FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met November 21, 2000. 2 drugs were added in the Formulary and 1 drug was added for an evaluation. 3 dosage forms were deleted. 3 drugs were designated not available.

◆ ADDED
  Gatofloxacin
  (Tevquin® by Bristol-Myers Squibb)
  Pantoprazole
  (Protonix® by Wyeth)

◆ ADDED FOR EVALUATION
  Crotalide polyvalent immune fab, ovine
  (CroFab® by Protherics)

◆ DELETED
  Estradiol valerate
  (eg, Delestrogen® by Bristol-Myers Squibb)
  Terbutaline inhaler
  (Brethaire® by Novartis)
  Omeprazole capsules
  (Prilosec® by Astra)

◆ NONFORMULARY, NOT AVAILABLE
  Levofloxacin
  (Levaquin® by Ortho McNeil)
  Omeprazole capsules
  (Prilosec® by Astra)
  Rabeprazole
  (Aciphex® by Janssen)

◆ THERAPEUTIC INTERCHANGE

Pantoprazole selected as the only proton pump inhibitor

Proton pump inhibitors (PPIs) are among the most commonly prescribed drugs in the United States. They are also commonly used in the hospital setting and Shands at UF is no exception.

For many years, PPIs have been therapeutically interchanged at Shands at UF. Omeprazole has been the PPI listed in the Formulary. It was selected over lansoprazole when these 2 PPIs were the only products on the market. There are now 4 different oral PPIs on the market. An injectable PPI may be approved as soon as the 1st quarter of 2001.

The P&T Committee re-evaluated the PPI listed in the Formulary and has decided to switch from omeprazole to pantoprazole. Effective January 1, 2001 pantoprazole will be the proton pump inhibitor available at Shands at UF. There will be 1 exception. An extemporaneously prepared omeprazole solution (2 mg/mL) will remain available for use in very young children and in patients with tubes (eg, J-tube). Currently, there is insufficient data to support the use of pantoprazole by this method.

The interchange doses for the "non-formulary-and-not-available" PPIs are listed in the table below. Since pantoprazole is only available as a 40-mg tablet, most of the equivalent dosages are 40 mg once a day.

When these interchanges are made, a new order will be written in the Orders section of the chart. Also, a note will be written in the Progress Notes explaining the interchange.

<table>
<thead>
<tr>
<th>DRUG/DOSAGE ORDERED</th>
<th>EQUIVALENT PANTOPRAZOLE DOSAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omeprazole (Prilosec®) 10 mg QD</td>
<td>Pantoprazole (Protonix®) 40 mg QD</td>
</tr>
<tr>
<td>Omeprazole 20 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Omeprazole 40 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Omeprazole 20 mg BID</td>
<td>Pantoprazole 40 mg BID</td>
</tr>
<tr>
<td>Omeprazole 40 mg BID</td>
<td>Pantoprazole 40 mg BID</td>
</tr>
<tr>
<td>Lansoprazole (Prevacid®) 15 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Lansoprazole 15 mg BID</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Lansoprazole 30 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Lansoprazole 30 mg BID</td>
<td>Pantoprazole 40 mg BID</td>
</tr>
<tr>
<td>Rabeprazole (Aciphex®) 20 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
<tr>
<td>Rabeprazole 40 mg QD</td>
<td>Pantoprazole 40 mg QD</td>
</tr>
</tbody>
</table>

Gatifloxacin is a fluoroquinolone antibiotic with activity against gram-positive organisms, particularly respiratory pathogens. When trovafloxacin was removed from the Formulary, it created a need to add a fluoroquinolone in the Formulary with more gram-positive coverage compared with ciprofloxacin. The (continued on next page)
Tetanus toxoid in short supply, but...

There is a nationwide shortage of tetanus toxoid; however, at this time Shands at UF is able to get a limited supply of both tetanus toxoid and tetanus and diphtheria toxoids (Td). An allocated amount of the multi-dose vials of both tetanus toxoid and Td are available each week; thus the shortage has not yet cause major concerns here. The unit-dose syringes are not available, however. Thus, the Shands IV Center must draw up doses into syringes. The Emergency Department (ED) is using the multi-dose vials and drawing up each dose as needed.

This shortage resulted from 2 coincident situations: 1) a decrease in the number of lots of Td released by Wyeth Lederle, and 2) a temporary decrease in inventory of Td following routine maintenance activities at the production facilities by Aventis Pasteur that lasted longer than anticipated. Approximately half of the usual number of Td doses has been distributed this year. Although there have been no decreases in production of tetanus toxoid, availability is low because of increased use during the Td shortage. On the basis of information provided by Aventis Pasteur, vaccine supplies should be restored early in 2001. Until then, Aventis Pasteur will be limiting orders to assure the widest possible distribution of available doses.

(continued on next page)
TAMIFLU®: Test not required

Oseltamivir was added in the Formulary in September 2000. This antiviral has activity against both influenza A and B and was added for use in debilitated patients (eg, immuno-compromised patients).

Because there were concerns about inappropriate over-prescribing, a restriction was put on the use of oseltamivir. Oseltamivir could only be used if a rapid test for influenza A and B was ordered. The 2nd day’s doses would only be dispensed if the test was positive. However, this restriction was lifted because the test is not considered to be reliable.

Published studies show that the rapid influenza test is greater than 90% accurate. Studies done here at Shands at UF based on samples taken from patients with positive viral cultures for influenza A or B were not as reliable. Instead of >90% accuracy, only 50% or less of these culture-positive patients were positive using the rapid test. This questions whether the influenza quick test should be used at all. Thus, the diagnosis of influenza should be based on clinical symptoms.

All of the following 3 diagnostic criteria must be met or the patient has to have a positive antigen test or culture for influenza A or B virus. The patient 1) must have respiratory tract symptoms [ie, cough], 2) must have a fever or other systemic symptoms [malaise, myalgias, chills], and 3) must have these symptoms in the influenza season [winter months or when influenza is known to be circulating in the community]. At the end of this influenza season, an audit of the use of oseltamivir will be done to determine the appropriateness of its use and whether additional restrictions are needed.

ZOSYN®: ID Consult required

In April 2000, the P&T Committee designated Zosyn® nonformulary and not available through the normal nonformulary process. Because there may be a rare patient with an organism sensitive to Zosyn® and resistant to the agents listed in the Formulary, Zosyn® use was allowed after a clinical pharmacist reviewed the culture and sensitivity report. This process did not avoid the use of Zosyn® in patients who had culture positive results, but who were not infected (eg, colonization). In order to allow the appropriate diagnosis before the use of Zosyn®, an ID Consult is now needed before Zosyn® can be used nonformulary.

Linezolid: Criteria for use

Linezolid was added in the Formulary in October 2000. Prior to admission in the Formulary, it was available nonformulary only after an ID Consult. When listed in the Formulary, this restriction was continued.

Linezolid is a novel antibacterial agent that has clinical utility in the treatment of infections caused by resistant aerobic gram-positive bacteria. It can be used in patients infected with vancomycin-resistant enterococcus or mexitelillin-resistant staphylococcus. Because of its utility in resistant infections, linezolid needs to be reserved for these difficult infections. Overuse could decrease the utility of this valuable agent.

The P&T Committee has approved the use of linezolid in 2 situations: the treatment of serious infections caused by vancomycin-resistant Enterococcus faecium and Enterococcus faecalis or the treatment of serious gram-positive infections in patients who fail or who are intolerant of other therapies (ie, vancomycin). Agents that are less toxic and less expensive should be used for other indications.

SYNERCID®: Criteria for use

Synercid® requires an ID Consult before it will be dispensed. Also like linezolid, it should be reserved for resistant organisms.

The P&T Committee has approved 2 uses for Synercid®. Synercid® should be used for the treatment of serious infections caused by vancomycin-resistant Enterococcus faecium. It is not active against Enterococcus faecalis. Synercid® may also be useful in the treatment of serious gram-positive infections in patients who fail or who are intolerant to other therapies (ie, vancomycin or linezolid). Due to the cost, ease of administration (does not require a central line) and oral availability, linezolid is considered the preferred agent over Synercid® for susceptible organisms. Synercid® is considered a 3rd-line agent after linezolid.

SHORTAGES, FROM PAGE 2

The shortage impacts persons aged ≥ 7 years who require tetanus prophylaxis in wound management, have not completed a primary series (3 doses) of vaccine containing Td, or have not been vaccinated during the preceding 10 years with Td, diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) or diphtheria and tetanus toxoids (DT). This shortage will not affect vaccination of children aged < 7 years who require additional doses of a vaccine containing tetanus toxoid; they should receive DTaP or pediatric DT, which are not in short supply.

Td IS REQUIRED FOR TETANUS TOXOID BECAUSE Td PROVIDES PROTECTION AGAINST BOTH TETANUS AND DIPHTHERIA.

However, during this shortage, if Td is not available, tetanus toxoid can be used as an alternative for persons aged ≥ 7 years who require immediate boosting with tetanus (eg, wound management), or who are unlikely to return to a clinic if vaccination is delayed. If tetanus toxoid is administered to patients and healthcare providers must weigh the risks and benefits of subsequent vaccination with Td. Arthus-type reactions may occur among persons who receive multiple doses of tetanus toxoid, especially within short intervals (< 10 years). However, if vaccination with Td is delayed for > 10 years following their last Td administration, persons may be protected inadequately against diphtheria. After the shortage is resolved, Td should again be considered preferable to tetanus toxoid.

The CDC recommends that clinics experiencing shortages of Td prioritize their use of available supplies. If administration of Td is delayed, clinics should implement a callback system when vaccine is available. Recommendation for use (highest to lowest priority) of Td are:

1. Persons traveling to a country where the risk for diphtheria is high.*
2. Persons requiring tetanus vaccination for prophylaxis in wound management.
3. Persons who have received < 3 doses of vaccine containing Td.
4. Pregnant women and persons at occupational risk for tetanus-prone injuries who have not been vaccinated with Td within the preceding 10 years.
5. Adolescents who have not been vaccinated with a vaccine containing Td within the preceding 10 years.
6. Adults who have not been vaccinated with Td within the preceding 10 years.

*Travelers to certain countries may be at substantial risk for exposure to toxigenic strains of C. diphtheriae, especially with prolonged travel, extensive contact with children, or exposure to poor hygiene. On the basis of surveillance data and consultation with the World Health Organization, countries with highest risk are in Africa (Algeria, Egypt, and sub-Saharan Africa); the Americas (Brazil, Dominican Republic, Ecuador, and Haiti); Asia/Oceania (Afghanistan, Bangladesh, Cambodia, China, India, Indonesia, Iran, Iraq, Laos, Mongolia, Myanmar, Nepal, Pakistan, Philippines, Syria, Thailand, Turkey, Vietnam, and Yemen); and Europe (Albania and all countries of the former Soviet Union).
OUTPATIENT PHARMACY

4 brand name drugs — update

In the June 2000 issue of the Bulletin, we reported that the legislature changed the healthcare benefits for patients with Medicaid that limits the number of brand name drugs that will be covered as part of the Medicaid drug benefit. Patients are now limited to 4 brand name drugs per month. The original legislation excluded anti-retrovirals, mental health drugs, contraceptives, and diabetic supplies from the limit. Recently, immunosuppressive drugs were also excluded, which is welcome relief for our transplant patients.

The 4-brand-name-drug limit has had a big impact on Medicaid patients. As predicted, many patients had to scramble to find less expensive alternatives for their brand name prescriptions when the change was implemented in September. Because of their limited funds, many patients have to change their drug therapy or choose not to have some of their prescriptions refilled. Patients have started paying cash for their less expensive medications. They are using more generics. Many patients on proton pump inhibitors, which are only available as brand name products, have been switched to a H2-blocker. Generic enalapril has become a popular ACE-inhibitor. Cerivastatin is commonly being used as an HMG-CoA inhibitor. Although cerivastatin is a brand-name drug, it only costs 10 to 20% of other

HMG-CoA inhibitors at Shands Pharmacies. This can have a large impact on low-income patients who are paying “out of their pocket.”

There is a phone number that a prescriber can call to try to get an exception to the 4-brand-name limit for medical reasons. The prescriber can call (877) 553-7481. A pharmacy cannot get an exception approved. The prescriber must make the call. This program, once again, emphasizes the importance of prescribers knowing how their patients pay for their prescriptions. It is recommended that patients be asked, “How do you pay for your medications?” before the prescription is written. Medicaid and other 3rd-party payers have limits on what is covered. By asking this question, modifications in the prescription can be made before the patient is at the pharmacy and cannot pay for their medication. It will also help you avoid telephone calls and pages to get a patient’s prescriptions changed.

A medication regimen review may be able to identify drugs that could be switched to generic alternatives or which brand name drugs would cost the patient the least out-of-pocket expenses. The clinical staff in the Outpatient Pharmacy may be able to help. You can get assistance by contacting the Shands Medical Plaza Pharmacy by calling 265-8276, or by e-mailing Bill Harbilas, PharmD, at harbijw@shands.ufl.edu