	
• Does the physician need to be present to administer the drug or monitor the patients	No	
• Special delivery system – i.e. pump, etc.?	Yes	Intradermal skin testing; education will be provided and protocol developed.
• Documentation required? (i.e. double check, etc.)	Yes	
• Nurse education?		
Monitoring		
• Interactions, adverse effects, efficacy, changes in renal function, etc.?	No	
• Narrow therapeutic index?	No	
• Follow-up laboratory tests?	No	
• Education?	Yes	Education and the protocol will address interpretation of skin test results.

* LASA=Look-alike, sound-alike

FORMULARY UPDATE

XARELTO® (RIVAROXABAN)

BACKGROUND: Rivaroxaban is an oral anticoagulant that inhibits platelet activation and fibrin clot formation via direct, selective and reversible inhibition of factor Xa in both the intrinsic and extrinsic coagulation pathways. Factor Xa catalyzes the conversion of prothrombin to thrombin. Thrombin both activates platelets and catalyzes the conversion of fibrinogen to fibrin.

Rivaroxaban was originally approved for formulary addition at the October 2011 P&T meeting following its initial approval for prevention of DVT following knee or hip surgery. Since this initial approval Rivaroxaban has also gained approval for stroke prophylaxis in patients with non-valvular atrial fibrillation (July 2011) and most recently for treatment of DVT or PE and for the reduction in the risk of recurrent DVT and/or PE (November 2012).

COMPARATIVE DOSING & ADJUSTMENTS PER INDICATION:

1) Nonvalvular Atrial Fibrillation

Creatinine Clearance	Recommended Dose
> 50 ml/min	20 mg QDAY (with evening meal)
15-50 ml/min	15 mg QDAY (with evening meal)
< 15 ml/min or HD patient	Avoid Use

2) Postoperative Thromboprophylaxis (Knee or Hip)

- Dose = 10 mg daily (Avoid use if CrCl < 30 ml/min.)
- **Initiate therapy after hemostasis has been established (~10 hours postoperatively).**
- Use for 12 to 14 days for knee replacement.
- Use for 35 days for hip replacement.

3) DVT/PE Treatment

Creatinine Clearance	Recommended Dose
> 30 ml/min	15mg BID for 21 days, Then 20mg QDAY (Take with food.)
< 30 ml/min	Avoid Use

RISK MITIGATION STRATEGIES: Due to the confusion that can be associated with the dosing and appropriate dose adjustments, the following steps have been taken to minimize the risks associated with the use of rivaroxaban.

- Quick reference sheets developed to assist with physician and pharmacist education including the following:
  - Assistance with converting other anticoagulants to rivaroxaban or from rivaroxaban to other anticoagulants
  - Appropriate dosing including renal adjustments when appropriate
- Development of anticoagulant reversal guidelines for rivaroxaban & other anticoagulants
- Daily pharmacist activities
  - Concurrent review of all rivaroxaban orders for appropriate dosing, etc.
  - Patient education for all new starts on rivaroxaban

ADVERSE DRUG REACTION SUMMARY
1ST QUARTER (FY 12)
July 2012 – September 2012

Category 1: Commonly recognized ADR's which are expected and do not result in serious medical consequences or extended hospitalization (e.g. antibiotic rash, nausea, mild hypokalemia).

Category 2: Significant ADR's which extend hospitalization and/or require extensive therapeutic measures (e.g. gastrointestinal bleed secondary to NSAIDs, Aminoglycoside nephrotoxicity.

Category 3: A serious or rare ADR which has abnormal characteristics compared with published reports of the reaction (e.g. heparin induced platelet aggregation resulting in limb amputation). ADR's from this category should be reported to the manufacturer and/or the FDA (MedWatch or the Vaccine Adverse Event Reporting System).

Inpatient: 141 (28.3%) Prior to hospitalization: 358 (71.7%)

Category 1: 349
Category 2: 149
Category 3: 1

Category 3: Trach aspirate MSSA, cefazolin started and patient developed toxic epidermal necrolysis which was confirmed by dermis biopsy. There was also extreme angioedema, tongue biopsy was negative.

Inpatient ADRs:

32% were steroids. Most common reaction was hyperglycemia.

13% were antibiotics, with 36% of those being Vancomycin. Reactions included thrombocytopenia, swelling, rash, redness, and acute hepatic injury.

12.7% were narcotics. Reactions included over sedation, hallucinations, confusion, encephalopathy, itching.

4.9% were anticoagulants, with 57% of those being Coumadin®. Reactions included hematomas, hematuria, and blood in resp secretions, HIT reported once due to heparin.

Total ADRs:

13% were steroids.

13% were antibiotics with 31% of those being Bactrim®.

10% were anticoagulants, with 88% being Coumadin®.

8.7% were narcotics.

5% were chemotherapy related.

KETOROLAC
AUTOMATIC DOSE LIMIT PROPOSAL

BACKGROUND & PROPOSAL: Ketorolac is an injectable and oral nonsteroidal anti-inflammatory (NSAID) agent that possesses both antipyretic and analgesic properties. Injectable ketorolac is most often used peri-operatively and post-operatively to assist in the management of post-operative pain. It is included on many post-operative order sets for continued post operative pain control but is often written without limits to the intended duration of therapy.

The current recommendations designate that the total systemic therapy should not exceed 5 days. This is due to the increased risk of developing severe gastrointestinal events that can result from prolonged courses of therapy.

It is recommended to limit the total duration of all ketorolac orders (oral and IV) to not exceed 5 total days of therapy if no duration of therapy has already been indicated by the prescriber. Pharmacy will automatically schedule the ketorolac order to discontinue following 5 total days of therapy and the prescriber will be notified via written communication of this change. Additionally, all order sets will also be modified to reflect this change.

Samsca® (tolvaptan)
Medication Use Evaluation

In November 2012, a medication use evaluation was performed to evaluate the use of tolvaptan (Samsca). The purpose of this MUE was to identify the types of prescribers with highest utilization, provide information about current expenditures, and determine the usual indications surrounding its use to identify potential opportunities for savings associated with tolvaptan use.

Tolvaptan is the only oral non-peptide V2 vasopressin receptor antagonist. At over $250 per 30 mg tablet, there is significant cost associated with the use of this oral medication.

The following results were collected from 50 randomly selected patients who received tolvaptan between October 2011 and October 2012:

Who Orders Tolvaptan (Samsca):		
Cardiology	51	47%
Nephrology	40	37%
Internal Medicine	15	14%
General Surgery	1	< 1%
Intensivists	1	< 1%
CTVS	1	< 1%
Total Doses	109	

What Doses are Ordered:		
7.5 mg	22	20.2%
15 mg	68	62.4%
30 mg	19	17.4%
Total Doses	109	

Number of Doses per Patient:	
Average	2.18
Pts receiving 1 dose	21
Pts receiving > 1 dose	29
Average Cost/Patient	$331.95
Total Doses	109

Indications	**# Patients**	**%**	**Avg. Beginning Na+**	**Avg. Doses per patient**
CHF	24	48%	127	3
SIADH/euvolemic	12	24%	123	1.9
Chronic hyponat., unspecified	6	12%	125	2
Hyponatremia, unspecified	5	10%	128	1.8
Hypervolemic, unspecified	3	6%	123	1.3
Total Patients	50		125	2.2

Indications & Background:
Tolvaptan is an oral V2 vasopressin receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (i.e., serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH). Hypervolemic hyponatremia is usually associated with elevated levels of arginine vasopressin (antidiuretic hormone) which can result in impairment of free water excretion and contributes to the development of hyponatremia. Tolvaptan selectively binds to the V2 receptors of the distal nephron which results in an increase in free water excretion, an increase in serum sodium concentrations, a decrease in urine osmolality, and an increase in urine output.

Tolvaptan has been shown to induce short-term clinical improvements but has not demonstrated improvement in long-term outcomes such as mortality or hospitalizations. Tolvaptan has not been compared to other therapies such as hypertonic saline.

The FDA has placed black box warning that restricts the initiation and re-initiation of tolvaptan to the hospital setting, where the serum sodium can be monitored closely. Since rapid correction of hyponatremia may cause osmotic demyelination resulting in severe neurological complications and possible death, caution should be advised with concomitant use of tolvaptan and hypertonic saline.

Current Formulary Status
Tolvaptan was approved for formulary addition in October 2009 with its use restricted to nephrology, cardiology, and intensivist use only.

Discussion
Based on the collected data, the largest majority of patients treated with tolvaptan were those with hypervolemia (54%) with CHF being the most commonly encountered hypervolemic state. Cardiology was responsible for the majority of the orders for patients with hypervolemia secondary to CHF. This subgroup of patients had the highest average serum sodium level at initiation of therapy as compared to the other treated indications (127 mEq/L vs. 124 mEq/L). 72% of these patients had a serum sodium level of $\geq$ 125 mmol/L at the initiation of tolvapatan therapy with the highest observed beginning sodium level of 146 mEq/L. Tolvaptan is indicated for the treatment of clinically significant hyponatremia (serum sodium < 125 mEq/L) but however can be used in patients with less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction. Tolvaptan has been studied in CHF patients in a multicenter trial to evaluate the short-term and intermediate-term effects of tolvaptan in patients hospitalized with HF. This study included patients who were admitted for worsening HF, LVEF < 40% and systemic congestion after initial in-hospital therapy for HF. Tolvaptan was initiated within 96 hours of admission if they continued to have signs and symptoms of congestion despite standard therapy (including diuretics) regardless of their sodium status. Although not specifically FDA approved for this indication, the study demonstrated the following: a dose-independent and significantly higher decrease in body weight as compared to placebo, higher urine output and fewer patients with dyspnea, jugular venous distention, and peripheral edema on discharge as compared with placebo (only statistically significant with dyspnea). 78.7% of the patients treated in this study had a sodium level $\geq$ 136 at the time of randomization indicating that many of these patients were treated with tolvaptan with the absence of true hyponatremia per laboratory findings.

The next highest populations of tolvaptan utilization were observed in patients with euvolemic disorders such as SIADH (24%) which was almost entirely ordered by a nephrology specialist. The average sodium at initiation of therapy in this population was 123 mEq/L which correlates well with the labeled indications for use.

Cost & Utilization (October 2011 – October 2012)
Total patients treated: 63 patients
Tolvaptan 15 mg - $130.67 per dose
Tolvaptan 30 mg - $259.33 per dose

Annual cost (based on utilization): $39,426.18

Summary
Although the total number of patients treated with tolvaptan is relatively low, the extremely high cost per dose can result in a high average cost per patient treated with this therapy and large annual expenditures of

this low use agent. The overall average length of therapy for all indications is low (2.2 days) but it is highest in the CHF population (3 days). Although the overall average beginning serum sodium was 125 mEq/L it was highest in the CHF population with an average sodium of 127 mEq/L with a few variances above 135 mEq/L. The nephrology usage of tolvaptan appears to be limited to patients with severe hyponatremia usually reserved as a 2nd line agent in patients with persistent hyponatremia. The use of tolvaptan in the CHF population may represent the greatest opportunity for further investigation. Despite some published data supporting its use in patients with or without hyponatremia the cost effectiveness of this agent should be further examined with cardiology's input to determine if the cost versus benefit warrants the use of tolvaptan in this population of inpatients.

CATHOLIC HEALTH INITIATIVES

Memorial Health Care System

Chattanooga, Tennessee

POLICY

Title: **LOOK ALIKE – SOUND-ALIKE MEDICATIONS**			
		Page 1 of 1	
Policy Number: NPSG-06611		Date Last Reviewed/Revised: 1/10	Valid Until: 1/11
Department(s) Affected: All Clinical Areas		Review Period: every year	
Signature(s):		Medical Staff Signature if applicable	
National Patient Safety Goal Chapter Leader:	Medication Management Chapter Leader:	VP/Chief Nurse Executive Signature:	

OUTCOME:

To improve the safety of using medications and reduce medication errors related to drugs which have either Look-Alike or Sound-Alike properties by implementing precautions and risk reduction strategies.

POLICY & PROCEDURE:

Memorial Health Care System will identify a list of routinely used drugs with Look-Alike/Sound-Alike properties that could result in error. This list is not meant to be all inclusive and is reviewed at least annually by the Pharmacy and Therapeutics Committee. (Refer to attachment: Look-Alike / Sound-Alike Drug list 2010.)

Actions and/or error prevention strategies used may include one or more of the following:

1. Tall man lettering in Pyxis and Meditech.
2. Pyxis pop-up warning.
3. Indication specific alerts in Meditech upon ordering for designated drugs.
4. Do not store next to each other.
5. Name alert on MAR.

Workgroup/Committee Chair/Key Contact: Jayne McGarey, Pharmacy
Approved/Reviewed by: Sandy Vredeveld, Pharmacy Director, Pharmacy and Therapeutics Committee, 12/09
Reference(s): Joint Commission National Patient Safety Goal 3
Institute for Safe Medication Practices (ISMP)
Joint Commission Standard: NPSG.03.03.01, MM.04.01.01 EP4
Attachment(s): Look-Alike/Sound-Alike Drug List 2010
Date First Effective/Revisions: 7/09 **Revised:** 1/10
Distribution: MHCS Intranet
Hard Copy location: Memorial and Memorial North Park Command Centers

CATHOLIC HEALTH INITIATIVES

Memorial Health Care System

Look Alike/Sound Alike Drug List 2013

Drug Name	Drug Name	Potential Errors	Prevention Strategies
NovoLIN 70/30	NovoLOG MIX 70/30	Similar names and strengths	1. Tall man lettering in Pyxis &Meditech 2. Pyxis pop-up warning 3. Two nurses sign off on MAR prior to administering
hydrOXYzine	hydrALAzine	Similar names	1. Tall man lettering in Pyxis &Meditech 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR and indication.
DOXOrubicin *Liposomal*	DOXOrubicin *Conventional* and DAUNOrubicin	Similar names	1. Tall man lettering in Pyxis & Meditech. 2. Pyxis pop-up warning. 3. Do NOT store next to each other. 4. Name alert on MAR
metroNIDAZOLE	metFORMIN	Similar names and strengths	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning 3. Do NOT store next to each other. 4. Name alert on MAR.
oxyCODONE controlled-release	oxyCODONE immediate-release	Similar names	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning. 3. Name alert on MAR.
CeleBREX®	CeleXA® and CereBYX®	Similar names	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning 3. Name alert on MAR. 4. Do NOT store next to each other.
cloniDINE	KlonoPIN®	Similar names	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning. 3. Name alert on MAR. 4. Do NOT store next to each other.
Wellbutrin SR®	Wellbutrin XL®	Similar names	1. Pyxis pop-up warning. 2. Name alert on MAR. 3. Do not store next to each other.
MuciNEX®	MucoMYST®	Similar names	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning. 3. Name alert on MAR. 4. Do not store next to each other.
PrenisoLONE	predniSONE	Similar names and strengths	1. Tall man lettering in Pyxis & Meditech 2. Pyxis pop-up warning. 3. Name alert on MAR. 4. Do NOT store next to each other.
Plavix®	Pradaxa®	Similar names and strengths	1. Pyxis pop-up warning 2. Name alert on MAR. 3. Do NOT store next to each other.

Presented December 13, 2012,
Pharmacy and Therapeutics Committee

Title: **Standing Orders: Anaphylactic Reaction Intervention**		
	Page 1 of 2	
Policy Number: PHRM –	***Date Last Revised:*** 12/12	***Valid Until:*** 12/15
Department(s) Affected: Pharmacy	***Review Period:*** every 3 years	
Signature(s):	**Medical Staff Signature if applicable**	
	VP/Chief Nurse Executive Signature:	

OUTCOME:

To allow for immediate intervention in response to a suspected anaphylactic reaction. These standing orders should NOT be used for localized reactions. An anaphylactic reaction should be suspected in patients exhibiting any of the following symptoms:

- Urticaria: Severe, progressing, and generalized itching, wheels, erythema, edema, hives
- Angioedema: Diffuse and painful swelling of loose subcutaneous tissue, dorsum of hands and feet, eyelids, lips, genitalia, and mucous membranes
- Edema of upper airways with potential or actual respiratory distress.

POLICY:

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

A. Immediately stop all medications being infused and call rapid response.

B. Remove the following medications from the Pyxis MedStation via override function by selecting: Patient, Remove Meds, Kits List (on bottom of screen) then Anaphylaxis Protocol. This will open appropriate drawers.
   1. Epinephrine 1:1000 (1 mg/1mL) injection x 2 vials
   2. Diphenhydramine (Benadryl) 50mg/1mL injection
   3. Hydrocortisone (Solu-Cortef) 100 mg injection

C. Administer **0.3 mg** (0.3mL) Epinephrine 1:1000 intramuscularly (IM – anterior or lateral thigh) (Preferred) or subcutaneously (sub-Q). May repeat Epinephrine 0.3 mg every 5 to 10 minutes, up to 3 doses.

D. Obtain intravenous (IV) site if patient IV site not available. Call for IV therapy support if needed.

E. Monitor airway. Call Code Blue for respiratory distress.

F. Notify attending physician “STAT”.

G. If symptoms are relieved, follow physician orders for additional medications.

If no response to Epinephrine x 1, OR if symptoms worsen, call code Blue and proceed with the following:

1. Administer Diphenhydramine 50 mg IV
2. Administer Hydrocortisone 100 mg IV
3. Infuse IV fluids: Normal Saline at 150 mL/hr
4. Elevate feet and legs above level of heart

H. Write order for specific medications used (dose and route) “per standing order” and forward to pharmacy. The patient’s physician is to subsequently sign the order in the medical record.

I. Document medication administration appropriately in the medical record.

J. Return unused items to Pyxis MedStation.

Workgroup/Committee Chair/Key Contact: Patrick Ellis, Pharm D., Pharmacy Coordinator
Approved/Reviewed by:
Reference(s): TJC MM.04.01.01
Attachment(s): None
Date First Effective/Revisions: 12/13/12 **Revised:**
Distribution: MHCS Intranet
Hard Copy location: Pharmacy

ALLERGIC REACTION/ANAPHYLAXIS ORDERS

Date/Time	

1. **For MINOR adverse reactions (such as itching or hives):**
   - **X Stop infusion & notify physician**
   - **X** Benadryl (diphenhydramine) 50 mg IVP x 1 dose.

2. **For SERIOUS adverse reactions. An anaphylactic reaction should be suspected in patients exhibiting any of the following symptoms:**
   - Urticaria: Severe progressing, and generalized itching, wheels, erythema, edema, hives
   - Angioedema: Diffuse and painful swelling of loose subcutaneous tissue, dorsum of hands and feet, eyelids, lips, genitalia, and mucous membranes
   - Edema of upper airways with potential of actual respiratory distress.

Medication Therapy

- **X** Immediately stop all medications being infused and call Rapid Response Team & attending physician.
- **X** Epinephrine 1:1000 (1mg/1ml) x 1 dose IM – anterior or lateral thigh (preferred) or SC, may repeat every 5 to 10 minutes, up to 3 total doses.
- **X** Obtain IV site if patient IV site not available

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

- ☐ Diphenhydramine 50 mg IV x 1 dose
- ☐ Hydrocortisone 100 mg IV x 1 dose
- ☐ Normal saline at 150 ml/hr

_____

Physician's Signature

POLICY

Title: MEDICATION ORDERS – PHARMACIST REVIEW		
	Page 1 of 1	
Policy Number: PHRM-POL-503	Date Last Reviewed/ Revised: 12/12	Valid Until: 12/15
Department(s) Affected: Pharmacy	Review Period: every 3 years	

OUTCOME:

Prescription orders are reviewed and appropriate action is taken.

POLICY:

1. Prior to entering or verifying a medication order in the clinical information system, the pharmacist will review for potential interactions, incompatibilities, duplicate therapy, unusual doses and indications, allergies, etc. using clinical expertise and computer applications. Should the appropriate laboratory data not be available, the pharmacist may order necessary laboratory tests in consideration of patient safety and improved patient care.

2. All concerns, issues or questions are clarified with the individual prescriber before dispensing

3. The pharmacist review of medication orders occurs before dispensing or removal from Pyxis unless the licensed independent practitioner controls the ordering, preparation, and administration of the medication; or in urgent situations when the resulting delay would harm the patient, including situations in which the patient experiences a sudden change in clinical status. See Pyxis Medstation Policy MM-05429 for emergency meds and overrides

4. After hours Memorial Hixson medication review is conducted by Memorial Glenwood Campus except in the emergency situations described above.

Workgroup/Committee Chair/Key Contact: Sandy Vredeveld, Pharmacy
Approved/Reviewed by: Sandy Vredeveld
Reference(s):
Joint Commission Standard: MM.05.01.01
Attachment(s): None
Date First Effective/Revisions: 01/19/98, 1/07, 10/09, 2/10, 9/12

Pharmacy & Therapeutics Committee					
Pharmacy Clinical Dashboard					
September-October					
FY13					
		May-June	**July-Aug**	**Sept-Oct**	%Chg Mo.
Documented Clinical Interventions		8,747	8,960	8,751	-2.3%
Major ADE's Prevented		12	31	27	-12.9%
Pharmacokinetic Service					
# Patients		498	523	512	-2.1%
# Doses		2,162	2,395	2,367	-1.2%
TPN Utilization					
# Patients		44	59	62	5.1%
#Pts./1,000 Adj.Pt.days		1.1	1.6	1.7	6.2%
# Doses		352	503	411	-18.3%
# Doses/1,000 Adj.Pt.days		9.25	14.08	11.4	-19.0%
Average # days of TPN		8	8.5	5.6	-34.1%
Central line bloodstream infections pts on TPN		0	1	1	0.0%
Coumadin Dosing by Pharmacy					
# Patients		63	68	59	-13.2%
# Doses		261	311	359	15.4%
Antimicrobial Stewardship Clinical Interventions		267	297	279	-6.1%
Chemotherapy Doses		322	304	337	10.9%