Pharmacy & Therapeutics Committee News

March 2015

**Shortage update**
The shortage of IV Moxifloxacin (Avelox) appears to be resolved. Levofloxacin (Levaquin) IV is nonformulary and not stocked.

**N-acetylcysteine (aka NAC; Mucomyst) PO**
In 2013 based upon the results of the ACT trial, the P & T Committee removed NAC from the Formulary for prevention of contrast induced nephropathy. Since ACT was published, three additional randomized controlled trials have been completed and all have resulted in no clinical benefit. The fourth reference below is a subgroup analysis of diabetic patients from the ACT trial; no clinical benefit identified. # Acetylcysteine for prevention of renal outcomes in patients undergoing coronary and peripheral vascular angiography. Circulation 2011; 124:1250-1259. Editorial Circulation 2011; 124: 1210-1211.

Based upon current level of information and the lack of an FDA approved indication for a commercial NAC product, the P & T Committee continues to keep NAC non-formulary for this indication. It is important to the Committee that a cohesive message is delivered to all patients. The use of compounding pharmacies to provide a non-FDA approved product to out-patients and then denial of utilization of such product in the hospital should the patient require admission sends a mixed message. Based upon the lack of benefit compared to placebo and the inherent risks associated with using compounding pharmacies, NAC PO is nonformulary and patients will not be allowed to take product they bring into the hospital.


**Target Specific Oral Anticoagulants (TSOACs): Formulary Status**
Order sets for dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis) and edoxaban (Savaysa) are mandatory in EPIC. All agents are on formulary for atrial fibrillation patients with two exceptions:
1. Edoxaban in patients with Creatinine Clearance > 95ml/min is Contraindicated/Black Box Warning due to inferiority to warfarin.
2. Edoxaban 15mg tablets (nonformulary, not stocked) are only indicated in transition; as an alternative parenteral anticoagulation may be selected.

The only agents on formulary for the acute treatment of DVT and/or PE are rivaroxaban (Xarelto) and apixaban (Eliquis). Dabigatran (Pradaxa) and edoxaban (Savaysa) are nonformulary for acute treatment of DVT and/or PE because patients must first receive 5-10 days of parenteral anticoagulation.

**Nonformulary Medications**
The following agents are nonformulary.
- Oritavancin (Orbactiv) IV
- Dalbavancin (Dalvance) IV
- Tedizolid (Sivextro) IV/PO
- Ticarcillin-clavulanate IV (Timentin)
- Peramivir (Rapivab) IV
- Urokinase (Abbokinase)

**Therapeutic Substitution Revisions**
Suvorexant (Belsomra) PO, an orexin receptor antagonist for insomnia, is nonformulary. Patients with orders for suvorexant will have the orders automatically converted to zolpidem. Suvorexant has a similar adverse effect and efficacy profile compared to other insomnia agents with the following exceptions.
1. Contraindicated in patients with narcolepsy or taking strong CYP 3A4 inhibitors or inducers.
2. Sleep paralysis, an inability to move or speak for several minutes during sleep wake transitions, hypnagogic/hypnopompic hallucinations and cataplexy-like symptoms may occur.
Restricted Medication List Revisions

<table>
<thead>
<tr>
<th>Restricted Medication</th>
<th>Revisions</th>
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</thead>
<tbody>
<tr>
<td>N-acetylcysteine (aka NAC; Mucomyst) PO</td>
<td>Nonformulary, no POM for prophylaxis of contrast induced nephropathy.</td>
</tr>
<tr>
<td>Erectile dysfunction drugs: Viagra (sildanafil); Cialis (tadalafil); Stendra (avanafil); Levitra/Staxyn (vardenafil)</td>
<td>When NOT prescribed as daily dosing for Pulmonary Hypertension or BPH the pharmacist will automatically discontinue the order. Nonformulary, Not stocked, No POM.</td>
</tr>
<tr>
<td>Epi-Pen &amp; Epi-pen Jr/Auv Q Epinephrine Auto-Injectors</td>
<td>When ordered via Medication Reconciliation the pharmacist will automatically discontinue the order. Nonformulary, No POM.</td>
</tr>
<tr>
<td>Naloxone (Evzio) Auto-injector</td>
<td>When ordered via Medication Reconciliation the pharmacist will automatically discontinue the order. Nonformulary, Not stocked, No POM.</td>
</tr>
<tr>
<td>Contrave PO (bupropion 90mg/naltrexone 8mg)</td>
<td>Nonformulary, Not stocked, No POM. Pharmacist will call prescriber to discuss plan to assess and address patient risk of bupropion withdrawal &amp; management.</td>
</tr>
<tr>
<td>Sodium-glucose co-transporter 2 inhibitors: Farxiga (dapagliflozin) Jardiance (empagliflozin) Invokana (Canagliflozin)</td>
<td>Nonformulary, Not stocked, No POM. Patient already on insulin – pharmacist will auto-discontinue the order. Patient not on insulin – pharmacist will call prescriber to recommend insulin order &amp; get discontinue order for Sodium-glucose co-transporter 2 inhibitors.</td>
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<td>GLP-1 receptor agonists: Albiclutide (Tanzanum); Dulaglutide (Trulicity); Exenatide (Byetta); Exenatide (Bydureon); Liraglutide (Victoza)</td>
<td>Nonformulary, Not stocked, No POM. Patient already on insulin – pharmacist will auto-discontinue the order. Patient not on insulin – pharmacist will call prescriber to recommend insulin order &amp; get discontinue order for GLP-1 receptor agonist.</td>
</tr>
<tr>
<td>Ofev (Nintedanib) PO &amp; Esbriet (perfenidone) PO For pulmonary fibrosis</td>
<td>Nonformulary, Not stocked, No new hospital starts. <em>May use POM.</em></td>
</tr>
<tr>
<td>Harvoni (Ledipasvir/sofosbuvir) PO Viekira Pak (ombitasvir, paritaprevir, ritonavir) For Hepatitis C</td>
<td>Nonformulary, Not stocked, No new hospital starts. <em>May use POM.</em></td>
</tr>
<tr>
<td>Tranexamic acid, Topical or IV Orthopedic surgery</td>
<td>Once surgeon completes the screening tool and selects route of administration the pharmacist will automatically adjust the dose based on renal function.</td>
</tr>
</tbody>
</table>

PICC Lines and TPN
PICC lines inserted for TPN infusion should be ordered 24 hours in advance of starting the TPN. If the PICC line is placed after 2pm the TPN will not start until the next day. Dextrose 10% can be ordered to bridge patient until TPN starts.

How to request a nonformulary drug for use in one specific patient (aka Fast Track Process)
All requests for nonformulary injectable products and some oral products with special circumstances 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.

Meeting Schedule
The P & T Committee meets monthly (with some exceptions) on the fourth Tuesday morning each month in Room 201B at 0700. Approvals are forwarded to the next possible Medical Department and Medical Executive Committee meetings.

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