

Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met July 17, 2012. 3 products were added in the *Formulary*, and 1 drug was deleted from the *Formulary*. 7 products were designated nonformulary and not available and 5 interchanges were approved. 2 drugs were restricted and a new potassium policy was approved.

◆ ADDED

Anakinra (Kineret®)*

*IV administration prohibited

Bicalutamide (Generic)

Ketotifen Ophthalmic 0.025%
(Generic)

◆ DELETED

Lepirudin (Refludan®)†

†Nonformulary and not available

◆ NONFORMULARY AND NOT AVAILABLE

Azelastine Ophthalmic
(Generic)‡

Epinastine Ophthalmic
(Generic)‡

Lepirudin (Refludan®)

**Meningococcal Groups C and Y
and Haemophilus B Tetanus
Toxoid Conjugate Vaccine**
(MenHibrix®)

Olopatadine Ophthalmic 0.1%
(Patanol®)‡

Olopatadine Ophthalmic 0.2%
(Pataday®)‡

‡Interchanged, patient may use their own

Tazarotene Foam (Fabior®)

◆ HIGH-PRIORITY NONFORMULARY DRUGS

Glucarpidase (Voraxaze®)*

*Obtained when needed because of high cost

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ADVERSE DRUG REACTIONS

Can dabigatran CAUSE clots?

On the surface, such a question seems illogical. How can a drug cause the problem that it is supposed to treat or prevent? Actually, such an occurrence is neither unique nor unknown. For example, most antiarrhythmic agents, including amiodarone, are considered proarrhythmic. Also, all antibiotics, even when used appropriately, can cause overgrowth of nonsusceptible organisms including other bacteria and fungi. Among the anticoagulants, unfractionated heparin may cause thrombosis in patients who develop heparin-induced thrombocytopenia (HIT). Warfarin may do likewise in patients who develop skin necrosis early in therapy because of rapid inhibition of the protein C, a natural anticoagulant, before its effect on other clotting factors are realized.

The possible association of dabigatran with thrombotic events comes from a recent examination and re-examination of adverse events reported in the RE-LY (Randomized Evaluation of Long Term Anticoagulation) trial. RE-LY was the key study for the approval of dabigatran (Pradaxa®) by the FDA in October 2010 for its labeled indication, the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.¹ In RE-LY, 2 blinded doses of dabigatran (110 and 150 mg twice daily) were prospectively compared with open-label warfarin whose dose was adjusted to achieve an INR value between 2 and 3.² 18,113 patients with atrial fibrillation and at least 1 risk factor for stroke were included in the final results. After a median follow-up of 2 years, the frequency of stroke or systemic embolism in patients assigned to warfarin was 1.7% compared with 1.54% and 1.11% in the low-dose and high-dose dabigatran groups, respectively. Frequency of major bleeding in patients assigned to warfarin was greater than that observed in those taking low-dose dabigatran (3.57% vs 2.87%) but was comparable

to that observed in patients in the high-dose dabigatran group (3.57% vs 3.31%). Intracranial bleeding was observed less often in both dabigatran groups (0.23% and 0.3%, respectively) than in the warfarin group (0.74%). Hemorrhagic stroke was likewise (0.1% for both dabigatran groups vs 0.38% for warfarin-treated patients).

Notably, new onset myocardial infarction (MI) in the original report was noted less frequently in those taking warfarin (0.53%) than in those taking either dose of dabigatran (low-dose, 0.72%, high-dose, 0.74%). Subsequently, numerous additional safety outcome events were identified that changed these numbers dramatically. Specifically, frequency of new onset MI in the study groups changed to 0.82%, 0.81%, and 0.64%, respectively.

There was enough concern about these potentially prothrombotic effects of dabigatran that another group of investigators combined data from the RE-LY trial and 6 other trials involving dabigatran, warfarin, enoxaparin, and placebo in a meta-analysis.³ The purpose of this analysis was to determine if use of dabigatran was associated with an increase in risk of occurrence of either acute coronary syndrome (ACS) or MI. The 7 trials included 30,514 patients. Patients were studied in 3 short-term deep venous thrombosis trials, 2 stroke prophylaxis in patients with atrial fibrillations trials, a trial evaluating anticoagulation in acute thromboembolism, and a trial evaluating anticoagulation in ACS. These data revealed that use of dabigatran was associated with a higher risk of either MI or ACS compared with the other agents (1.19% vs 0.79%). These differences persisted when revised RE-LY trial results were used or when short-term trials were excluded from the data analyses. Authors of this meta-analysis concluded, "Clinicians should consider the potential of

(continued on page 6)

◆ **HIGH-PRIORITY
NONFORMULARY DRUGS**

Isotretinoin (Absorica®)*

*Handle like Accutane®

Sodium Oxybate (Xyrem®)*

*Patients will use their own supply of a controlled substance

◆ **INTERCHANGES**

Ketotifen Ophthalmic 0.025% for Azelastine Ophthalmic†

†1 drop 3 times a day for all dosages

Ketotifen Ophthalmic 0.025% for Epinastine Ophthalmic†

†1 drop 3 times a day for all dosages

Ketotifen Ophthalmic 0.025% for Olopatadine 0.1% Ophthalmic (Patanol®)†

†1 drop 3 times a day for all dosages

Ketotifen Ophthalmic 0.025% for Olopatadine 0.2% Ophthalmic (Pataday®)†

†1 drop 3 times a day for all dosages

Pancrelipase (Zenpep®) for **Pancrelipase** (Pertzye®)†

†Pertzye with 16,000 units lipase converted to Zenpep 15,000 units lipase

◆ **CRITERIA FOR USE CHANGES**

Acetylcysteine Inhaled*

*Restricted to oral use for the prevention of radiocontrast-induced nephropathy

Pertuzumab (Perjeta®)*

*Added in the Chemotherapy Policy

◆ **ADDITIONAL ISSUES**

Potassium, Intravenous Policy Updated

Anakinra is an interleukin-1 (IL-1) receptor antagonist used to treat conditions in which there is excess IL-1. Anakinra works by blocking the activity of IL-1 through competitive inhibition of the IL-1-receptor, which decreases the IL-1 inflammatory response. It has been used in a variety of immune conditions such as systemic onset juvenile arthritis, but it is only currently FDA labeled to treat rheumatoid arthritis (RA).

RA treatment goals are to reduce the signs and symptoms of disease and slow the progression of structural damage with the goal of inducing remission and preventing further disease progression. Anakinra is administered subcutaneously

and generally takes about 1-3 weeks to show a therapeutic response.

Trials demonstrate anakinra's safety and efficacy and compare it to competitor drugs such as the tumor necrosis factor (TNF) blockers used to treat the same indications. Evidence is limited; available trials show anakinra to be better than placebo, but less effective compared to TNF blockers.

The American College of Rheumatology guidelines for the treatment of RA do not recommend anakinra, but the American College of Rheumatology guidelines for the treatment of juvenile idiopathic arthritis (JIA) includes anakinra use during systemic onset juvenile idiopathic arthritis (SOJIA) because TNF blockers have not shown much efficacy. Overall, studies in JIA are lacking because it is hard to enroll pediatric patients in the studies. Equal efficacy and greater convenience of administration with TNF blockers still make them a preferred option.

A study was completed evaluating the dose, duration, and frequency that determined anakinra is most effective when administered daily. The effects of the interruption of anakinra therapy have not been explicitly studied. This is perplexing as anakinra is a daily medication and compliance is inevitably lower than with weekly, biweekly, and monthly options. There are several studies evaluating anakinra's use in indications other than RA that demonstrate disease flare within several days after discontinuing anakinra. Anakinra has a shorter half-life than the TNF blockers so it is unreasonable to assume that its effects would last as long as those of the TNF blockers after discontinuation.

Cost-effectiveness data do not favor using anakinra in RA. A cost-effectiveness analysis provided comparisons between the biologic drugs used for RA, and the results indicated that anakinra was the least costly of the treatment options, but it was the least effective when compared to the TNF blockers that were analyzed.

Because of concern for flare upon discontinuation of the anakinra due to its short half-life, it was added in the *Formulary*.

Anakinra has been prescribed intravenously (IV) when it was prescribed for nonformulary use. Although there are data about the IV route of administration for anakinra, there are no safety or efficacy data regarding use of the subcutaneous formulation when given IV, nor is there information regarding appropriate diluent for intravenous injection in pediatric patients. The IV route has been used as a "holiday" from the daily subcutane-

ous route of administration, which can be painful. Since anakinra has not been studied using the IV route and using this route has unknown implications, IV use will only be allowed as a component of a prospective, IRB-approved safety and efficacy study.

Bicalutamide is an oral nonsteroidal antiandrogen (NSAA), approved by the FDA in 1995 as an antihormonal agent in combination therapy with a luteinizing hormone-releasing hormone analog (LHRH-A) for the treatment of advanced (D₂ metastatic) prostatic carcinoma. Bicalutamide was reviewed proactively because of a high volume of nonformulary use. It is now available as a generic.

Combination therapy with a LHRH-A achieves a nearly complete antagonism of testosterone. The LHRH-As suppress testosterone output, while bicalutamide interferes with binding of remaining testosterone at the testosterone receptor. When initially started, LHRH-As cause an increase in testosterone production (flare), and it is important that patients receive a NSAA agent to block the effects of this flare.

The NSAAs currently approved in the United States for the treatment of Stage D₂ metastatic prostate carcinoma are bicalutamide, flutamide [Eulexin®], and nilutamide [Nilandron®]. Bicalutamide and flutamide are indicated for use in combination with LHRH-A therapy, and nilutamide is approved for use in combination with orchiectomy.

Bicalutamide is structurally related to flutamide, which has long been listed in the *Formulary*. Unlike flutamide, bicalutamide has a long plasma half-life that allows once-daily dosing compared with 3 times daily for flutamide. In addition, bicalutamide is more selective for the peripheral androgen receptor and has less activity at the central androgen receptor on the hypothalamic-pituitary axis. Nilutamide appears to offer no benefit over bicalutamide or flutamide and has the least favorable toxicity profile.

The cost of bicalutamide (generic) per 50-mg tablet is \$0.25. The cost of flutamide (generic) per 125 mg capsule is \$0.53 each. The cost of nilutamide is \$16.68 per tablet.

The most frequent adverse event for both bicalutamide and flutamide is hot flashes (53%). Bicalutamide has predictable adverse effects, does not require dosage adjustments for renal or hepatic impairment, is less expensive than other NSAAs, and has no black-box warnings. Bicalutamide
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Formulary update, from page 2

was added in the *Formulary* and is not restricted.

Ketotifen ophthalmic solution was added in the *Formulary* after a class review of H₁-antagonists/mast cell stabilizers used for the treatment of allergic conjunctivitis. This class was reviewed because of a high volume of **olopatadine ophthalmic solution** use. All doses of olopatadine, **azelastine**, and **epinastine ophthalmic solutions** were designated nonformulary and not available and will be interchanged to ketotifen solution 1 drop 3 times a day. Prescribers can continue the patient's home medication with an appropriate order in EPIC, if they do not want the patient to be changed to ketotifen.

The American Academy of Ophthalmology and American Optometric Association do not endorse a specific dual-action agent for the treatment of allergic conjunctivitis. Although newer topical medications such as olopatadine, epinastine, and ketotifen are more efficacious and well tolerated, none stands out as the drug of choice. It is recommended that other ophthalmic agents should be used before corticosteroids.

Olopatadine was the first agent to exhibit dual actions against mast cells. It has a low bioavailability after topical administration, thus the primary effect site is the conjunctiva sac. Patanol® has been studied extensively in field studies and conjunctival allergen challenge models. Although the allergen challenge model has emerged as the leading protocol and gained acceptance from FDA, both methods of comparing ophthalmic pharmaceuticals have advantages and disadvantages. Patanol® is dosed twice daily with an 8-10 hour interval while Pataday® is once a day. Pataday® efficacy data are extrapolated from Patanol®, thus the drug experience is limited.

Clinical trials comparing H₁-antagonists/mast cell stabilizers ophthalmic solutions have shown minor or no differences in efficacy. Olopatadine often prevailed in allergen conjunctival challenge models but field studies found no differences. Olopatadine has similar efficacy and comfort level to other dual-action agents like ketotifen. Continuing olopatadine in long-term users does not improve outcome, as there is no additional benefit after 15 days.

Common adverse effects with these products like burning and blurred vision are mild. Contact lenses

should be removed before using ketotifen and the patient should wait at least 10 minutes before reinserting lenses after each use.

Olopatadine is available only as a brand name product. The costs of azelastine, epinastine, and ketotifen are \$52.73, \$73.88, and \$5.24, respectively. Patanol® and Pataday® cost \$111.25 and \$104.22, respectively. The relative equivalent efficacy supports the use of a less costly drug like ketotifen.

Lepirudin is a direct thrombin inhibitor that had a labeled indication for anticoagulation in patients with heparin-induced thrombocytopenia (HIT) and associated thromboembolic disease in order to prevent further thromboembolic complications. It has also been used as an anticoagulant in other clinical situations (eg, cardiopulmonary bypass surgery) in patients with a history of HIT.

The manufacturer of lepirudin announced that it will stop manufacturing this product for business reasons (ie, low use). Argatroban, bivalirudin [Angiomax®], and fondaparinux [Arixtra®] are options listed in the *Formulary* that could be used in patients with HIT or a history of HIT. The primary treatment for HIT is to discontinue heparin and begin a non-heparin anticoagulant. Once the thrombocytopenia is resolved, the patient can be managed with warfarin.

Argatroban is a direct thrombin inhibitor, like lepirudin, and has a labeled indication for the treatment of HIT. Bivalirudin is a direct thrombin inhibitor and has been used off-label for this indication. Bivalirudin has a labeled indication for patients with HIT or who are at risk of HIT undergoing a percutaneous intervention (PCI).

The synthetic heparin analogue fondaparinux, a factor Xa inhibitor, is used off-label to treat HIT. It has FDA labeled indications for prevention and treatment of venous thromboembolism. It is long acting, can be given once daily, and does not require routine monitoring, which may offer advantages over the direct thrombin inhibitors. It should not, however be used in patients with a creatinine clearance less than 30 ml per minute.

Fabior® is a topical foam dosage form of the retinoid **tazarotene** with a labeled indication for the treatment of acne vulgaris in patients 12 years of age or older. It is the only topical foam dosage form for acne. Common adverse effects include application site irritation, dryness, erythema, and exfoliation. Its use is contraindicated in pregnancy and can cause fetal harm in pregnant women.

This agent was designated nonformulary and not available, but patients may use their own supply from home.

MenHibrix® is a combination of **meningococcal groups C and Y and haemophilus b tetanus toxoid conjugate vaccine**. It has a labeled indication for the prevention of invasive disease caused by *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b in children between 6 weeks through 18 months of age. Consistent with most vaccines, this combination product was designated nonformulary and not available.

Glucarpidase is a recombinant bacterial enzyme used as a rescue therapy to inactivate methotrexate, thus providing an alternate route of elimination to renal excretions. It is not a substitute for and must be used in conjunction with leucovorin.

In January 2012, FDA approved glucarpidase injection for the treatment of toxic plasma methotrexate concentrations in patients with delayed methotrexate clearance due to impaired renal function. A proactive review of glucarpidase was completed in February 2012. In March, the P&T Committee designated glucarpidase a high-priority nonformulary drug because it was only available via an investigational protocol. The EPIC entry for this drug included instructions on the process needed to obtain this drug to facilitate timely acquisition.

Glucarpidase is now commercially available. A dose for an 80-kilogram adult will cost about \$90,000. Since use is anticipated to be very low and a short delay in acquisition is not problematic [even on weekends], it remains a high-priority nonformulary drug with instructions on acquisition when it is needed. The use of glucarpidase at Shands will be more restrictive than the labeling and follow the investigational protocol under which it was previously available.

Absorica® is a new capsule dosage form of the retinoid isotretinoin, which has a labeled indication for the treatment of severe recalcitrant nodular acne in patients 12 years of age or older. It is only given to patients enrolled in the iPLEDGE limited distribution program, which requires enrollment by patients, prescribers, and pharmacies. This program has several important requirements to prevent adverse effects including adequate contraception and pregnancy testing to prevent teratogenic effects. According to its manufacturer, this product will be launched in the fourth quarter of 2012.

It was designated a high-priority nonformulary drug and patients must use their own supply similar to

(continued on next page)

Formulary update, from page 3

Accutane®. Although similar to Accutane®, Absorica® is more bioavailable (better absorbed on an empty stomach) and it is not interchangeable with Accutane® or a generic equivalent of Accutane®.

Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB). Although sodium oxybate is a schedule III controlled substance, GHB is a schedule I illicit drug. Sodium oxybate was approved in 2002 with a labeled indication for the treatment of narcolepsy with cataplexy. In 2005, treatment of daytime sedation in patients with narcolepsy was added as a labeled indication. Xyrem® is only available via a restricted distribution system from a single central pharmacy.

This creates an unusual situation. Since Xyrem® is a controlled substance, patients cannot use their own supply according to current policy. However, Shands cannot purchase and stock this product. Since Xyrem® should not be stopped upon admission to the hospital, an exception to the “patient’s own controlled substance policy” was needed.

Therefore, it was designated a high-priority nonformulary drug with instructions that the patient must use their own supply. A procedure will be established to store this controlled substance in its own drawer in the Omnicell® cabinet.

Pertzye® brand of **pancrelipase** is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis (CF) or other conditions.

Patients with CF have a more viscous intestinal lumen, which causes luminal obstruction, fibrosis, and exocrine pancreatic insufficiency. Severe disease can lead to unabsorbed substrates reaching the colon and excreted in the feces. Enzyme insufficiency can occur in the course of chronic pancreatitis and pancreatic carcinoma. Consequences of the loss of exocrine function are malabsorption, steatorrhea, weight loss, and malnutrition. Pertzye® ultimately replaces the enzymes that aid in digestion of fats, protein, and carbohydrates, thereby acting like digestive enzymes physiologically secreted by the pancreas.

Pertzye® is a delayed-release pancrelipase capsule containing 8,000/28,750/30,250 units of lipase, protease, and amylase, respectively; or 16,000/57,500/60,500 units of lipase, protease, and amylase, respectively.

FDA labeling of all pancreatic enzyme products states that they are not interchangeable. However, this applies to the community setting. In July 2010, the P&T Committee approved an interchange for pancrelipase products provided the difference in lipase dose does not exceed 20%.

Because of lipase content in Pertzye®, interchanging a patient taking Pertzye® (Lipase 8,000 units) to the most similar Formulary agent (Zenpep® [Lipase 10,000 units]) would result in a difference in lipase

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Formulary update, from page 4

dose greater than 20%. Pertzze® (16,000 units) could be interchanged to Zenpep® (Lipase 15,000 units) and meet the interchange criteria.

Therefore, Pertzze® 16,000 unit lipase will be interchanged to Zenpep® 15,000 unit lipase. If an order for Pertzze® 8,000 unit lipase is received, it will be treated like any other nonformulary drug. If the patients have their own supplies, use of their own medication will be encouraged. The volume of nonformulary use of this strength of Pertzze® will be monitored.

The complete interchange grid for pancrelipase products can be found on the Portal.

Acetylcysteine inhalation is again a shortage item. In June 2011, the P&T Committee voted to restrict the use of inhaled acetylcysteine to address a shortage. Supplies of inhaled acetylcysteine were limited to oral use for the prevention of radiocontrast-induced nephropathy. Because of the urgent need to begin this restriction, it has been immediately re-implemented until the shortage resolves.

Pertuzumab is a HER2/neu receptor antagonist with a labeled indication in combination with trastuzumab [Herceptin®] and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. There are FDA-approved tests to identify a patient's HER2 status.

Pertuzumab is given as an IV infusion over 60 minutes. It is anticipated that this drug will primarily be used in the outpatient setting.

The P&T Committee approved revisions to the **Potassium Administration Policy**.

Several changes removed inconsistencies with current practices and should improve patient safety. Adult and pediatric guidelines were updated (see attached). The policy is more liberal about the total amount of potassium that may be replaced intravenously, but requires appropriate monitoring of the effects of these larger doses.

The maximum potassium infusion rate was changed to 10 mEq per hour on a general ward and 20 mEq per hour on a floor with telemetry, when using a peripheral vein. If a central line is used, the maximum rates increase to 20 mEq and 40 mEq, respectively. The P&T Committee limited the maximum dose of 40 mEq per hour with a central line to intensive care units (ICUs). This change does not allow this high rate on floors with telemetry, which routinely monitor for arrhythmias and not ECG changes associated with hyperkalemia (widening of QRS complex and increased height of T waves).

The total allowable amount replaced before a repeat potassium level was changed to 60 mEq, if the patient is not on telemetry, or 80 mEq if they are on telemetry. The maximum replacement dose definition refers to acute replacement doses (ie, "riders"). A potassium serum concentration will be drawn at least 1 hour after the end of a dose to allow the potassium to distribute.

If you have any questions, refer to the complete policy on the Portal.

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**Clots from dabigatran?,
from page 1**

these serious harmful cardiovascular effects..." when using dabigatran.

While these data are disturbing, it should be noted that this analysis has limitations. First, 57% of the patients in this meta-analysis and 74% of events reported originated in the RE-LY trial, which was the largest of the trials and larger than all of the other studies combined. Second, in the RE-LY trial, MI was a secondary endpoint, a finding which has a greater likelihood to be associated with chance as compared with a primary endpoint. Lastly, when data from RE-LY were excluded in a separate analysis, MI or ACS occurred with dabigatran no more frequently than with the other anticoagulants.⁴

It appears there probably is not an association between the use of dabigatran and MI or ACS. These observations suggest that use of dabigatran is associated with new clots no more often than either warfarin or enoxaparin. Nevertheless, while the data from the RE-LY trial regarding occurrence of MI were considered nonsignificant, the clinical relevance of these differ-

ences remains debatable. Additionally, dabigatran has been available for clinical use for less than 2 years, although clinical experience with the drug continues to accumulate. It is prudent for clinicians to be vigilant for the possible occurrence of new clots in patients receiving dabigatran until more definitive data become available.

By Larry Lopez, PharmD

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Or submit your question online at www.shands.org/professionals/druginfo/default.asp

- This service is for referring physicians and other healthcare professionals taking care of Shands patients
- Phones are staffed from 9 am to 4:30 pm, Monday – Friday
- All answers are thoroughly researched and referenced

For emergent questions that do not need thorough research, go to the pharmacy servicing your area.