Pharmacy & Therapeutics Committee Meeting
Private Dining Room
February 27, 2014 7:00 a.m.

| Agenda Items | Individual Responsible |
|---|---|
| 1. Call to Order | Richard Pesce, MD |
| 2. Approval of October, 2013 Minutes | Richard Pesce, MD |
| 3. Therapeutic Interchanges and Formulary Decisions | Page |
| A. Arzerra® (ofatumumab) | Karen Babb, Pharm.D….....4 |
| B. Exparel® (liposomal bupivacaine)..... | …Dr. Hartley……...…...5-6 |
| C. Ofirmev® (IV acetaminophen) ..... | Patrick Ellis, Pharm.D….7-8 |
| D. Combivent® – Formulary Interchange ..... | ……...9 |
| E. Tudorza® (aclidinium for inhalation)…. ..... | ……...10-11 |
| F. Inhaled Cortiscosteroid/β-Agonist – Formulary Interchange. ..... | ……...12 |
| 4. Medication Safety | |
| A. ADR review ..... | Sarah Smith, Pharm.D...13-14 |
| 5. MUE | |
| A. Vitamin K – Warfarin Reversal ..... | Sarah Smith, Pharm.D...15-16 |
| 6. Policy, Procedure & Protocols | |
| A. Pneumonia Standing Orders …..... | Patrick Ellis, Pharm.D...17-18 |
| B. Tamiflu® (oseltamivir) – Automatic Stop Proposal …. ..... | .....19 |
| C. IV to PO – IV Synthroid®…. ..... | ..... |
| D. Sterile Compounding Outsourcing..... | Sandy Vredeveld, DPh…… |
| 7. Nutrition Support Team | |
| A. Pivot 1.5 – addition to nutrition formulary…. ..... | ....Brian Jones, RD……20-21 |
| B. Enteral Nutrition – Order Set & Policy Revision…..... | ....22-23 |
| 8. Adjournment | |

Next Meeting will be April 12, 2014 at 7:00am in the Private Dining Room

CATHOLIC HEALTH INITIATIVES
Memorial Health Care System

**PHARMACY AND THERAPEUTICS COMMITTEE**

DATE: October 10, 2013 CALLED TO ORDER: 7:03 A.M.
LOCATION: Private Dining Room ADJOURNED: 7:476 A.M.

| **Members Present**: | | **Members Absent**: | | **Guests**: |
|---|---|---|---|---|
| Richard Pesce, M.D. | Karen Babb, Pharm.D. | Allen Atchley, M.D. | Patrick Hagan, Finance | Rachel Kyle, Pharm.D. |
| Mark Anderson, M.D. | Vickie Burger, Lab | Nathan Chamberlain, M.D. | Keith Lockwitz, RN | Darrin Majors, Pharm.D. |
| Nathan Schatzman, M.D. | Patrick Ellis, Pharm.D. | Samuel Currin, M.D. | Nan Payne, RN | Sarah Smith, Pharm.D. |
| Michael Stipanov, M.D | Lila Heet, Pharm.D. | David Dodson, M.D. | | |
| | Brian Jones, RD, LDN | William Oellerich, M.D. | | |
| | Elvie Smith, RN | Melissa Roden, RN | | |
| | Sandy Vredeveld, DPh | Beverly Slate, Supply Chain | | |
| | Hannah Walker, RN | Diona Brown, RN,C.N.O | | |

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

| AGENDA ITEM | FINDINGS OR CONCLUSION | ACTION, RESPONSIBILITY | STATUS |
|---|---|---|---|
| **Minutes** | The August 8, 2013 minutes were approved as submitted. | | Complete |
| **Therapeutic Interchanges and Formulary Decisions** | The following medications were reviewed:<br>1. **Nesina® (alogliptin)** – Oral DPP-4 inhibitor used to improve glycemic control in adults with type 2 diabetes mellitus. It was recommended to not add alogliptin to formulary and sitagliptin will be substituted via a therapeutic interchange when alogliptin is ordered. | 1. Therapeutic interchange approved | Complete |
| | 2. **Tivicay® (dolutegravir)** – New antiviral medication used for treatment of HIV. It was recommended to add dolutegravir to formulary in order to provide continuity of care for patients who take this medication as a home therapy. | 2. Approved | Complete |
| | 3. **Simponi Aria® (golimumab)** – Intravenous monoclonal antibody indicated for the treatment of moderately to severely active rheumatoid arthritis. This medication was just recently FDA approved and there is currently not a specific HCPCS "J" code to be utilized for outpatient reimbursement. It was recommended to conditionally add golimumab to the outpatient infusion formulary but it will not be used until a medication specific "J" code is available in order to guarantee reimbursement. | 3. Conditional Approval | Pending |
| | 4. **Alpha-1 Proteinase Inhibitor (Aralast®, Prolastin®)** – Intravenous therapies used for patients with alpha-1 proteinase inhibitor deficiency. Neither product is available for direct purchase by the hospital's medication distributors and thus the facility is unable to bill for the drug if administered in the hospital's infusion centers. It was recommended to remove these agents from formulary and no longer accept future patient requests for administration of these therapies at MHCS infusion centers. | 4. Formulary removal approved | Complete |
| | 5. **Kadcyla® (Ado-trastuzumab)** – New chemotherapy agent used for patients with metastatic breast cancer who have received prior treatment with trastuzumab and/or other chemotherapy agents. Due to the unique mechanism of action and supporting clinical data it was recommended to add this agent to formulary. | 5. Approved | Complete |
| | 6. **Biosimilar Medication Review –** A brief explanation was provided to the committee on "biosimilar" medications and the criteria that will need to be utilized when evaluating biosimilar medications for | 6. Information | Complete |

| AGENDA ITEM | FINDINGS OR CONCLUSION | ACTION, RESPONSIBILITY | STATUS |
|---|---|---|---|
| | formulary approval as these medications are introduced to the market.<br>7. **Granix® (Tbo-Filgrastim)** – A "biosimilar" version of Neupogen® (filgrastim) which is indicated for the reduction in the duration of chemotherapy associated neutropenia. Numerous studies have determined that the therapeutic effect of tbo-filgrastim is therapeutically equivalent to the same dose of filgrastim. It was recommended to automatically interchange all filgrastim orders for tbo-filgrastim at the same dose as prescribed for filgrastim. Expected availability: November, 2013. | 7. Therapeutic interchange approved | Complete |
| **Medication Safety** | • **ADR Review –** Patrick reviewed findings from 4th Quarter, April, 2013 – June, 2013<br>• **Antiemetic orders –** Patrick reviewed a proposed standardized set of antiemetic orders to replace current antiemetic orders on all existing order sets as suggested by the Medical Executive Committee. This was created to help minimize the risk of IV promethazine related phlebitis. Dr. Stipanov suggested to also include an option for ondansetron 8 mg for patients with "moderate" nausea. The proposed orders were approved along with the above mentioned addition. The proposal will now be forwarded to the Medical Executive Committee for input and final approval. | Information<br>Approved | Complete<br>Complete |
| **Medication Use Evaluation** | • **Argatroban –** Rachel reviewed the analysis of a recent evaluation to examine the effectiveness of the existing argatroban weight based dosing protocol. A significant number of dose titration errors were observed. Weight based protocol changes were proposed to streamline and improve the existing protocol. | Protocol Changes Approved | Complete |
| **Policy, Procedure & Protocols** | • **Argatroban, Bivalirudin** – It was recommended to add argatroban and bivalirudin to the High Alert Medications policy to improve patient safety when these medications are utilized via their respective weight based protocols. This will require documentation of 2nd nurse verification when new bags are hung, all dosage/setting changes, and shift change verification of settings.<br>• **Heparin Therapeutic Range –** Therapeutic range for heparin weight based protocols will be changing on October 30th due to a PTT laboratory reagent change.<br>• **Penicillin Allergy Surgery Antibiotic Administration –** Current policy requires vancomycin to be utilized for all patients with anaphylaxis to penicillins or any reaction to <u>any cephalosporin</u>. It was recommended to modify the policy to allow patients who claim a non-anaphylactic reaction to any cephalosporin other than cefazolin to still be given cefazolin.<br>• **Intravevnous to Oral Therapy** – Policy updated to clarify inclusion/exclusion criteria. | Approved<br>Approved<br>Approved<br>Approved | Complete<br>Complete<br>Complete<br>Complete |

There being no further business, the meeting was adjourned at 7:47 A.M. The next P&T meeting is December 12, 2013.

Respectfully submitted,

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

Approved by,

Richard Pesce, M.D. Chairman

**FORMULARY REVIEW**

**GENERIC NAME:** OFATUMUMAB

**PROPRIETARY NAME:** Arzerra (GlaxoSmithKline)

**INDICATIONS:**
Ofatumumab is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.

**CLINICAL PHARMACOLOGY:**
Ofatumumab is a fully human monoclonal antibody that binds specifically to the CD20 molecule expressed on normal B lymphocytes and on B-cell chronic lymphocytic leukemia (CLL), which causes B-cell lysis and death. In October 2009, the FDA granted ofatumumab accelerated approval for the treatment of patients with CLL refractory to fludarabine and alemtuzumab. Ofatumumab targets the same antigen as rituximab, but it binds a novel, membrane proximal epitope, and dissociates from its target at a slower rate compared to rituximab.

**PHARMACOKINETICS:**
Ofatumumab is eliminated through a target-independent route and a B cell-mediated route. Clearance of ofatumumab is dose-dependent within the dose range of 100—2000 mg. After the first infusion of ofatumumab, clearance decreases substantially due to the depletion of B cells and subsequent decrease in B cell-mediated clearance. The mean elimination half-life between the 4th and 12th infusions was approximately 14 days. Renal and hepatic impairment should have no effect on the elimination or dosing of ofatumumab.

**ADVERSE REACTIONS:**
The most common adverse reactions occurring in clinical trials with ofatumumab were neutropenia (43%), pneumonia (23%), pyrexia (20%), cough (19%), diarrhea (18%), anemia (16%), fatigue (15%), dyspnea (14%), rash (14%), nausea (11%), bronchitis (11%), and upper respiratory tract infection (11%).

Serious infusion-related reactions have been reported with ofatumumab therapy; reactions occur more often during the first couple of infusions. Clinical trial data of patients being treated for CLL have shown infusion-related reactions occurred in 44% of patients on the day of the first infusion (300 mg), 29% of patients on the day of the second infusion (2000 mg), and less frequently during subsequent infusions. It is recommended that patients should be pre-medicated with acetaminophen, an antihistamine, and a corticosteroid prior to each infusion. Monitor patients closely during the ofatumumab infusion. The infusion should be stopped if a patient experiences an infusion reaction and the infusion restarted at a slower rate. Therapy should not be resumed in patients who develop a grade 4 infusion reaction.

**COST:**
300 mg (per dose) - $1,394
2000 mg (per dose) - $9,292

**DOSING:**
The recommended ofatumumab dosage is 300 mg as the initial dose (dose 1), followed 1 week later by 2,000 mg weekly for 7 doses (doses 2 to 8), followed 4 weeks later by 2,000 mg every 4 weeks for 4 doses (doses 9 to 12), for a total of 12 doses. All infusions require slow rate titrations to minimize risk of infusion reactions.

**CONCLUSION:**
Ofatumumab offers an alternative therapy for patients with CLL refractory to fludarabine and alemtuzumab. The response rate observed in a single-arm clinical trial was higher than that previously reported with other salvage therapies in this population. Due to the risk of adverse infusion related reactions it will be vital to ensure that the appropriate pre-medications and slow dose titration are utilized to help minimize the risk for infusion reactions. Additionally, the anaphylaxis protocol and the appropriate medications will need to be available in the event that a patient experiences a severe infusion related reaction.

**FORMULARY REVIEW**

**GENERIC NAME:** Bupivacaine Liposomal

**PROPRIETARY NAME:** Exparel (Pacira)

***Requested for trial use by Dr. Hartley for use in total joint replacement***

**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. Systemic plasma levels of bupivacaine following administration are not correlated with local efficacy. For the FDA approved indications the difference in pain intensity when compared to placebo occurred only during the first 24 hours following study drug administration. Between 24 and 72 hours after study drug administration, there was minimal to no difference between liposomal bupivacaine and placebo on mean pain intensity.

**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 non-bupivacaine-based local anestheics.

**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 |
| Hemorrhoidectomy | 266 mg | 20 mL |

**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.

Bupivacaine liposome injectable suspension must NOT be mixed with or come in direct contact with non-bupivacaine-based local anesthetics, including lidocaine. These products may cause an immediate release of bupivacaine from the liposomes. Bupivacaine hydrochloride products if injected immediately before bupivacaine liposome injectable suspension may alter the pharmacokinetic and/or physicochemical properties of the drugs if the dose of bupivacaine hydrochloride solution exceeds 50% of Exparel dose.

**ORTHOPEDIC STUDY RESULTS:**

Liposomal bupivacaine versus conventional bupivacaine – wound infiltration, total knee arthroplasty

A phase 2 study has been published that performed a randomized, double blind study comparing wound infiltration of liposomal bupivacaine to bupivacaine HCL for postsurgical analgesia in total knee arthroplasty. The study compared 150 mg of conventional bupivacaine to liposomal bupivacaine in doses of 133 mg, 266 mg, 399 mg, and

532 mg. The study medications were diluted in 60 ml of 0.9% saline and were injected via local infiltration in the deep tissues, the capsulotomy incision, and the subcutaneous tissues intraoperatively. The primary outcome measure was the AUC of numerical rating system (NRS) pain scores through post-op day #4. Secondary measures such as total consumption of opioid medications, etc. were also compared. There was no statistically significant difference observed between the groups for the primary outcome measure of the mean AUC NRS pain scores with activity. Additionally, there was no detectable difference in the groups with regard to mean numeric rating scale pain scores, total consumption of rescue opioids, or the time to resumption of work or normal daily activities. Some of the daily NRS scores were significantly lower at some of the time points although the primary outcome measure failed to demonstrate a statistically significant difference when compared to bupivacaine regardless of the liposomal dose. The highest dose regimen of 532 mg liposomal bupivacaine did demonstrate numerically lower NRS scores at all time points through day 5 although only the scores at day 1 & 5 demonstrated a statistically significant difference.

Liposomal bupivacaine versus femoral nerve block – total knee arthoplasty (un-published study)
An unpublished abstract is available that shows data evaluating the use of liposomal bupivacaine as part of a multimodal postsurgical pain management regimen versus a femoral nerve block with local anesthetic (matched cohort of 200 patients). The investigators stated an improvement in average pain scores, knee flexion, and length of stay as compared to femoral nerve block but no statistics or specific details of the study design have been described to date.

**COST:** $285/20 ml

**Ofirmev™ Literature Summary**

**Introduction**

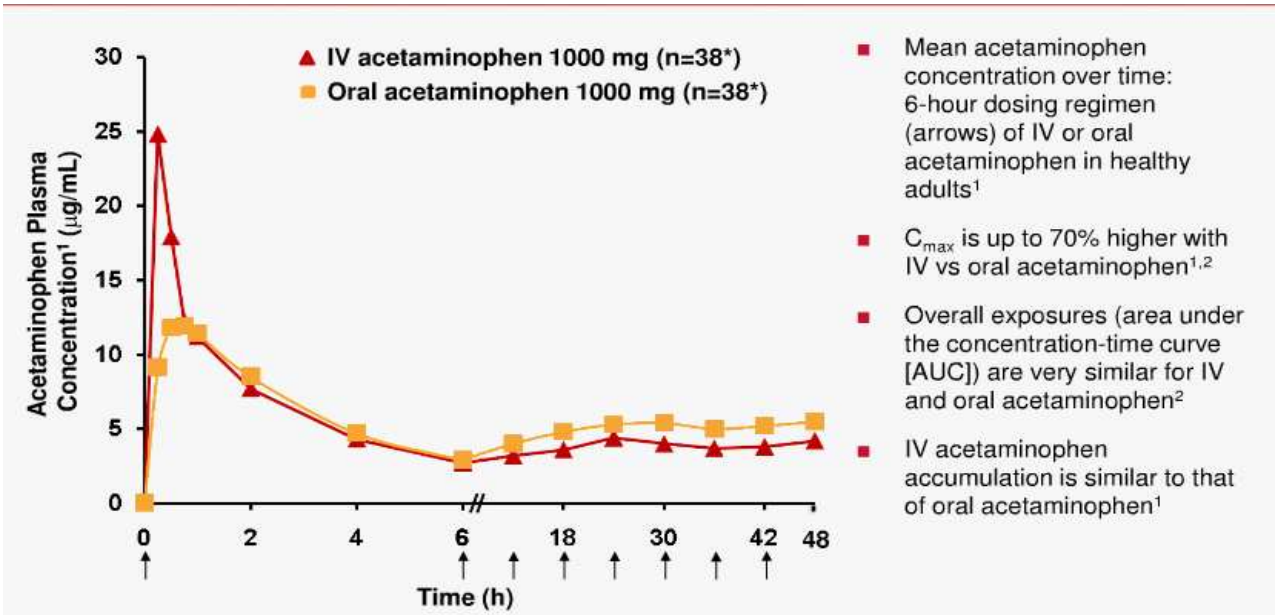
Postoperative pain is reported in more than 80% of surgical patients, and a focus on managing pain utilizing therapy with varying mechanisms of action is considered the current best practice. Multimodal techniques for pain management include the administration of two or more drugs that act by different mechanisms for providing analgesia. These drugs may be administered *via* the same route or by different routes. Approved by the FDA in November 2010, acetaminophen injection (Ofirmev™) is the first non-opioid, non-NSAID analgesic available for IV administration in the United States.

**Pharmacology/Pharmacokinetics**

Acetaminophen is thought to exert its analgesic and antipyretic effects centrally through inhibition of cyclooxygenase.

The maximum blood concentration (Cmax) of Ofirmev is higher than with oral or rectal administration; however, it is important to note that the Cmax with Ofirmev (29 mcg/mL) remains below the 150 mcg/ mL concentration considered potentially hepatotoxic. Despite the difference in Cmax, overall volume of distribution and area under the curve (AUC) values remain similar for all acetaminophen formulations.

| Form | PO | IV |
|---|---|---|
| *onset of action* | <1 hour | 5-10 minutes<br>peak effect 1 hour |
| *duration of action* | 4-6 hours | 4-6 hours |
| *time to peak* | 10-60 minutes | 15 minutes |
| *AUC* | 42.2 h*mcg/ml | 47 h*mcg/ml |
| *Cmax* | 15.1 mcg/ml | 28.4 mcg/ml |




**Efficacy Pain Studies**

In the US, three pivotal trials evaluating IV acetaminophen efficacy in pain and fever resulted in its approval by the FDA. In both pain trials, IV acetaminophen was superior to placebo as measured by the primary outcome of weighted sum of pain intensity difference over 24 hours.

In a meta-analyses of the efficacy of acetaminophen for the prevention or treatment of postoperative pain, IV acetaminophen was found to be superior to placebo, however there was no difference between IV acetaminophen and either NSAIDs or opioids for the treatment of pain.

In regards to morphine consumption, six placebo controlled trials showed a significant decrease in consumption of rescue medication (morphine, meperidine, oxycodone) compared to placebo. Three placebo controlled trials showed no difference between the groups.

A meta-analysis evaluating 7 studies comparing patient-controlled analgesia (PCA) with morphine plus APAP against PCA morphine alone (6 studies involving IV APAP and 1 involving PO APAP) aimed to determine the effects of acetaminophen on morphine side-effects and consumption after major surgery. The analysis found that, relative to PCA morphine alone, administration of PCA morphine with acetaminophen resulted in no significant reduction in post-operative nausea and vomiting despite a 20% decrease in morphine use in the first 24 hour postoperatively.

In reviewing the literature for pain studies specifically done in the abdominal surgery population, six articles were found. The first study looked at women undergoing laparascopic sterilization who received IV paracetamol versus placebo with alifentanyl as rescue PCA. During the four hour post-operative study period, alifentanyl consumption was reduced in patients who received IV paracetamol. A second RCT looking at postoperative analgesia in laparascopic cholecystectomy studied 30 females under 50 who were given 1 gm of IV acetaminophen or placebo ten minutes after induction of anesthesia. Patients with liver or kidney disease were excluded, as were those with opioid or alcohol dependence. No significant difference was appreciated for IV morphine consumption or first morphine requirements.

A meta-analysis reviewed nine eligible studies (five orthopedic, one liver surgery, one C-section delivery) and found that 24 hour morphine consumption was reduced, with a mean reduction of 9 mg. The clinical significance of this has not been validated.

A randomized, double-blind, placebo-controlled multicenter study of two acetaminophen dosing regimens for the treatment of pain after abdominal surgery was published in 2010. Comparison was made between two doses of IV acetaminophen and placebo, and rescue PCA of either morphine or dilaudid was available. Ofirmev in combination with either morphine or dilaudid PCA was superior to placebo in reducing pain intensity scores but not in time to rescue medication. Significant, important exclusion criteria limit the applicability of this study.

**Conclusions**

The American Society of Anesthesiology published practice guidelines for management of acute pain in the perioperative setting and strongly recommends the use of acetaminophen, NSAIDs, or COX-2 inhibitors as a part of the multimodal approach to managing pain. However, the guidelines suggest that the medication choice, strength, route, and duration should be individualized.

While many years of non-US clinical experience exist to support the safety and efficacy of IV acetaminophen in the treatment of pain, most of the data is lacking statistical significance, robust sample size, or involves significant exclusion criteria that make applicability difficult. Only a small number of studies were head-to-head or active-controlled trials.

In acute pain, the advantages of IV acetaminophen when used for short periods include a slightly faster onset of action than oral acetaminophen; potential decreased risk of adverse events relative to injectable morphine (although this finding requires better designed trials for confirmation); and lower risk of gastrointestinal adverse events relative to oral NSAIDs. The combination of IV acetaminophen and morphine postoperatively compared with PCA morphine alone may lower opioid requirements to a relatively small degree, but seems to have no effect on the incidence of opioid-related gastrointestinal effects.

The possible advantages of IV acetaminophen are offset by drug acquisition cost that is significantly higher than alternative non-oral agents currently available on Memorial Hospital Formulary.

**FORMULARY REVIEW**

COMBIVENT (ALBUTEROL/IPRATROPIUM) SUBSTITUTION

THERAPEUTIC INTERCHANGE

**BACKGROUND:**
Combivent Respimat (ipratropium bromide 20mcg/albuterol 100mcg) is replacing all commercially available Combivent MDI by December 2013. Combivent Respimat contains the same active ingredient as Combivent MDI but uses a physically different inhaler mechanism that does not rely on chlorofluorocarbons (CFCs) for medication delivery. This mechanism allows the inhaler to be compliant with the international Montreal Protocol agreement which requires that products containing CFCs are phased out to protect the ozone layer.

Due to its new design, the new respimat version of the inhaler is not compatible with ventilator adaptors or the spacers currently utilized as part of the common canister process that is used for inhaled meter dose inhalers.

**PRODUCT COMPARISONS:**
There are distinct differences in the concentrations between Combivent Respimat, Combivent MDI, and Duoneb. This can be explained by the differences in the inhaler mechanisms (Respimat vs MDI) and route of administration (inhaler vs nebulizer). However the FDA approved indications are the same.

| Product Name | Dose | FDA |
|---|---|---|
| **Combivent MDI**<br><br>Each actuation delivers 18 mcg of ipratropium bromide and 103 mcg of albuterol sulfate (equivalent to 90 mcg albuterol base) | 2 inhalations four times daily,<br><br>May use additional inhalations PRN; not to exceed 12 inhalations/day | Use in patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator. |
| **Combivent Respimat**<br><br>Each actuation from the COMBIVENT RESPIMAT inhaler delivers 20 mcg ipratropium bromide (monohydrate) and 100 mcg albuterol (equivalent to 120 mcg albuterol sulfate) | 1 inhalation four times daily, Do not exceed 6 inhalations/day | Patients with chronic obstructive pulmonary disease (COPD) on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator |
| **Duoneb (ipratropium/albuterol)**<br><br>One 3-mL vial delivers ipratropium bromide 0.5 mg and albuterol sulfate 3 mg [albuterol base 2.5 mg] per 3 mL) | Duoneb or generic equivalent via NEBULIZATION 4 times daily; MAX 6 doses per 24 hours | Indicated for the treatment of COPD for patients on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator |

**PRODUCT COST COMPARISON:**
Combivent Respimat – $213.21 per inhaler
Albuterol / Ipratropium nebulizer solution – $0.80 per day of therapy (4 treatments per day)

**DRUG UTILIZATION & PRODUCT EXPENSE:**
- **2013** – 240 patients had orders for Combivent (mostly continuation of home regimens)

**COST COMPARISON & EXPENSE PROJECTIONS:**
- **2013 actual spend –** $7,400 (utilized as common canister)
- **Projected annual spend (if respimat device dispensed to each patient)** – $51,170 ($43,770 annual cost increase)
- **Projected annual spend (if albuterol / ipratropium nebulizer substituted)** – $3,100 ($4,300 added annual savings)

**RECOMMENDATION & SUMMARY:**
Due to therapeutic equivalency, improved cost profile and inability to utilize the new Combivent device as part of the hospital's current common canister program it is recommended to automatically substitute all Combivent orders to an equivalent dose of albuterol & iptratropium via nebulizer. This represents roughly a 95% savings as compared to adding the new respimat device to formulary.

**FORMULARY REVIEW**

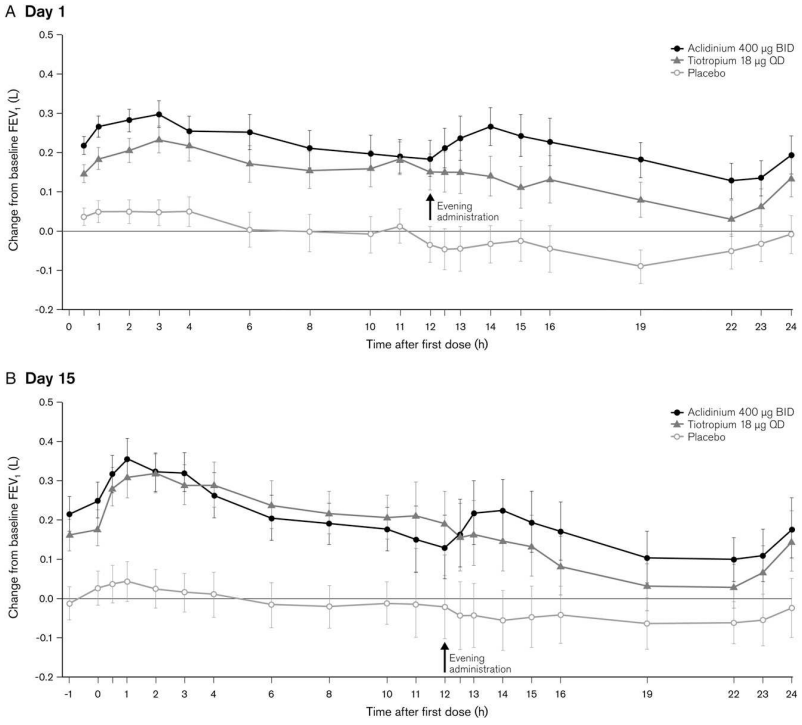
**GENERIC NAME:** ACLIDINIUM BROMIDE

**PROPRIETARY NAME:** Tudorza™ (Forest)

**INDICATIONS:**
Aclidinium Bromide was approved by the FDA in July 2012 for the long-term, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

**CLINICAL PHARMACOLOGY:**
Aclidinium bromide is a long-acting antimuscarinic agent, which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation. The competitive and reversible nature of antagonism was shown with human and animal origin receptors and isolated organ preparations. In preclinical *in vitro* as well as *in vivo* studies, prevention of acetylcholine-induced bronchoconstriction effects was dose-dependent and lasted longer than 24 hours. The clinical relevance of these findings is unknown. The bronchodilation following inhalation of aclidinium bromide is predominantly a site-specific effect.

**COMPARATIVE EFFICACY:**
Only one trial has been published thus far comparing Aclidinium to Tiotropium (Spiriva). It is a randomized, double-blind, double-dummy, crossover trial with 30 patient with moderate to severe COPD. Participants received aclidinium BID, tiotropium ONCE DAILY, and placebo for 15 days, with a 9-15 day washout period between treatment periods.




Bronchodilation after aclidinium BID administration was comparable to once-daily tiotropium. Also, improvements from baseline FEV1 and FVC were significantly greater for aclidinium vs. tiotropium over the last 12 hours of both days 1 and 15. These improvements in bronchodilation can be attributed to the evening dose of aclidinium.

**ADVERSE REACTIONS:** *Most common adverse effects* (>1%)
Headache (6.6%), nasopharyngitis (5.5%), cough (3%), diarrhea (2.7%), sinusitis (1.7%), rhinitis (1.6%), toothache (1.1%), fall (1.1%), vomiting (1.1%)

Potential for anticholinergic side effects: dry mouth, constipation, tachycardia, blurry vision, new-onset or worsening of narrow-angle glaucoma, and urinary retention.

**DOSING:**
The recommended dose of aclidinium bromide is one oral inhalation of 400mcg **twice daily**.

**PRODUCT AVAILABILITY and COST:**
Unlike Spiriva, the capsules are contained inside the Tudorza Pressair inhaler (similar to Advair).

| | Institutional size | Days of therapy per inhaler | Cost per day of therapy |
|---|---|---|---|
| **Spiriva** | **$74.29** | **5** | **$14.86** |
| **Tudorza** | **$57.17** | **15** | **$3.81** |

**CONCLUSION & RECOMMENDATION:**
Based on similar efficacy and safety between Spiriva and Tudorza the products can be considered therapeutically equivalent. Tudorza recently released an institutional size inhaler (15 days of therapy) which could allow this product to be utilized in the hospital setting. The current price as indicated above indicates a $17.12 cost savings per device and also contains 15 days of therapy within each institutional size inhaler. The manufacturer of Spiriva does offer some modest volume based discounts but even at the highest tier of savings the price advantage per device is still greater than $10 in favor of Tudorza.

**CHI's Group Purchasing Organization (GPO) is currently evaluating this product line for potential cost savings either through contracting or product discounts and recommendations are expected from them in March. Due to this pending evaluation, it is recommended to declare these agents therapeutically equivalent so that if a product change is recommended by our purchasing group that we can quickly move to the preferred agent to optimize savings. It is therefore recommended to now add Tudorza to formulary due to its pricing advantage and availability in an institutional size product and maintain Spiriva on formulary pending the above mentioned GPO evaluation.**

**FORMULARY REVIEW**

INHALED CORTICOSTEROID / BETA-AGONIST COMBINATION

**Proposed addition:**
Breo Elipta® (mometasone-formoterol) was recently approved as a once daily inhaled corticosteroid and long-acting beta agonist combination for the management of obstructive airway disease. This product did show superiority when compared to placebo but direct comparative trials with the other available agents are lacking. Due to the expected therapeutic equivalency of this product with the other agents in this class it is recommended to add Breo Elipta® to the already existing therapeutic interchange as outlined below. Symbicort® remains the most cost effective agent within this class of medications.

| **Inhaled Corticosteroid/Beta-agonist Combination** | |
|---|---|
| **ORDERED** | **SUBSTITUTION** |
| Fluticasone-salmeterol (Advair Diskus®)<br>100 mcg-50 mcg, 1 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-salmeterol (Advair Diskus®)<br>250 mcg-50 mcg, 1 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-salmeterol (Advair Diskus®)<br>100 mcg-50 mcg, 1 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-salmeterol (Advair HFA®)<br>45 mcg-21 mcg, 2 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-salmeterol (Advair HFA®)<br>115 mcg-21 mcg, 2 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-salmeterol (Advair HFA®)<br>230 mcg-21 mcg, 2 puff BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Mometasone-formoterol (Dulera®)<br>100 mcg-5 mcg, 2 puffs BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Mometasone-formoterol (Dulera®)<br>200 mcg-5 mcg, 2 puffs BID | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |
| Fluticasone-vilanterol (Breo Elipta®)<br>100 mcg-25 mcg, 1 puff DAILY | Budesonide-formoterol (Symbicort®)<br>160 mcg-4.5 mcg, 2 puffs BID |

Adverse Drug Reaction Summary
July - November 2013

**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.

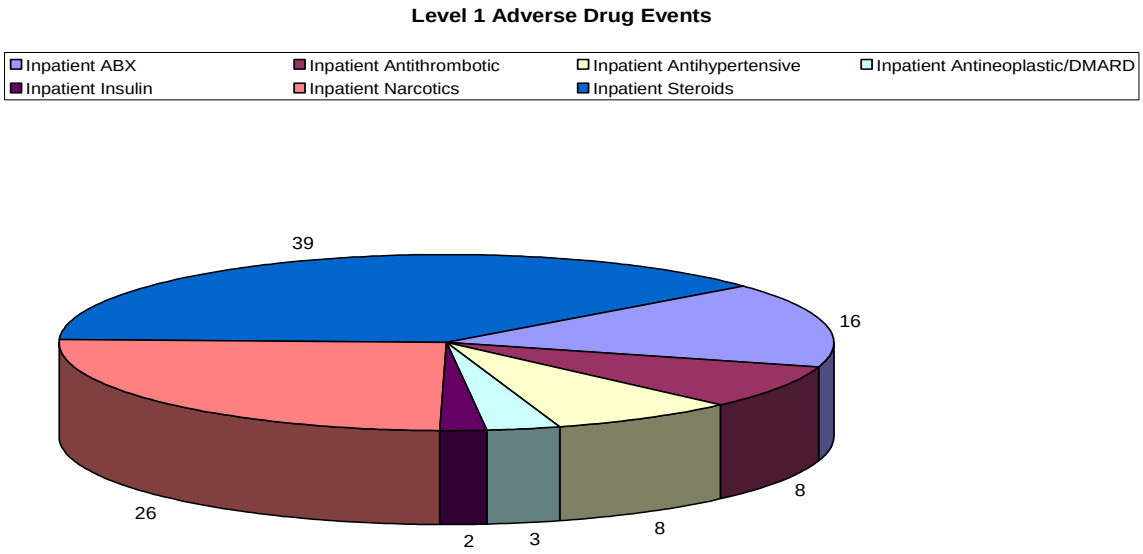
**Category 3**: A serious or rare ADR which has abnormal characteristics compared with published reports of the reaction (e.g. heparin induced platelet aggregation resulting in limb amputation). ADR's from this category should be reported to the manufacturer and/or the FDA (MedWatch or the Vaccine Adverse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

**Inpatient**: 111
**Prior to hospitalization**: 386
**Total:** 497

Category 1: 361
Category 2: 135
Category 3: 1 (outpatient)

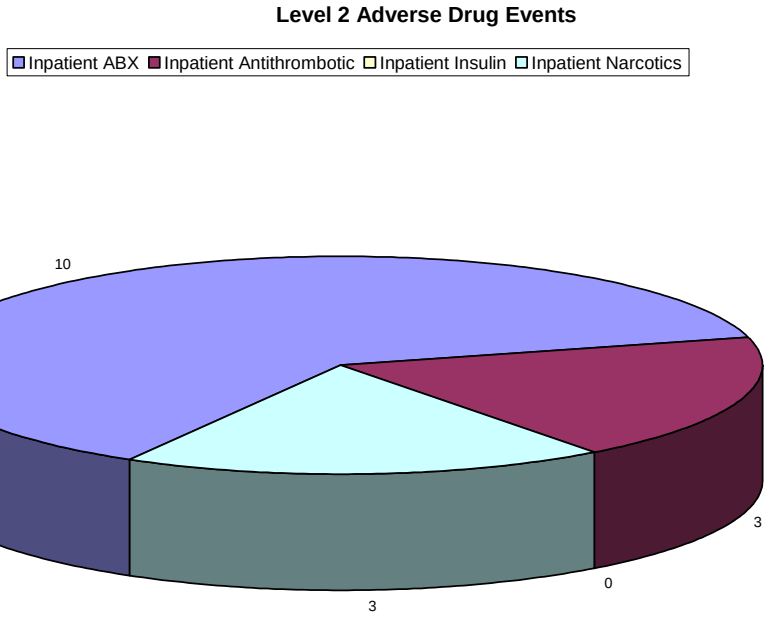
**Category 3 to be discussed:**
An 84 year old male with past medical history significant for pulmonary emboli, recent bilateral lower extremity DVT with significant swelling and anasarca s/p IVC filter placement, B-cell lymphoma s/p radiation, type 2 diabetes, atrial flutter who was discharged four days prior to a skilled nursing facility on therapeutic dose of Lovenox. On admission hemoglobin was 4.5 and CT showed a complex liquefying subacute hematoma involving the left iliopsoas muscles extending into the pelvis along the posterior lateral retroperitoneum. Patient received blood transfusions and pressor support with Levophed and neosynephrine. Hematuria noted on inspection of patient's Foley catheter. Patient's h/h remained stable post transfusion but overall body edema worsened and he required intubation and mechanical ventilation. Patient deteriorated becoming more hypotensive on max pressor support. Patient became acidotic and was unresponsive to diuresis. Discussion with the family which resulted in a transition to comfort measures, and the patient expired.

**In patient Level 1 Adverse Drug Events**




Antibiotics: one patient experienced red man syndrome from Vancomycin rapid infusion rate
Antithrombotics: one patient on Lovenox experienced HIT
Opioid analgesics: several elderly patients experienced AMS and encephalopathy.
Glucocorticoids: hyperglycemia, leukocytosis

**Inpatient Level 2 Adverse Drug Events**




Antibiotics: one patient receiving Biaxin and Flagyl reportedly had a seizure with hallucinations. Six patients receiving Vancomycin experienced an increase in SCr or AKI.
Antithrombotics: three patients experienced GI bleeding while on antithrombotics. One patient was receiving Lovenox, one patient was receiving Plavix and Aspirin, two patients were on concurrent Lovenox and Coumadin.
Opioid analgesics: two code blues: one dilaudid, one Fentanyl, Versed, Propofol. The patient who received the Dilaudid had 1 mg administerd at 1345, again at 1448, and 2 mg pushed at 1525 and coded (NPER)

**Vitamin K Use Evaluation**
**Memorial Health Care System**
**February 2014**

**Introduction**
Data from patients receiving vitamin K for reversal of coagulopathy or bleeding associated with warfarin were evaluated to determine if the appropriate route and indication are being administered at Memorial Hospital.

**Methods**
All patients receiving vitamin K from January 2013 through July 2013 were included in this evaluation (203 patients), however those patients who received vitamin K but were not on warfarin were excluded (80 patients). Data collected: reason for admission, warfarin indication, vitamin k route and dose, INR pre- and post-administration of vitamin k, other reversal agents used (FFP), other antithrombotics on patient medication use record, and rationale for vitamin k use, bridging data, and discharge disposition.

**Results: N=123**

| **Criteria 1 – Appropriate Route and Indication** | **Patients** | **Appropriate** |
|---|---|---|
| o **PO**<br>• **Reversal for non-urgent surgery**<br>• **No significant bleeding** | **N=14 (11.3%)**<br>7/14<br>7/14 | **100%** |
| o **IV**<br>• **Reversal for non-urgent surgery**<br>• **No significant bleeding**<br>• **Serious or life-threatening bleeding, at any elevation INR** | **N= 18 (14.6%)**<br>6/18<br>5/18<br>7/18 | **72%** |
| o **SQ**<br>• **Reversal for non-urgent surgery**<br>• **No significant bleeding**<br>• **Serious or life-threatening bleeding, at any elevation INR**<br>o **IV Push**<br>o **IM** | **N= 84 (68.3%)**<br>34/84<br>25/84<br>25/84<br>**N=8 (6.5%)**<br>**N=2 (1.6%)** | **0%** |
| **Average INR reduction in 24 hours** | | |
| o **PO**<br>• **INR ≤ 2***<br>• **Average reduction in INR** | **66.7%**<br>**3.3** | NA |
| o **IV**<br>• **INR ≤ 2***<br>• **Average reduction in INR** | **100%**<br>**4.5** | NA |
| o **SQ**<br>• **INR ≤ 2***<br>• **Average reduction in INR** | **18%**<br>**2.7** | NA |

**measured when INR ≥3 prior to vitamin K administration*

**Data Summary**
- Two patients with intracranial hemorrhage received vitamin K administered subcutaneously.
- Of the forty-seven patients who received vitamin K for warfarin urgent reversal for planned surgery, nineteen (40%) experienced a delay to surgery of ≥ 24 hours. All patients who experienced a delay in surgery received vitamin K via the subcutaneous route.
- Eighty patients who received vitamin K for bleeding or elevated INR were not on warfarin therapy.

**Conclusions**
- Current evidenced-based, clinical practice guidelines provide recommendations for the management of elevated INRs in patients receiving warfarin, including when it is appropriate to use vitamin K
    - In patients taking VKAs with INRs between 4.5 and 10 and with no evidence of bleeding, routine use of vitamin K is not recommended
    - For patients taking VKAs with INR > 10 and no evidence of bleeding, vitamin K administered orally is recommended
    - Subcutaneous vitamin K has been shown to be less effective than low-dose oral vitamin K
- Administration of vitamin K to patients with coagulopathy secondary to hepatic disease is not recommended since the use of INR to test coagulation in this population poorly correlates to occurrence of gastrointestinal bleeding and the administration of vitamin k does not improve coagulation parameters in the majority of patients

- Education should be conducted regarding administering vitamin K via the IM and IVP routes as they increase the risk of anaphylactic reactions (~1 in 3000 doses)

<table>
<tr><th colspan="3">Strategies to reverse the effects of VKAs</th></tr>
<tr><th>Patient Consideration</th><th>Type of Reversal</th><th>Rationale</th></tr>
<tr><td>• Asymptomatic patient with excessively elevated INR (>10)</td><td>• Interruption of warfarin<br>• Low dose PO vitamin K</td><td rowspan="4">Interruption of warfarin<br>• Time to effect: within days<br>• ~2.5 days for INR 6-10 to decrease to < 4.0<br><br>Low dose (1-2.5 mg) PO vit K<br>• Time to effect: within 24 hrs<br>• ~1.4 days for INR 6-10 to decrease to <4.0<br><br>Low dose (1-2.5 mg) IV vit K<br>• Time to effect: within 4-6 hrs<br>• ~24 hours for INR 6-10 to decrease to <4.0</td></tr>
<tr><td>• Elective invasive procedure</td><td>• Interruption of warfarin<br>• Low dose PO vitamin K</td></tr>
<tr><td>• Urgent procedure</td><td>• Low dose IV vitamin K<br>• FFP</td></tr>
<tr><td>• Serious bleeding</td><td>• IV vitamin K<br>• 4-Factor PCC (Kcentra)</td></tr>
<tr><td colspan="3">Fresh Frozen Plasma<br>• Fast (partial)<br>• Immediate replacement of vitamin K dependent coagulation factors – but the correction of coagulopathy is partial and wears off in 12-24 hours<br><br>4-Factor Protein Complex Concentrate (PCC)<br>• Rapid (complete; within 10-15 minutes)<br>• Immediate replacement of vitamin K dependent coagulation factors plus IV vitamin K<br><br>5 mg PO vitamin K = 1 mg IV vitamin K at 24 hours</td></tr>
</table>

Adapted from 2012 American College of Chest Physicians Evidenced-Based Clinical Practice Guidelines, 9th ed.

**PNEUMONIA STANDING ORDERS**

**Proposed Changes to Antibiotic Orders**

**Background:**
The most recent literature still recommends the use of combination gram negative antibiotic therapy for patients with healthcare acquired pneumonia and risk factors for MDR pathogens such as *Pseudomonas* to better ensure that one of the agents will have activity against the offending organism. At MHCS the combination of Zosyn® (piperacillin/tazobactam) + ciprofloxacin has been utilized for double gram negative coverage in this population as per the current Pneumonia Admission Orders. Worsening fluoroquinolone resistance has threatened the usefulness of ciprofloxacin as part of this regimen. The below data demonstrates that Zosyn® remains the most effective agent per current microbiology data and tobramycin now appears to be a better option based on susceptibility data when an additional gram negative agent is needed for treatment of possible MDR pathogens.

*Pseudomonas aeruginosa*
Piperacillin/tazobactam – 94% susceptible
Ciprofloxacin – 68% susceptible
Tobramycin – 92% susceptible

*Pseudomonas aeruginosa* – isolates resistant to piperacillin/tazobactam
Ciprofloxacin – 57% susceptible
Tobramycin – 79% susceptible

**Summary:**
The above data indicates that tobramycin offers a higher probability of providing effective antimicrobial coverage when used in combination with Zosyn® due to the higher likelihood of Tobramycin offering coverage in the event that the isolate is resistant to Zosyn®. Based on this data it is recommended to modify the healthcare acquired pneumonia regimen to remove ciprofloxacin as the preferred dual antibiotic regimen and instead utilize Zosyn® + Tobramycin as indicated on the following page.

**Current Pneumonia Orders:**

| NON-ICU PATIENT | ICU BOUND PATIENT |
|---|---|
| ☐ Levofloxacin (Levaquin) 750 mg IV q 24 hrs* | ☐ Ceftriaxone (Rocephin) 2 gm IV (if age>65 give 1gm) q 24 hrs PLUS Levofloxacin (Levaquin) 750 mg IV q 24 hrs* |
| ☐ Ceftriaxone (Rocephin) 1 gm IV q 24 PLUS Azithromycin (Zithromax) 500 mg IV q 24 hrs | ☐ Ceftriaxone (Rocephin) 2 g IV (if age > 65 give 1gm) q 24 hrs PLUS Azithromycin (Zithromax) 500 mg IV q 24 hrs |
| | ☐ If Anaphylactic Penicillin allergy, Levofloxacin (Levaquin) 750 mg IV q 24 hrs* PLUS Aztreonam (Azactam) 1 gm IV q 8 hrs |

**Pseudomonas Risk/ Healthcare-Associated Pneumonia**

| |
|---|
| ☐ Piperacillin/Tazobactam (Zosyn) 3.375 gm IV over 4 hours q 8 hrs PLUS Ciprofloxacin (Cipro) 400 mg IV q 12 hrs (DNS) ** Infuse Ciprofloxacin first. When infused, immediately start Zosyn (Zosyn incompatible with Ciprofloxacin). |
| ☐ Piperacillin/Tazobactam (Zosyn) 3.375 gm IV over 4 hours q 8 hrs PLUS Azithromycin (Zithromax) 500 mg IV q 24 hrs PLUS Tobramycin 5 mg/kg IV x 1 then pharmacy to dose ** Infuse Tobramycin first. When infused, immediately start Azithromycin When infused, immediately start Zosyn (all are incompatible). |
| ☐ if Penicillin allergy, use Aztreonam (Azactam) 2 gm IV q 8 hrs PLUS Ciprofloxacin (Cipro) 400 mg IV q 12 hrs (DNS) |

**Suspected MRSA (check below to add Vancomycin to any of above orders)**

| |
|---|
| ☐ Vancomycin 1 gram IV Q 12 hrs<br>☐ Vancomycin 1 gram IV Q 24 hrs<br>☐ Vancomycin 1 gram IV x 1, then pharmacy to dose per protocol |

**PROPOSED CHANGES:**

| COMMUNITY ACQUIRED PNEUMONIA (CAP) | |
|---|---|
| **non-ICU Treatment** | ☐ Levofloxacin 750 mg IV Q 24 hrs<br>**OR**<br>☐ Ceftriaxone 2 gm IV Q 24 hrs<br>**PLUS**<br>Azithromycin 500 mg IV Q 24 hrs |
| **ICU Treatment** | ☐ Levofloxacin 750 mg IV Q 24 hrs<br>**PLUS**<br>Ceftriaxone 2 gm IV Q 24 hrs |
| **ICU Treatment**<br>**(Severe PCN Allergy)** | ☐ Levofloxacin 750 mg IV Q 24 hrs<br>**PLUS**<br>Aztreonam 2 gm IV Q 8 hrs |
| **Suspected Pseudomonas**<br>**(non-ICU or ICU)** | ☐ Piperacillin/tazobactam 3.375 gm IV x 1 dose over 30 mins, then 3.375 gm IV Q 8 hrs (4 hr infusion)<br>**PLUS**<br>Tobramycin 7 mg/kg IV now then Pharmacy to dose<br>**PLUS**<br>Azithromycin 500 mg IV Q 24 hrs |
| **Suspected Pseudomonas**<br>**(Severe PCN Allergy)** | ☐ Levofloxacin 750 mg IV Q 24 hrs<br>**PLUS**<br>Tobramycin 7 mg/kg IV now then Pharmacy to dose<br>**PLUS**<br>Aztreonam 2 gm IV Q 8 hrs |

| HEALTHCARE ASSOCIATED / HOSPITAL ACQUIRED PNEUMONIA**<br>(HCAP/HAP/VAP) | |
|---|---|
| **HCAP / HAP / VAP** | ☐ Piperacillin/tazobactam 3.375 gm IV x 1 dose over 30 mins, then 3.375 gm IV Q 8 hrs (4 hr infusion)<br>**PLUS**<br>Tobramycin 7 mg/kg IV now then Pharmacy to dose |
| **HCAP / HAP / VAP**<br>**(Severe PCN Allergy)** | ☐ Aztreonam 2 gm IV now then Q 8 hrs<br>**PLUS**<br>Tobramycin 7 mg/kg IV now then Pharmacy to dose<br>**PLUS**<br>Vancomycin 1 gm IV x 1 dose, then Pharmacy to dose |

****** hospitalized for > 2 days within the previous 90 days, nursing home/long term care facility resident, received recent IV antibiotic therapy, chemotherapy or wound care in the previous 30 days, dialysis patient

| SUSPECTED MRSA<br>**(check box below to add Vancomycin to any of above orders)** |
|---|
| ☐ Vancomycin 1 gm IV x 1 dose, then Pharmacy to dose |

**TAMIFLU (OSELTAMIVIR)**

**Automatic Stop & Renal Dosing Adjustments**

**Normal Dose:**

- Treatment of Influenza A: 75 mg BID x 5 days
- Treatment of Influenza A (critically ill patients): 150 mg BID x ≥ 10 days

**Renal Dosing:**

| | **Non-critically ill patients** | **Critically Ill Patients** |
|---|---|---|
| **CrCl < 30 ml/min** | 75 mg DAILY | 75 mg BID |
| **CRRT** | 75 mg BID | 150 mg BID |
| **Hemodialysis** | 30 mg after every other HD session* | 30 mg DAILY* |

***** give after dialysis on dialysis days

**Proposal:**

To prevent inappropriately long durations of treatment it is proposed to institute a 5 day automatic stop for oseltamivir when used for non-critically ill patients and a 10 day automatic stop for critically ill ICU patients. Additionally, due to the possibility of increased side effects in patients with impaired renal function it is recommended to allow this drug to be automatically adjusted in patients with impaired renal function as allowed per the *Renal Dosing Adjustments* policy.

**Summary Review of Pivot 1.5**

*Therapeutic, Peptide-Based Very-High-Protein Nutrition for Metabolic Stress*

**Proprietary Name:** Pivot 1.5 Cal
Abbott Laboratories Nutrition
Product of USA

**Indications/Use:**

- Provides 1.5 Cal/mL—concentrated calories for fluid-restricted patients.
- Very high protein (93.8 g/L, 25% of calories) to support protein synthesis, tissue repair and wound healing.
- Immune support:
  - Arginine (13 g/L, 3.5% of calories) to support proliferation and function of immune cells.
  - Glutamine (inherent) (7.6 g/L) for GI-tract integrity and energy for immune cells.
  - Omega-3 fatty acids (EPA, 2.6 g/L; DHA, 1.1 g/L) to help modulate inflammation and support immune function.[1,2]
- Tolerance:
  - Advanced blend of hydrolyzed protein, structured lipid, and prebiotic (NutraFlora® scFOS®*) to promote absorption and tolerance.
  - Hydrolyzed, peptide-based protein system.
  - MCT/fish oil structured lipid, a well-tolerated[3,4] and absorbed[4] next generation fat to promote absorption of fatty acids.
  - 1.8 g of NutraFlora scFOS/8 fl oz (7.5 g/L). scFOS are prebiotic soluble fibers that stimulate the growth of beneficial bacteria in the colon.
- Elevated antioxidants vitamin C, vitamin E and beta-carotene to help reduce free radical damage.
- Meets or exceeds 100% of the RDI for 24 vitamins and minerals in 1500 Cal (1000 mL).
- Halal.
- Gluten free.
- Suitable for lactose intolerance.

**Nutritional Content:**

**Serving Size:** 1 L

Amount Per Serving

| |
|---|
| **Nutrient Density, Cal/mL**: 1.5 |
| **Protein, % Cal**: 25.0 |
| **Fat, % Cal**: 30.0 |
| **Carbohydrate, % Cal**: 45.0 |
| **MCT:LCT**: 20:80 |
| **Cal to Meet 100% RDIs**: 1500 |
| **mL to Meet 100% RDIs**: 1000 |
| **Total Cal:g Nitrogen**: 100:1 |
| **Nonprotein Cal:g Nitrogen**: 75:1 |
| **Osmolality, mOsm/kg H2O**: 595 |
| **Renal Solute Load, mOsm/L**: 692 |
| **Minimum Tube Size for Gravity/Pump Feeding (Fr)**: Not Recommended/8 |
| **Protein, g**: 93.8 |
| **Fat, g**: 50.8 |
| **Carbohydrate, g**: 172.4 |
| **Dietary Fiber, g**: 7.5† |
| **L-Carnitine, mg**: 150 |
| **Taurine, mg**: 150 |

| |
|---|
| **Water, g**: 759 |
| **Calories**: 1500 |
| **Vitamin A, IU**: 10000 |
| **Beta-Carotene, mg**: 4.8 |
| **Vitamin D, IU**: 400 |
| **Vitamin E, IU**: 250 |
| **Vitamin K, mcg**: 80 |
| **Vitamin C, mg**: 300 |
| **Folic Acid, mcg**: 600 |
| **Thiamin (Vitamin B1), mg**: 2.3 |
| **Riboflavin (Vitamin B2), mg**: 2.6 |
| **Vitamin B6, mg**: 3.0 |
| **Vitamin B12, mcg**: 9.0 |
| **Niacin, mg**: 30 |
| **Choline, mg**: 600 |
| **Biotin, mcg**: 450 |
| **Pantothenic Acid, mg**: 15 |
| **Sodium, mg**: 1400 |
| **Sodium, mEq**: 60.9 |
| **Potassium, mg**: 2000 |
| **Potassium, mEq**: 51.2 |
| **Chloride, mg**: 1600 |
| **Chloride, mEq**: 45.1 |
| **Calcium, mg**: 1000 |
| **Phosphorus, mg**: 1000 |
| **Magnesium, mg**: 400 |
| **Iodine, mcg**: 150 |
| **Manganese, mg**: 5.0 |
| **Copper, mg**: 2.0 |
| **Zinc, mg**: 25 |
| **Iron, mg**: 18 |
| **Selenium, mcg**: 70 |
| **Chromium, mcg**: 120 |
| **Molybdenum, mcg**: 150 |

**Conclusion:**
Pivot 1.5 would be unique to our formulary as it would provide a very-high-protein, calorically dense, immune-supporting, hydrolyzed, peptide-based enteral formula for use in metabolically stressed, immunosuppressed patients.

**Recommendations:**
It is recommended by the Nutrition Support Team to implement use of this product as an enteral source of complete nutrition for patients who are metabolically stressed and immunosuppressed, such as those with major elective surgery, trauma, burns, and head and neck cancer.

CATHOLIC HEALTH INITIATIVES

Memorial Health Care System

2525 deSales Avenue Chattanooga, TN 37404
2051 Hamill Road Hixson, TN 37343

(Order Set· 1905) Revised· (2/2014)

Date/Time Ordered

**ENTERAL NUTRITION ADULT (Tube Feeding)**

1. ☐ Registered Dietitian to manage tube feeding.

2. Nutrition Consult: Evaluate enteral feeding regimen.

3. Pharmacy Consult: Evaluate PO medication for liquid substitution.

4. Route of feeding: ☐NGT ☐OGT ☐DHT ☐PEG ☐PEJ ☐Other_____

5. **Full strength formula:**_____
   - Start full strength formula at 30ml/hr & advance at a rate of 10ml every 8 hours as tolerated to **goal rate of**:_____ml/hr.
   - **Flush feeding tube** with 30ml H20 every 4 hours unless otherwise ordered:_____
   - **Modular supplement**: _____
   - **P.O. Diet with tube feeding**:_____

6. Weigh Daily

7. Labs: CMP, Mg, Phos, Prealbumin – Now if not already done and then weekly (okay to run off blood already in lab).

8. Strict Input and Output.

9. Keep Head of bed at a 30-45 degree angle at all times for continuous feedings unless contraindicated. Intermittent feedings: only during feeding and for 1 hour past feeding.

10. Check residuals Q6 hours for NGT, OGT, PEG and G-tube only. Do not check residuals w/small bore tubes positioned postpylorically, such as DHT or PEJ.
    - If less than 500ml, reinstill and continue tube feeding.
    - If greater than 500ml, discard residual; consider repositioning patient & stop feeding for 2 hours - then recheck.
    - If residuals are still greater than 500ml, stop feeding. Call MD.

11. Medication Administration: Hold TF for administration of following PO meds:
    - Coumadin (Warfarin) – Hold 1 hour before and 1 hour after.
    - Dilantin (Phenytoin) – Hold feeding 1 hour before and 1 hour after.
    - Fluoroquinolones (Cipro, Levaquin). Hold 1 hour before and 2 hours after.
    - *Consult pharmacy for any combination of above medication for scheduling of administration.*

12. To unclog feeding tube:
    - Instill 15-20ml warm water into tube. Repeat, if needed.
    - If unsuccessful after several attempts, request Pancrelipase from pharmacy. Open Pancrelipase capsule & mix contents with 325mg of Sodium Bicarbonate. Add 5 ml of water and instill into feeding tube. Clamp for 5 minutes. If needed, repeat. If unable to resolve with Pancrelipase, please notify MD.

Physician Signature:_____Date:_____Time:_____
**OR**
See written order from Dr._____ Date:_____

_____RD/RN

*Approved by Medical Executive Committee XX/XX/XXXX*

# Revision to Enteral Nutrition (Adult) policy PC-07129

Proposal for Pharmacy and Therapeutics
2/13/2014

The American Society for Parenteral and Enteral Nutrition recommends the use of standardized order forms when prescribing an enteral nutrition regimen. Here at Memorial Hospital utilization of the *Enteral Nutrition Adult (Tube Feeding)* order set has been very low over the past 3 years of utilization (~14% of total orders). To increase utilization, the order set has been simplified and streamlined. In addition, the following change to policy is recommended to increase utilization of this order set:

| *Title:* **ENTERAL NUTRITION (ADULT)** | | |
|---|---|---|
| Page 1 of 4 | | |
| Policy Number: PC- 07129 | Date Last reviewed/Revised: XX/XX | Valid Until: XX/XX |
| Department(s) Affected: All Clinical Areas | Review Period: every 3 years | |

**OUTCOME:**
Initiation of enteral feeding provides nutritional support to patients unable to consume adequate nutrition orally. Adequate enteral nutrition decreases catabolic response to injury, maintains gut integrity, decreases translocation of gut bacteria, and improves wound healing.

| | |
|---|---|
| **POLICY:**<br>1. Enteral Nutrition requires a physician order. Order should include type of feeding, goal rate, and route. | Enteral feeding is delivered into the stomach, the jejunum or the duodenum, depending on the location of the tip of the tube. |
| **2. If the physician does not utilize the standing order set to prescribe enteral nutrition, the RN or RD will implement the Enteral Nutrition Adult order set using the information provided by the physician and call for clarification as needed.** | **Standing order sets address all needed parameters when ordering enteral nutrition. Order sets are an enteral nutrition practice recommendation from A.S.P.E.N. (1)** |
| 3. Enteral Nutrition may be administered continuously or intermittently. | Continuous feeding may offer additional prophylaxis for peptic ulcers. |
| 4. The RD will manage the tube feeding when so ordered by the physician. | The RD needs a physician order to manage the tube feeding. |
| 5. Do not add anything to the tube feedings, including water, fiber or protein. | The tube feeding bottles are a closed system. This minimizes the risk of contamination. |
| 6. All formulas are started at full strength. When a decreased strength is ordered by the physician, the equivalent full strength rate will be initiated the RD will note the substitution in the progress notes for the physician. | Example: ½ strength at 50 mL/hr = full strength at 25 mL/hr will be started. |

(1) Journal of Parenteral and Enteral Nutrition, Vol. 33, No. 2, 122-167 (2009) DOI: 10.1177/0148607108330314

Respectfully submitted,
*Memorial Hospital Nutrition Support Team*