

A Publication of the Department of Pharmacy
Saint Francis Hospital and Medical Center

Pharmacy Information

This edition of Pharmacy Information includes formulary changes approved at the September 2007 and January 2008 Drug Therapy Management Committee meetings.

Formulary Changes

*DTM Meetings
September 2007 & January 2008*

Additions to Formulary

Ranolazine (Ranexa®) is an anti-anginal and anti-ischemic agent whose effects do not depend upon reductions in heart rate or blood pressure. It does not effect the rate-pressure product, a measure of myocardial work, at maximal exercise. It is indicated for the treatment of chronic angina. Ranexa® prolongs the QT interval and should be reserved for patients who have not achieved an adequate response with other anti-anginal drugs. Ranexa® is restricted to prescribing by Cardiology.

Decitabine (Dacogen®) is a therapy approved to treat myelodysplastic syndromes (MDS). Decitabine is incorporated into DNA where it inhibits DNA methyltransferase causing hypomethylation and cell death. The dose limiting toxicity is bone marrow suppression. Dacogen® is restricted to prescribing by Oncology.

Modafanil (Provigil®) is used to improve wakefulness and mental alertness in adults who experience excessive sleepiness (ES) due to one of the following diagnosed sleep problems: obstructive sleep apnea/hypopnea syndrome (OSAHS), shift work sleep disorder (SWSD), or narcolepsy. It is restricted to prescribing by Pulmonary and Neurology.

Hydroxocobalamin (Cyanokit®) is an antidote indicated for the treatment of known or suspected cyanide poisoning. In the presence of cyanide, each hydroxocobalamin molecule can bind one cyanide ion by displacing it for the hydroxo ligand linked to the cobalt ion, forming cyanocobalamin. A single 5gm infusion over 15 minutes is the typical adult dose, followed by a second 5gm infusion only if needed over 15 to 120 minutes.

Aripiprazole (Abilify®) is an atypical antipsychotic used to treat acute bipolar mania or schizophrenia. The drug had been available on the formulary only in an oral formulation. Now the intramuscular formulation is available and this injection is restricted to use in Behavioral Health and ED patients.

Levonorgestrel (Plan B®) is an agent that may be employed to prevent a pregnancy after a sexual assault. It is restricted to use as dictated in the policy on administration of emergency contraceptive medications to victims of sexual assault (ED 2.006).

Omeprazole (Prilosec®) is a proton pump inhibitor used widely for the management of gastric and duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis, and other conditions caused by excess stomach acid. Omeprazole will replace esomeprazole oral capsules on the formulary offering in the proton pump inhibitor class.

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Deletions from Formulary

- Vancomycin oral capsules – The Pharmacy Department will be manufacturing vancomycin oral solution using the intravenous formulation and simple syrup. Unit dose cups of 250mg per 10ml (25mg/ml) will replace the 250mg capsules.
- Esomeprazole oral capsules – Replaced with omeprazole capsules
- Cyanide Antidote Kit – Replaced with Cyanokit®

Denied Addition to Formulary

- The following medications were recently evaluated for formulary addition and denied due to a lack of evidence that they would have a therapeutic, safety or cost effectiveness benefit beyond similar agents currently available on the formulary:
 - Arformoterol (Brovana®) inhalation is a nebulized, long-acting bronchodilator for chronic obstructive pulmonary disease (COPD).
 - Sitagliptin (Januvia®) is a DPP-4 inhibitor that, along with diet and exercise, helps lower blood sugar levels in patients with type 2 diabetes.
 - Cefixime (Suprax®) 400mg suspension is a semi-synthetic cephalosporin antibiotic for oral administration.

Approvals for Ambulatory Clinics Sampling Purposes Only

- Budesonide/formoterol (Symbicort®) turbuhaler is indicated for the long-term maintenance treatment of asthma in patients 12 years and older. Symbicort® is NOT indicated for the relief of acute bronchospasm and does not replace fast-acting inhalers. Symbicort® is not indicated in patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of inhaled short-acting beta₂-agonists.

Medications with Nationwide Shortages

The following list includes the medications that are experiencing nationwide shortages:

<u>Medication</u>	<u>Shortage</u>	<u>Alternative</u>
IVIG	On Allocation	
Lymphazurin 5ml Vials	Discontinued	Expect return to market in March 08
Transderm—Scop® Patches	Short Supply	
Rabies Immune Globulin	On Allocation	
Menomune® Vials	On Allocation	
Neostigmine 1:1000 10 ml Vials	Short Supply	
Labetalol 20 ml Vials	Short Supply	
Lopressor 5 ml Vials	Short Supply	
Meruvax® II Vial	Long Term Back Order	
Demedex® ampules (all strengths)	Not Available	

Formulary Change in Proton Pump Inhibitor

- **Oral omeprazole has replaced oral esomeprazole** on the formulary following the recent price increase of all proton pump inhibitors. This recommendation for change in formulary PPI offering comes with the support of the Department of Gastroenterology and the members of the Medical Drug Therapy Management Subcommittee. Omeprazole is now the least expensive proton pump inhibitor (PPI) available for use. Since the oral PPIs are considered to be therapeutically interchangeable when dose equivalently, omeprazole should be prescribed when clinically appropriate as the only available PPI on formulary whenever the oral route is permissible. Patients unable to swallow oral dosage forms will continue to be offered the lansoprazole orally disintegrating tablet. Our formulary intravenous PPI will remain as esomeprazole (restricted to prescribing by the Department of Gastroenterology).
- **Oral omeprazole dosing schema:**
 - **Active duodenal ulcer:** Oral: 20-40 mg/day
 - **Gastric ulcer:** Oral: 40 mg/day
 - **Symptomatic GERD:** Oral: 20 mg/day
 - **Erosive esophagitis:** Oral: 20 mg/day
 - **Peptic ulcer disease:** Eradication of *Helicobacter pylori*: Oral: Dose varies with regimen: 20 mg once daily or 40 mg/day as single dose or in 2 divided doses; requires combination therapy with antibiotics
 - **Pathological hypersecretory conditions:** Oral: Initial: 60 mg once daily; doses up to 120 mg 3 times/day have been

Information for Healthcare Professionals

- Recently, the prescribing community was informed of an update to the package insert for ceftriaxone regarding the potential risk associated with the concomitant use of ceftriaxone with calcium-containing solutions or products. This drug interaction is widely described in the neonatal population but to date no reports of this phenomenon have been reported in other patient populations, none-the-less, the theoretical possibility exists and it is our duty to inform our providers. The clinical information system now contains a level 1 drug interaction between ceftriaxone and calcium-containing solutions or products (including TPN and lactated ringers) and a detailed warning has been created to warn prescribers of the potential interaction. Providers may elect to use cefotaxime (our alternative third-generation cephalosporin) or convert the patient to another appropriate anti-infective based on culture/sensitivity data.
- The U.S. Food and Drug Administration (FDA) recently announced that, at the agency's request, Bayer Pharmaceuticals Corp. has agreed to a marketing suspension of Trasylol®, a drug used to control bleeding during heart surgery, pending detailed review of preliminary results from a Canadian study that suggested an increased risk for death. FDA requested the suspension in the interest of patient safety based on the serious nature of the outcomes suggested in the preliminary data. FDA has not yet received full study data but expects to act quickly with Bayer, the study's researchers at the Ottawa Health Research Institute, and other regulatory agencies to undertake a thorough analysis of data to better understand the risks and benefits of Trasylol®. There are not many treatment options for patients at risk for excessive bleeding during cardiac surgery. Thus, FDA is working with Bayer to phase Trasylol® out of the marketplace in a way that does not cause shortages of other drugs used for this purpose.
- A recent FDA Alert highlights revisions to the labeling for haloperidol (marketed as Haldol® Haldol® Decanoate and Haldol® Lactate). The updated labeling includes WARNINGS stating that Torsades de Pointes and QT prolongation have been observed in patients receiving haloperidol, especially when the drug is administered intravenously or in higher doses than recommended. Haloperidol is not approved for intravenous use. Our clinical information system has been altered so that the default administration for injectable haloperidol is IM. Providers are encouraged to monitor QTc in patients receiving haloperidol (particularly if IV administration is required or if doses exceed those recommended in the package insert).

Anticoagulant Safety Taskforce

The Joint Commission 2008 National Patient Safety Goal 3E describes the need for hospitals to reduce the likelihood of patient harm associated with the use of anticoagulation therapy. The Goal is applicable to hospital and ambulatory settings that provide anticoagulant therapy and allows for a one year phase-in period for planning and testing of systems aimed at development of a standardized program to individualize the care provided to each patient receiving anticoagulant therapy. Significant “milestones” of progress are expected at 3 month intervals months during 2008 with full implementation by January 1, 2009. To comply with this safety goal, the hospital has created a multi-disciplinary taskforce to analyze care delivery and identify steps in the clinical workflow which will have the maximum impact. Performance tracking and monitoring will be performed with the plan to integrate protocols into clinical workflow.

Required elements of titratable infusion orders:

Medication orders for **titratable infusions** must contain all of the following elements for compliance with our regulatory/accrediting organizations. The clinical information system has been modified to prompt prescribers for this information.

Time and date the order is prescribed	Name/license of individual prescribing the medication
Name of drug	Drug dosage
Route of administration	Strength (concentration) as applicable
Frequency (with duration as appropriate)	Units (example: mg/hour and microgram/kg/hour) if applicable
Infusion rate (as applicable)	Specific goal of titration using approved objective criteria
Titrated IVs: MUST include a maximum dose	Incremental dose changes specified by physician/licensed independent provider

Proper destruction of controlled substances:

A new policy has been approved that defines and delineates the procedure for the documentation of administration and proper wasting of controlled drugs. A controlled substance requiring destruction will be placed in the approved hazardous waste container containing an absorbent material to render such substances unrecoverable in the following manner.

- Tablets should be crushed and the powder poured into the container.
- Capsules should be opened and contents emptied into the container
- Fluid should be withdrawn from the ampule/vial/bag of the injectable and expressed into the container
- Transdermal patches should be cut in half with fluid contents (if applicable) expressed and placed into the container.



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