Proton Pump Inhibitor (PPI) Formulary and Policy Revisions: Launch date 8/19/2015

In early 2015 Protonix (pantoprazole) intravenous was restricted and automatically substituted with Pepcid (famotidine) intravenous due to an ongoing nationwide shortage. The exception to the substitution was active gastrointestinal (GI) bleed patients. At the May 2015 P & T Committee meeting, the success of this initiative was discussed and the Committee approved it as a permanent policy revision. In addition to this discussion, PPI product selection, dose & administration, efficacy, safety and cost issues were discussed at length.

Intermittent IV vs Continuous Infusion IV PPI for Active GI Bleed (JAMA Intern Med. 2014;174(11):1755-1762)
Meta-analysis of randomized trials have shown that bolus/continuous infusion PPI compared to placebo or no therapy decreases further bleeding in patients with high-risk bleeding ulcers after endoscopic therapy. Further bleeding was also decreased by intermittent IV PPI compared to no therapy or placebo as reported in another meta-analysis. Based upon this information, the authors designed a systematic review and meta-analysis to determine if intermittent IV PPI would be non-inferior to bolus/continuous infusion PPI. Trials/patients were included if the study population had gastric or duodenal ulcer(s) with active bleeding and excluded patients with flat spots and clean bases due to low rate of clinically significant rebleeding.

The primary outcome of recurrent bleeding within 7 days (-2.64%) was deemed non-inferior and “well below the predefined margin of +3%. Risk ratios for secondary outcomes (urgent interventions, transfusion, LOS, rebleeding within 30 days, mortality) demonstrated no increased risk for intermittent therapy.

Based upon the published literature, feedback from gastroenterologists and Committee discussion, the Committee approved removing bolus/continuous infusion pantoprazole from formulary. Patients with active GI bleed will receive pantoprazole 40mg IV q12h instead.

Prevacid (Lansoprazole) Solutab is Non-formulary
Patients with enteral tubes or difficulty swallowing whole tablets or capsules have been receiving lansoprazole solutabs for greater than the past 5 years. Product cost has increased dramatically to greater than 10 dollars per dose. Alternative PPI dosage forms were investigated but they are either costly or difficult to administer properly to enteral tube patients. For these reasons, lansoprazole solutab will be nonformulary. In patients with GI bleed, pantoprazole IV will be substituted. If no GI bleed is present, ranitidine syrup will be substituted.

PPI Formulary Revision Summary
1. Pantoprazole IV will be restricted to patients who are NPO & have a GI bleed. All other NPO patients will receive famotidine IV.
2. Pantoprazole continuous IV infusion will be nonformulary. GI bleed patients will receive pantoprazole 40mg q12h. Requests for continuous infusion will require fast-track approval (see page 2 for process).
3. Lansoprazole solutab will be nonformulary, not stocked. Enteral tube patients will be converted to IV pantoprazole if they have a GI bleed. All others will be converted to ranitidine syrup.
4. The following policies will be revised as a result of these changes: Restricted Medication List, Therapeutic Substitution and Conversion of IV to PO.

Levothyroxine Intravenous Policy Revisions: Launch date 8/19/2015
Levothyroxine has a very long half-life, approximately 7 days. During periods of levothyroxine IV shortages, institutions have implemented conservation measures to take advantage of the pharmacokinetic parameters. These measures have included administering product only 2 times a week and/or holding for 5-7 days before administering the first dose to NPO patients with exceptions for high risk patients (ie myxedema coma). In many cases, patients are NPO for only a short amount of time and may resume PO levothyroxine before the hold expires. The institutions reported no impact on clinical outcomes, realized significant cost savings and therefore decided to continue the measure(s) even though the shortage resolved. A second conservation/cost savings measure adopted by many institutions is automatic pharmacist conversion of orders from IV to PO levothyroxine in appropriate patients.

Levothyroxine Policy Revisions
1. Levothyroxine IV will be held and not administered in NPO patients for the first 4 days they are NPO.
   a. Exceptions: Patients with clinical symptoms of myxedema coma or with a TSH greater than 50 mIU/L.
2. Levothyroxine IV will be automatically converted by the pharmacist per policy to levothyroxine PO with proper dose conversion.
3. The following policies will be revised as a result of these changes: Levothyroxine IV, Conversion of IV to PO and Restricted Medication List.
Formulary Changes (Miscellaneous)
1. Lanoxin brand name tablets (digoxin) will be replaced with an AB rated FDA approved generic. The majority of patients admitted to the hospital are already taking generic digoxin.
2. Tranexamic acid intravenous may be used peri-operatively in hip/knee replacement, spinal fusion or shoulder surgeries performed at SJH. Order set/downtime form with screening required.
3. Definity (perflutren) microsphere contrast is restricted to Cardiologist prescribing only.
4. Formoterol/arformoterol inhalation products.
   a. Perforomist (formoterol) is formulary.
   b. Brovana (arformoterol) is nonformulary, not stocked, no Patient’s Own Medication. Orders for Brovana will automatically get converted to Perforomist.
   c. Foradil (formoterol) is formulary.

Inhaler Dispensing Issues
Foradil (formoterol), Spiriva (ipratropium) and Nicotrol (nicotine) inhalers arrive in the pharmacy as a “kit” that contains drug as well as an “inhaler device”. This is different from other inhalers where the drug is contained internally in the device. The dosage form (dry powder capsule or cartridge) is attached to or placed in the “inhaler” prior to administration. The pharmacy is unable to obtain the “inhaler” separate from the medication units. In the past, manufacturers would supply this portion at no charge, but this does not occur any longer. Consequently if the “inhalers” are lost or damaged, the additional cost of ordering the drug in addition to the inhaler occurs. Every year drug product expires and is wasted because the inhaler portion had to be re-ordered.

<table>
<thead>
<tr>
<th>Nicotrol</th>
<th>Foradil</th>
<th>Spiriva</th>
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<tbody>
<tr>
<td><img src="image1.png" alt="Nicotrol" /></td>
<td><img src="image2.png" alt="Foradil" /></td>
<td><img src="image3.png" alt="Spiriva" /></td>
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Kayexalate (aka sodium polystyrene sulfonate) does NOT contain a laxative
Due to reports of colonic necrosis, SJH Pharmacy stocks a SORBITOL-FREE kayexalate (SPS). Lactulose is the recommended laxative to order with kayexalate.
Click here for FDA information on colonic necrosis, including patient risk factors. [http://www.fda.gov/safety/medwatch/safetyinformation/ucm186845.htm](http://www.fda.gov/safety/medwatch/safetyinformation/ucm186845.htm)

How to request a nonformulary drug for use in one specific patient (aka Fast Track Process)
All requests for nonformulary products will require completion of a fast-track request form located on-line in the forms catalog (Form # 20207). Please alert your pharmacist as soon as possible when considering these products. All requests require Pharmacy & Therapeutics Committee Leadership and VPMA approval before an order for the product can be placed. Retrospective review of all “fast-tracks” will occur at the following P & T meeting.

How to request addition or status change to the Formulary
Formulary additions, deletions and new policy development or revisions may be requested using the Form #18711. Formulary requests should only be completed by medical or hospital staff; requests from vendors are unacceptable.

For more information on Pharmacy & Therapeutics Committee actions, please contact Karen Whalen, Drug Information Pharmacist 448-6519.