FORMULARY UPDATE
The Pharmacy and Therapeutics Committee met June 17, 2008. 4 products were added in the Formulary, and 3 products were deleted while 16 products were designated nonformulary and not available. 9 interchanges were approved; 2 products were evaluated and designated high-priority nonformulary drugs; 1 criteria-for-use change was denied; and 1 restriction was lifted.

◆ ADDED
Bisoprolol (Zebeta® and Generics)
Calcitonin Nasal Spray (Fortical® by Upsher-Smith)
Carbidopa + Levodopa ER (Sinemet® CR and Generics)
Methocarbamol Tablets (Robaxin® Tablets and Generics)

◆ DELETED
Chlordiazepoxide Injection (Generic)*
Lidocaine + Prilocaine (EMLA®)*
Pindolol (Generic)*

◆ NONFORMULARY AND NOT AVAILABLE
Acebutolol (Sectral® and Generics)*
Betaxolol Tablets (Kerlone® by Sanofi-Aventis)*
Carteolol (Cartrol® by Abbott)*
Cyclobenzaprine ER (Amrix® by Cephalon)*
Histrelin Acetate Implant (Vantas® by Valera)
Lanreotide (Somatulin® Depot by Tercica)

POLICIES AND PROCEDURES

“Patients may take own meds" update

Physicians can continue home medications for their patients that are needed during an admission. If the drug is listed in the Formulary, the drug must be dispensed from the hospital’s supply. A recent policy change prevents patients from using their own supply of medications if the medica-

For patients to use their home medications in the hospital, a complete order must be written (eg, drug, strength, route, and frequency). Orders like, “May take home meds” are not accepted.

◆ Sliding scale insulin revisions
When the P&T Committee approved the standardized sliding scale insulin orders in January, it was specified that these orders would be appended to any order set including “sliding scale insulin.” Also, written sliding scale insulin orders are no longer honored. Because changes are expected to the standardized sliding scale insulin orders, these orders are now a separate set of orders. By not appending these orders to other orders, it facilitates changes when the time comes.

The first major revisions of the SSI orders were approved at the June P&T Committee meeting. An important component of this revision is a pre-printed Medication Administration Record (MAR) that facilitates documentation by the nursing staff.

INSIDE THIS ISSUE

◆ New anticoagulation policies
◆ Replace phenytoin with fosphenytoin?
◆ Factor VII MUE
◆ Registering NPI numbers
**NONFORMULARY AND NOT AVAILABLE (cont.)**

- Metaxolone (Skelaxin® by King)
- Methocarbamol Injection (Robaxin® Injection by Wyeth-Ayerst)
- Nebivolol (Bystolic® by Forest)§
  - *No automatic interchange*
- Orphenadrine IR and ER Tablets (Generic)§
  - *Injection remains in the Formulary*
- Penbutolol (Levatol® by Schwartz Pharma)§
- Sumatriptan + Naproxen (Treximet®)”
- Timolol tablets (Biocadren® and Generics)†

**THERAPEUTIC INTERCHANGES**

Atenolol (Generic) for Acebutolol (Sectral®)’

- Atenolol (Generic) for Betaxolol (Kerlone® Sanofi-Aventis)’
- Atenolol (Generic) for Carteolol (Carrol®)’
- Atenolol (Generic) for Penbutolol (Levatol®)§
- Atenolol (Generic) for Pindolol (Generic)’
- Calcitonin Nasal Spray (Fortical®) for Calcitonin Nasal Spray (Miacalcin®)”
  - *Same dosage*
- Cyclobenzaprine IR (Generic) for Cyclobenzaprine ER (Amrix® by Cephalon)”
  - *IR 5 mg TID for each 15 mg ER daily*
- Propranolol (Generic) for Timolol (Biocadren®)”
- Sumatriptan + Naproxen for Treximet**
  - *Interchanged to Sumatriptan 100 mg + Naproxen 500 mg*

**CRITERIA-FOR-USE CHANGES**

- Fosphenytoin Injection (Generic)”
  - *No longer restricted*
- Nesiritide (Natrecor® by Scios)”§
  - *Request to modify criteria rejected*

**EVALUATED BUT NOT ADDED**

- Protein C Concentrate (Ceprotin® by Baxter)”
  - *High-priority Nonformulary Drug*
- Rilonacept (Arcalyst® by Regeneron)™
  - *High-priority Nonformulary Drug*

Bisoprolol is a cardioselective beta-blocker that was added in the Formulary as part of a therapeutic class review of beta-blockers, which was done for the evaluation of nebivolol. Bisoprolol was added because of its relatively high nonformulary use, its availability as a generic, and because it has good outcome data in the treatment of heart failure.

Pindolol, a rarely used, nonselective beta-blocker, was deleted from the Formulary. Acebutolol (cardioselective), betaxolol tablets (cardioselective), carteolol (nonselective), nebivolol (cardioselective), pindolol (nonselective), and timolol tablets (nonselective) are all rarely used beta-blockers at Shands at UF that were designated nonformulary and not available. All of these “not available” beta-blockers will be automatically interchanged using the dosage equivalents in the following table (except nebivolol) (Table 1).

**TABLE 1**

<table>
<thead>
<tr>
<th>DRUG INTERCHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acebutolol 200 mg BID</td>
</tr>
<tr>
<td>Betaxolol 10 mg daily</td>
</tr>
<tr>
<td>Carteolol 2.5 mg daily</td>
</tr>
<tr>
<td>Penbutolol 20 mg daily</td>
</tr>
<tr>
<td>Pindolol 5 mg BID</td>
</tr>
<tr>
<td>Timolol 10 mg BID</td>
</tr>
</tbody>
</table>

**TABLE 2**

<table>
<thead>
<tr>
<th>ORDER WRITTEN</th>
<th>ALTERNATIVES SUGGESTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td></td>
</tr>
<tr>
<td>Nebivolol 5 mg daily</td>
<td>Atenolol 50 mg daily</td>
</tr>
<tr>
<td>Labetalol 200 mg BID</td>
<td></td>
</tr>
<tr>
<td>Heart Failure</td>
<td></td>
</tr>
<tr>
<td>Nebivolol 2.5 mg daily</td>
<td>Carvedilol 6.25 mg BID*</td>
</tr>
<tr>
<td>Bisoprolol 2.5 mg*</td>
<td></td>
</tr>
</tbody>
</table>

*Nebivolol is the most recently approved beta-blocker and was the reason behind the beta-blocker category review. Nebivolol has a labeled indication for the management of hypertension. It is regarded as a highly cardioselective beta-blocker and produces peripheral vasodilation mediated through nitric oxide production.

Nebivolol is available only as an oral tablet, and the recommended starting dose for hypertension is 5 mg once daily. The adverse event profile of nebivolol is similar to other beta-blockers and includes headache, bradycardia, dizziness, fatigue, and dyspnea. Nebivolol is cleared partially via CYP2D6 and should be used cautiously with agents known to inhibit or induce this particular isoenzyme (eg, fluoxetine).

In clinical trials, nebivolol demonstrated blood pressure-lowering similar to other beta-blockers. In trials with “long-term” follow-up periods (ie, 16 to 30 weeks), the incidence of adverse events secondary to nebivolol appears similar to other beta-blockers. Unfortunately, nebivolol has not been rigorously studied in patients with angina or in those who have had a recent myocardial infarction (despite being available in Europe for more than 10 years). There are no studies demonstrating a reduction of cardiovascular events or mortality when using nebivolol to treat hypertension.

Given the lack of data showing superiority over other agents, the relative equivalence in blood pressure-
Salmon calcitonin is produced chemically (Miacalcin®) or using recombinant DNA technology (Fortical®). It is more potent than human calcitonin and has a longer duration of action than the endogenous hormone. The P&T Committee approved therapeutic interchange of these products using the same dosage. The less expensive product will be available.

Calcitonin has multiple pharmacologic effects, but its primary effect is on bone, causing decreased bone resorption. Calcitonin nasal spray has a labeled indication for treatment of postmenopausal osteoporosis in women greater than 5 years postmenopause with low bone mass relative to healthy premenopausal women. Although not generally used as a first-line agent for osteoporosis, there are some clinical circumstances when nasal calcitonin is a therapeutic option when used in combination with calcium and vitamin D.

**Carbidopa-levodopa extended-release (ER) tablets** were added in the Formulary because of relatively frequent nonformulary use and the inability to interchange this product to the immediate-release (IR) combination product. Levodopa (L-dopa) is metabolized to dopamine and is used in the treatment of Parkinson’s disease. Carbidopa is added to levodopa to prevent the peripheral degradation of levodopa. Levodopa is available only in combination with carbidopa. There are no good guidelines for converting between the IR and the ER product.

**Methocarbamol injection** was designated nonformulary and not available as was cyclobenzaprine extended-release tablets, metaxalone, and orphenadrine tablets. Cyclobenzaprine ER tablets will automatically be interchanged to an equivalent dosage of IR cyclobenzaprine given 3 times a day. Metaxalone is a relatively commonly used nonformulary drug, while methocarbamol injection, cyclobenzaprine ER, and orphenadrine tablets are rarely used.

Skeletal muscle relaxants are a heterogeneous group of medications used for numerous indications including back pain (particularly lower back spasm and pain) and spasticity of multiple etiologies. About 2 million persons per year report use of a skeletal muscle relaxant (usually for back pain), and almost 300,000 of these patients are elderly with increased susceptibility to adverse effects. The clinical data supporting the use of these agents is relatively sparse considering how widely they are prescribed. Most patients using these agents continue their home medications.

The precise mechanism of action for skeletal muscle relaxants is not fully understood. Some (eg, methocarbamol) are simply CNS depressants that produce sedation with possible altered perception of pain. Dosing is variable depending on the particular medication, route of administration, and indication for use. In general, many skeletal muscle relaxants are sedating and have anticholinergic effects.

The P&T Committee concluded that the limited and mixed evidence on metaxalone does not support its use, especially when better studied alternatives are available. Metaxalone was designated nonformulary and not available. Patients can use their supply from home or use a similar agent listed in the Formulary.

Methocarbamol should not be a first-line agent since better studied alternatives are available. However, methocarbamol may provide a reasonable and inexpensive alternative to cyclobenzaprine for treatment of musculoskeletal conditions. Cyclobenzaprine is not a good option for patients with heart conditions or when drug interactions are an issue. Injectable methocarbamol is not needed, and orphenadrine injection is already available. Other agents are available for the off-label uses of methocarbamol. Alternatives to the nonformulary and not available agents are listed in the table below.

**Formulary update, from page 2**

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**DRUG** | **MECHANISM/USE** | **DOSEAGE**
--- | --- | ---
Baclofen | GABA analogue/Spasticity | 5 mg TID & titrate
Cyclobenzaprine | CNS depression/Spasm | 5 mg TID
Dantrolene | Muscle relaxant/Spasm-spasticity | 25 mg daily & titrate
Methocarbamol | CNS depression/Spasm | 1-2 G 4 times a day
Tizanidine | Central alpha agonist/Spasticity | 4 mg Q 4-6 hr & titrate
Diazepam | CNS depression/Spasm | 2-10 mg 3-times a day

**Fosphenytoin** is a water-soluble prodrug of phenytoin that allows intravenous administration without the high pH and propylene glycol required for injectable phenytoin. Fosphenytoin can also be given IM. Fosphenytoin has been restricted to loading doses without vascular access (eg, IM) and maintenance doses in patients who weigh less than 30 kg, who are less than 12 years old, who have significant cardiovascular disease, who have peripheral (continued on page 4)
was no difference between placebo and nesiritide in the primary outcome variable (ie, rate of death and dialysis). Secondary outcome variables and subset analyses showed less increase in serum creatinine in the immediate post-operative period, but this did not translate to differences in patient outcomes. Until a direct link between the effects on creatinine and hard outcomes are shown, the Committee felt the evidence was insufficient to justify changing the current nesiritide criteria for use.

Protein C concentrate is a plasma-derived injectable concentrate of protein C. It is the first drug approved for the prevention and treatment of venous thrombosis and purpura fulminans in patients with severe, congenital protein C deficiency. Congenital protein C deficiency is a rare genetic disorder (ie, only 20 known patients currently in the US and 1 to 2 cases per million births) that is normally treated with oral and injectable anticoagulants. Protein C is used during times of life-threatening clotting or, possibly, prior to surgery. It may also be used long-term for prophylaxis. Although not in a restricted distribution program per se, all patients that will use this product will be included in a registry, and product will be shipped on an emergent basis to newly diagnosed patients. The manufacturer does not recommend that this drug be stocked (ie, listed in the Formulary) but be acquired as needed. Therefore, Ceprotin® was designated a high-priority nonformulary drug with instructions on how to obtain the product, if it is ever needed.

Rilonacept is the first interleukin-1 inhibitor approved by the FDA. It has a labeled indication for the rare disease of Cryopyrin-Associated Periodic Syndromes (CAPS), which include Familial Cold Auto-inflammatory Syndrome (FACS), Muckle-Wells Syndrome (MWS), and Neonatal-onset Multisystem Inflammatory Disease (NOMID). These conditions are rare with about 300 known patients in the United States. It was approved by the FDA based on historical controls and questionnaire data in 47 patients. It is extremely expensive costing $5000 per week (ie, about $250,000 per year).

Rilonacept is available only via a Restricted Drug Distribution program and could not be considered for add-in in the Formulary. Therefore, it was designated a high-priority nonformulary drug with instructions on how to obtain the product, if it is ever needed.

POLICIES AND PROCEDURES

New anticoagulation policies

All Joint Commission-accredited hospitals must comply with the National Patient Safety Goals (NPSGs) for Anticoagulation (ie, Requirement 3E). This initiative is intended to reduce the likelihood of patient harm associated with the use of anticoagulation therapy, which has long been recognized as a high-risk therapy.

Unlike previous NPSGs, this standard must be phased in over 1 year with specific milestones set for 3, 6, and 9 months that will indicate how an institution is progressing. Full implementation of the standard is expected by January 2009.

As of July 1, 2008, an implementation work plan must be in place that identifies adequate resources, assigned accountabilities, and a time for full implementation of the standard. The required work plan has been established, which defines areas of partial and non-compliance that will be improved prior to full implementation.

The Joint Commission’s requirements for NPSG(3E) includes multiple specific expectations. Three expectations were emphasized at the June P&T Committee meeting.

- Expectation (M)C3 states: When pharmacy services are provided by the organization, warfarin is dispensed for each patient in accordance with established monitoring procedures.

- Expectation (M)A5 states: For patients being started on warfarin, a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust therapy.

- Expectation (M)C8 states: The organization has a policy that addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies.

The Shands at UF Anticoagulation Monitoring Policy was established to require a baseline PT/INR on all patients prior to ordering and dispensing warfarin. If a baseline INR is not available, a pharmacist will order an INR per P&T authorization and hold the dose of warfarin until the results are available. If the baseline INR is greater than 4, the satellite pharmacist will continue to hold the dose per P&T Committee authorization and contact the provider for further instructions. Although there was some debate as to whether the value for INR should be lower (eg, 3.5), the use of higher target INRs by some services justified calling only for INR values greater than 4. For pediatric patients, the INR measurement will be added to a morning laboratory draw.

The policy further states that an INR is the required laboratory test for routine warfarin monitoring and that there will be a minimum frequency for INR monitoring. This frequency will be 5 days. If the INR is greater than 4 during routine monitoring, the pharmacist will hold the next dose per P&T authorization and contact the prescriber for further instruction.
MEDICATION USE EVALUATION

Factor VII use evaluation

Recombinant activated factor VII (rFVIIa) was first approved by the FDA in 1999 for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. In 2006, the FDA approved labeled indications for the treatment of bleeding episodes and for the prevention of bleeding in surgical interventions or invasive procedures in patients with acquired hemophilia. Although rFVIIa is FDA-labeled for these 2 indications only, it is often used in clinical practice, with limited evidence, in conditions unrelated to hemophilia.

The use of rFVIIa at Shands at UF was evaluated in 30 patients between November 2007 and January 2008. The majority of rFVIIa administrations (86%) were administered in the operating room or in an intensive care unit (ICU). Forty percent of rFVIIa doses were written by the Thoracic Cardiovascular surgery service; however, critical care medicine, and trauma surgery were also frequent prescribers of rFVIIa. Thirty-three percent of patients received more than 1 dose, and 10% of patients received more than 2 doses. Cumulative doses ranged from 225 mcg to 288.9 mg with associated hospital costs of $243 to $312,012, respectively. The total hospital cost associated with all doses given to these 30 patients was $548,591.

None of the evaluated patients received rFVIIa for an FDA labeled indication. The most prevalent indication for rFVIIa use, accounting for 33% of cases, was to achieve hemostasis after weaning from cardiopulmonary bypass in cardiac surgery. Twenty percent of patients received rFVIIa due to excessive drainage of blood from chest tubes or abdominal drains after surgery. Many factors must be taken into account when assessing the appropriateness of rFVIIa, including amount of blood products given before use of rFVIIa, indication for use, coagulation parameters, and clinical severity and amount of blood loss. Fifteen percent of patients that received rFVIIa did not receive any fresh frozen plasma (FFP) prior to administration. Two patients did not appear to receive any blood products prior to administration; neither of these patients was a Jehovah’s Witness. The majority of patients appear to have received 4 to 7 units of FFP prior to administration of rFVIIa. Seven out of 23 (23%) administered doses of rFVIIa did not correlate with available vial sizes. Because acidemia profoundly decreases the effect of rFVIIa, the pH immediately prior to administration of the dose of rFVIIa was recorded. Ten percent of patients did not have documentation of pH. Only 1 patient had a pH less than 7.0; however, 52% of the recorded pHs were considered acidemic, defined as a pH less than 7.35. Nine patients did not have documentation of temperature prior to administration of rFVIIa. All patients that did have recorded temperatures were in the normothermic range.

Appropriate monitoring of coagulation parameters prior to and after the administration of rFVIIa is necessary to assess its appropriate use and effectiveness. It is recommended to obtain PT, aPTT, platelet counts, hemoglobin level, and fibrinogen before and after a rFVIIa infusion; however, fibrinogen was obtained prior to rFVIIa administration in only 30% of cases. Surprisingly, 2 patients did not have a coagulation panel recorded prior to administration of rFVIIa, and 1 patient did not have a recorded coagulation panel or a complete blood count.

In the past 12 months, Shands at UF has spent approximately $3.5 million on rFVIIa, which accounts for 14% of our expenditures for medications. In addition, there are some instances when our institution is not reimbursed for off-labeled use of rFVIIa. Because of this, it is important to analyze rFVIIa based on its cost-savings potential, as well as its clinical effectiveness and safety. In addition to these savings, an even greater financial benefit can be seen by recommending appropriate doses and rounding to the nearest vial size when ordering rFVIIa. In addition to avoiding wasted product from partially used vials, rounding to the nearest vial size will prevent wasting of full doses due to miscommunications among the physicians, nursing staff, and pharmacists. The pharmacy is able to dispense the full vials to the patient, and the nurse would then draw up the medication immediately prior to administration. Therefore, if the clinical situation changes prior to administration, the nurse can return the full vials back to the pharmacy without wasting any vials.

In addition to cost savings, rFVIIa should be assessed more carefully regarding efficacy and adverse effects. Since many patients that received rFVIIa were acidemic, the efficacy of rFVIIa could be significantly decreased. All patients should have a documented pH within normal range prior to receiving rFVIIa to maximize the cost-benefit ratio. Although adverse effects from rFVIIa were not monitored during this medication use evaluation, risks, such as thromboembolic events, must be acknowledged prior to prescribing rFVIIa.

Currently, there are limited data to support the use of rFVIIa for off-label indications. While rFVIIa must be considered for treatment in severe cases, it must be reserved for cases in which there are sufficient data to support its use. The P&T Committee passed a policy in April that allows for dosing rounding to the nearest vial size. Several other processes are currently in progress under the direction of an ad hoc committee, including dose standardization and development of criteria for use, to assure that rFVIIa is being used appropriately in each patient care area.

by Marlena Fox, PharmD

REFERENCES

NOTICE

Proposal to delete phenytoin injection

The P&T Committee will be considering whether to keep phenytoin injection in the Formulary at the August meeting. If adopted, phenytoin injection would be replaced by fosphenytoin injection. This would decrease inventory and would be cost neutral. Since phenytoin injection is now available as a generic, it is essentially the same cost as phenytoin injection.

By stock only fosphenytoin, there could possibly be decreased confusion between these products.

In some patients, there has been a preference for fosphenytoin. However, this notice is to determine whether there are any uses of phenytoin injection that could not be converted to fosphenytoin. Please send comments to hatton@ufl.edu by August 1, 2008.

If this proposal is adopted, oral forms of phenytoin (eg, suspension and capsules) would remain in the Formulary.
PRESCRIBING

Importance of registering NPI numbers

Health plans assign identification numbers to healthcare providers (ie, individuals, groups, or organizations that provide medical or other health services or supplies). The result is that providers who do business with multiple health plans have multiple identification numbers.

The National Provider Identifier (NPI) is a unique identification number for a healthcare provider that is used by all health plans. Health care providers and all health plans and healthcare clearinghouses use NPIs in the administrative and financial transactions specified by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Despite its establishment over 10 years ago, the NPI is just now being fully implemented. Not using this number could result in reimbursement problems for health services or supplies (eg, medications).

The NPI is a 10-position numeric identifier with a check digit in the last position to help detect keying errors. Unlike some identification numbers, the NPI contains no embedded intelligence; that is, it contains no information about the healthcare provider, such as the type of health care provider or State where the health care provider is located.

NPIs are given to healthcare providers that need them to submit claims or conduct other transactions specified by HIPAA. Physicians (attendings and housestaff) and other practitioners (nurse practitioners and physician assistants) must have an NPI, and they must be appropriately registered. If you do not have a number, you can obtain a number from the National Plan and Provider Enumeration System (https://nppes.cms.hhs.gov/NPPES/Welcome.do).

NPIs must be registered with Florida Medicaid for appropriate coverage of medications through this program. Registration links the NPI with the provider’s State license number and the Medicaid provider number. Incomplete registration can lead to reimbursement problems. This requirement is now in effect with Florida Medicaid. NPI compliance has been required for all health plans since May 23, 2008.

To register your NPI number with Florida Medicaid, you must complete a registration form and mail the original (ie, not a copy) to the State. The form is available online at http://floridamedicaid.consultec-inc.com/XJContent/NPI%20Registration%20Form?id=000004754915. The good news is that almost all attending physicians and housestaff have already registered. When completing the form, unlicensed housestaff should use their TRN number (issued by the Florida Board of Medicine) or UO number (issued by the Florida Board of Osteopathic Medicine) in the blank labeled Medicaid Provider Number on the form.

Soon Florida Medicaid will stop processing prescriptions if the provider who wrote the prescription is unregistered. When payment is denied, patients may not be able to receive their medications. Registration with the State will avoid this predicament.

Additional information on the NPI is available from the Centers for Medicare & Medicaid Services (CMS) of the Federal Department of Health and Human Services at http://www.cms.hhs.gov/NationalProvIdentStand/.