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Shands at the University of Florida

January 2010

Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met November 17, 2009. 4 products were added in the *Formulary*, and 1 was deleted. 5 products were designated nonformulary and not available with 1 interchange revised. Restrictions were added for 8 products. 4 drugs were evaluated, but could not be added in the *Formulary*.

◆ ADDED

Influenza A [H1N1] Monovalent Vaccine Injection (Various)*

**Restricted*

Omeprazole Capsules (Generic)

Omeprazole Oral Suspension (Compounded)

Treprostinil Inhalation Solution (Tyvaso® by United Therapeutics Corporation)*

Restricted

◆ DELETED

Lansoprazole Tablets (Prevacid® Solutabs®)†

†Nonformulary and not available

◆ NONFORMULARY AND NOT AVAILABLE

Cyclosporine Ophthalmic Solution (Compounded)

Glycerol Injection, Sterile (Compounded)

Papillomavirus Vaccine (Cervarix®)

Papillomavirus Vaccine (Gardasil®)

◆ INTERCHANGES

Omeprazole replaces **Lansoprazole‡**

‡Except patients on clopidogrel

(continued on next page)

PRESCRIBING

Prescription assistance programs and alternatives

Providing prescription medications to the uninsured population is a major concern. Approximately 45 million Americans have no health insurance and millions more are underinsured.[1] With the current economic situation and rising cost of prescription drugs, the uninsured and underinsured find it difficult to pay for their medications.

A recent survey showed that more Americans are failing to take their medications or taking lower doses than prescribed because of cost concerns. This can lead to serious health complications and increased hospitalizations.

A recent survey showed that more Americans are failing to take their medications or taking lower doses than prescribed because of cost concerns.[2] This can lead to serious health complications and increased hospitalizations. Escalating drug costs and reducing insurance coverage has emerged as an area of interest among the nation's lawmakers. While our government struggles to find a solution, there are options to reduce prescription drug costs for patients.

Prescription Assistance Programs (PAPs) are charitable programs offered typically by pharmaceutical drug companies.[3] Medications are provided at no cost or for a very low cost. The benefits of PAPs are numerous and include benefits to patients, healthcare providers, and drug manufacturers. These benefits include expanded access to needed medications, increased patient compliance, and decreased out-of-pocket expenses. Although specific eligibility requirements vary among manufacturers, patients must meet the following requirements: limited or no prescription drug coverage; a demonstrated financial need; legal United States residency or citizenship; and, long-term medication needs.

Together Rx Access is a type of prescription savings program that was created by 10 pharmaceutical companies. Like other PAPs, this program is restricted to brand-name prescription products and qualifications are based on financial need. The card generally provides a 25-40% discount and is accepted at most retail pharmacies.

Prescription assistance is also available to patients on a state and county level. The National Association of Counties (NACo), in partnership with Caremark, offers a prescription discount card to purchase medications not covered by insurance. Patients can enroll regardless of age, income level, or health condition. Currently, counties in Florida are members of NACo, with the exception of Baker, Duval, Orange, and Union Counties.

In Florida, there is also the *Florida Discount Drug Card*. This is a program available to Florida residents who lack drug insurance coverage or who may reach the Medicare prescription drug plan coverage gap (ie, "the doughnut hole"). There is no income limit for individuals who are age 60 years or older, but individuals younger than 60 years old must qualify financially.

Another option for patients, who reside in the catchment area for Shands at UF, is the *Shands Charity Care Progr*am. The program is available to patients who meet the income, asset, geographic, and participation guidelines. In order to meet the income qualifications, patients must have an annual family income of less than 200%

(continued on page 6)

Formulary update, from page 1

◆ CRITERIA-FOR-USE CHANGES

Amphotericin B Deoxycholate (Generic)**§**

§Must be ordered on an Amphotericin B Order Form

Amphotericin B Lipid Complex (Abelcet®)**§**

§Must be ordered on an Amphotericin B Order Form

Amphotericin B, Liposomal (AmBisome®)**§**

§Must be ordered on an Amphotericin B Order Form

Lansoprazole Capsules (Prevacid®)**‡**

‡Restricted to patients on clopidogrel

Lansoprazole Oral Suspension (Compounded)**‡**

‡Restricted to patients on clopidogrel

Ofatumumab (Arzerra®)**¶**

¶Must be ordered on a Chemotherapy Order Form

Pazopanib (Votrient®)**¶**

¶Must be ordered on a Chemotherapy Order Form

Pralatrexate (Folotyn®)**¶**

¶Must be ordered on a Chemotherapy Order Form

◆ EVALUATED BUT NOT ADDED

Eculizumab (Soliris®)******

***Patients must use their own supply*

Hydroxyprogesterone Caproate Injection (Compounded)**††**

††Obtained for a specific patient; Informed Consent required

Peramivir (No Brand Name)**‡‡**

‡‡Obtained on a patient-specific basis from the FDA

Vigabatrin (Sabril®)******

***Patient must use their own supply*

Influenza A [H1N1] monovalent vaccine was added in the *Formulary* to make it readily available for inpatients who meet the Centers for Disease Control (CDC) criteria for vaccination.[a] There are now several manufacturers (ie, CSL Limited, ID Biomedical Corporation of Quebec, Novartis, and Sanofi Pasteur) that supply the "swine flu vaccine." This inactivated injectable vaccine was developed and made just like the inactivated seasonal influenza vaccine injection, except it contains the antigens only from a unique strain of influenza (ie, A/California/7/09-like virus).

The H1N1 vaccine injection is expected to have the same safety profile and adverse effects as the seasonal vaccine (ie, mild fever, body aches, and fatigue for a few days after the vaccine, and soreness at the injection site). Since the vaccine is made in fertilized chicken eggs, people who have a severe (life-threatening) allergy to chicken eggs should not be vaccinated.

The CDC has developed criteria for whom should receive the swine flu vaccine. These criteria are based on perceived need for coverage. Because the vaccine took longer to produce than originally expected, the criteria were instituted with the highest-risk patients (eg, pregnant women and household contacts and caregivers for children less than 6 months of age, healthcare and emergency medical service personnel) targeted first. As these groups were vaccinated and more supply became available, patients at progressively lower risk (but at risk) were eligible to receive the vaccine.

Starting in December 2009, H1N1 vaccine will be available for inpatients. Based on CDC recommendations and product availability, the vaccine is indicated for all patients greater than or equal to 6 months of age without documented exclusion criteria. Ordering of the vaccine must be done through the use of an *H1N1 Order Form*. In addition, the patient/caregiver will be asked to sign a Florida Shots patient information release form in order to place vaccination information into the State of Florida's vaccine registry. If your patient denies release, it does not preclude them from getting vaccinated. Additonal questions regarding the H1N1 vaccine can be addressed through the CDC website. Since Shands at UF is following CDC recommendations, this website will provide the most up-to-date information on prevention and treatment of influenza.

The live H1N1 monovalent influenza A nasal spray (made by MedImmune) is not listed in the *Formulary*. Whether this live vaccine should be given to inpatients is an issue, since patients shed virus after they are vaccinated, which may put vulnerable patients at risk.

Omeprazole capsules and **suspension** were added in the *Formulary* and replaced **lansoprazole capsules** and **suspension** as the oral proton-pump inhibitors (PPIs) of choice. All oral PPIs will be interchanged to omeprazole, except when patients are also receiving clopidogrel [Plavix®].[b] Lansoprazole capsules and suspension remain in the *Formulary*, but are restricted to patients also receiving clopidogrel. Prevacid® Solutabs® were deleted from the *Formulary* and designated nonformulary and not available.

Takeda discontinued its nominal pricing agreement for lansoprazole capsules. The cost of Prevacid® capsules increase by 2200% in both the inpatient and outpatient settings. Prevacid® Solutabs® also have increased in price. These actions came as lansoprazole's patent expired and nonprescription lansoprazole is now available. If a change in the PPIs listed in the *Formulary* did not occur, pharmaceutical expenditures would increase by between $300,000 and a half a million dollars.

The P&T Committee previously approved the therapeutic interchange of PPIs. After collaboration between the Departments of Nursing and Pharmacy, a proposal was developed to list esomeprazole injection and omeprazole oral capsules and oral suspension. The perceived differences in drug-drug interactions with omeprazole and other PPIs was deemed acceptable. Drug interactions seen exclusively with omeprazole include CYP2C19 substrates such as diazepam, warfarin, and phenytoin; no clinically relevant drug interactions between those drugs and other PPIs (lansoprazole, pantoprazole, or rabeprazole) have been reported.

All other proposals were cost-prohibitive. Therefore, the original proposal was that oral omeprazole capsules and suspension replace lansoprazole capsules and oral suspension in the *Formulary*. Since patients are frequently converted from the capsules to the oral suspension and vice versa, it is important that the same PPI be listed as the oral capsule and suspension.

On November 17, 2009, the FDA published a MedWatch alert about the interaction between clopidogrel and omeprazole (and esomeprazole) that recommended that this combination not be used together.[c] Based on this information, patients on clopidogrel will receive lansoprazole capsules or suspension.

Esomeprazole injection remains the intravenous PPI listed in the *Formulary*. Orders for pantoprazole IV will continue to be changed to esomeprazole. Patients receiving oral clopidogrel and who are ordered an injectable PPI will be either switched to oral lansoprazole or converted to an injectable H2-blocker. Prasugrel [Effient®] is another alternative to clopidogrel in patients who must receive a platelet inhibitor and a PPI.

Tyvaso® is an inhalation solution of treprostinil, which was approved by the FDA in July with a labeled indication for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III

(continued on next page)

Formulary update, *from page 2*
symptoms to increase walk distance. It was reviewed proactively because of the potential for significant nonformulary use, difficult logistics on delivering drug, its cost, and its urgent nature (ie, if patients are already maintained on this medication). It was added in the *Formulary* for use in patients who have been started on it as an outpatient.

Treprostinil is a prostacyclin analogue like epoprostenol and iloprost. Treprostinil has been available as intravenous and subcutaneous formulations. However, intravenous treprostinil is difficult to maintain for ambulatory patients with risks of infection and complicated dosing. Subcutaneous treprostinil injections are rarely used because they are reported to be painful.

Prostacyclin is a potent vasodilator that acts on all endothelial cells. In patients with primary PAH, the enzyme responsible for the conversion of prostacyclin precursors to prostacyclin is reduced. As a prostacyclin analogue, treprostinil bypasses this step to replace the missing prostacyclin in the body. The drug causes direct vasodilatation of pulmonary and systemic arterial vascular beds, causing a decrease in pulmonary arterial pressure.

Various studies examining inhaled treprostinil's efficacy, dosing, inhalation formulation (metered dose inhaler, nebulizer), dose response, safety, and tolerability have been conducted, but few data exist with respect to head-to-head comparisons of inhaled treprostinil, iloprost, and epoprostenol. Tyvaso®'s place in therapy remains uncertain. Efficacy is primarily based on the 6-minute walk test, and there are no data describing the effect of inhaled treprostinil on disease progression and outcomes. Study effects were modest (ie, 20 to 60 meter increase in 6-minute walk test), but these numbers are affected by about half the patients who did not get any response. In some patients, treprostinil inhalation may provide important symptomatic relief. Inhaled treprostinil will be used in combination with other drugs. Patients may have improved performance during the hours immediately after the inhaled dose.

Adverse effects are modest with the inhaled dosage form of treprostinil compared with intravenous or subcutaneous administration. Cough and throat irritation, headache, gastrointestinal effects, muscle, jaw or bone pain, flushing, and syncope have been reported.

Each Tyvaso® starter kits cost $15,056. The cost of the monthly refill kits is $13,420. Thus, this adjuvant medication costs more than $160,000 per year! There is a 4-day hospital pack available only for hospital use. The 4-vial kit is the only product that Shands at UF will stock. Most patients will be started on Tyvaso® as outpatients or they will bring product into the hospital for use.

Tyvaso® was added in the *Formulary* for a 1-year evaluation after which inhaled treprostinil and/or iloprost will be re-evaluated. Because Tyvaso® will be administered by a nebulizer provided by the patient, hospital policy CP5.502 *Patient's Own Medical Equipment* will be updated to permit patients to use their own device to administer treprostinil inhalation solution while they are in the hospital.

Compounded cyclosporine ophthalmic solution is a higher concentration of the commercially available product (ie, Restasis®). At the August P&T Committee meeting, compounded cyclosporine was designated a high-priority nonformulary drug. This was contingent on the development of an informed consent required for all sterile products compounded from nonsterile ingredients. At the October P&T Committee, the P&T Committee passed a policy stating that any sterile product from nonsterile ingredients is designated nonformulary and not available until an informed consent has been approved by the Legal Department.

Since there is no informed consent for compounded cyclosporine solution, it was designated nonformulary and not available. Should an informed consent be developed in the future, compounded cyclosporine ophthalmic could be reconsidered for a high-priority nonformulary designation.

Sterile glycerol is a compounded injectable product used to chemically ablate nerves. In March 2005, the P&T Committee reviewed sterile glycerol. Sterile anhydrous glycerin (glycerol) was evaluated for use in chemical rhizotomies, which are used for nerve ablations in the treatment of trigeminal neuralgia. The cause of trigeminal neuralgia is believed to be arterial compression of the trigeminal nerve. When medical therapy fails and microvascular surgical decompression is not a viable option, percutaneous nerve ablation procedures are an alternative. Sterile anhydrous glycerin is injected around the trigeminal nerve root and ganglion damaging the nerve, which blocks pain signals. Glycerol injection is an alternative to radio-frequency ablation of the nerve.

Since there is no commercially available source of sterile anhydrous glycerol, it could not be added in the *Formulary.* It could be obtained on a patient-specific basis from an outside compounding pharmacy that compounds sterile products from nonsterile ingredients. An informed consent was never developed for this product, and it has never been used at Shands at UF. Consistent with the policy on sterile products from nonsterile ingredients, sterile glycerol was designated nonformulary and not available.

There are now 2 **papillomavirus vaccines** on the market (ie, **Cervarix®** and **Gardasil®**). These vaccines have labeled indications for the prevention of human papillomavirus infections, which are associated with cervical cancer. Thus, the goal is cancer prevention. This requires a series of 3 injections, and they are not intended for inpatient administration. Inpatient reimbursements are not intended to cover the costs of papillomavirus vaccines. This setting is also not ideal for assuring that the patient gets the 3-injection series at the appropriate times. Thus, papillomavirus vaccines were designated nonformulary and not available.

Amphotericin B is an injectable antifungal agent that has been on the market since the 1950s. Amphotericin B binds to sterols in cellular membranes of fungi. Unfortunately, it also binds to human cell membranes, which is the reason for some of its toxicities (eg, nephrotoxicity).

Amphotericin B deoxycholate or conventional amphotericin B is a yellow, water-soluble solution that is associated with infusion-related reactions (eg, rigors) and systemic adverse effects (eg, nephrotoxicity).

Amphotericin B lipid complex and **liposomal amphotericin** were developed in the 1990s in an attempt to make amphotericin tolerable. Although these agents are generally more tolerable than conventional amphotericin, they still exhibit the same systemic toxicities, just at a lower incidence. They are also very expensive.

Abelcet® has been listed in the *Formulary* since October 1999 and is the preferred agent for most patients. **AmBisome®** has been listed in the *Formulary* since August 2001 and is used in patients in whom Abelcet® is not tolerated. Abelcet® is preferred because it is less expensive than AmBisome®. Both agents must be approved by Infectious Diseases (or Dr. Wingard in the Bone Marrow Transplant Unit).

All amphotericin products are now limited to use with an *Amphotericin B Order Form.* This restriction was done to prevent medication errors and promote the safe use of the various forms of amphotericin. For example, conventional amphotericin B can no longer be used by the intravenous route of administration. Lipid amphotericin doses are much higher than conventional amphotericin.

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Formulary update, *from page 3*

Confusing the dosages for these products could cause patient harm. Conventional amphotericin can be used for bladder irrigation and other routes (eg, inhaled or intranasal irrigation). The *Amphotericin B Order Form* provides appropriate dosage recommendations and recommended adjuvant medications with their dosages.

Ofatumumab is a CD20-directed cytolytic monoclonal antibody with a labeled indication for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine [Fludara®] and alemtuzumab [Campath®]. Ofatumumab was approved under the FDA's accelerated-approval process, which allows for earlier approval of drugs that meet unmet medical needs. Accelerated-approval requires further study of the drug, and questions about its ultimate place in therapy remain.

The most serious risk associated with the use of ofatumumab is immunosuppression and resulting infection, including the risk of progressive multifocal leukoencephalopathy (PML).

Ofatumumab was added in Chemotherapy Policy, which requires that it be ordered nonformulary on a *Chemotherapy Order Form*.

Pazopanib is a kinase inhibitor with a labeled indication for the treatment of patients with advanced renal cell carcinoma. Pazopanib is an oral angiogenesis inhibitor. It is an alternative to sorafenib [Nexavar®], sunitinib [Sutent®], temsirolimus [Torisel®], everolimus [Afinitor®], and bevacizumab [Avastin®] for the treatment of renal cell carcinoma. It is most similar to sorafenib and sunitinib, which are also oral kinase inhibitors. Like pazopanib, sorafenib and sunitinib are nonformulary agents that must be ordered by a *Chemotherapy Order Form*.

Pralatrexate is a folate analogue metabolic inhibitor with a labeled indication for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). It is the first drug with this as a labeled indication. PTCL is an aggressive type of non-Hodgkins lymphoma.

Pralatrexate was approved under FDA's accelerated drug-approval process, which allows earlier approval of drugs that meet unmet medical needs. Pralatrexate was approved based on overall response rate. Clinical benefit, such as improvements in progression-free survival or overall survival, have not been demonstrated with pralatrexate.

Pralatrexate was added in *Chemotherapy Policy*, which requires that it be ordered nonformulary on a *Chemotherapy Order Form*.

Eculizumab is a complement inhibitor with a labeled indication for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. This product is available only via a restricted distribution system (OneSource™). The major risk of this product is immunosuppression and risk of meningococcal infection.

Shands at UF cannot purchase eculizumab; therefore, it cannot be listed in the *Formulary*. The OneSource™ program requires patients to use their own supply. Therefore, eculizumab was designated a high-priority nonformulary drug. Pharmacy computer entries will be created that describe the process that would allow patients to use their own supply, if it is needed during a hospitalization.

Hydroxyprogesterone caproate is an intramuscular dosage form of progesterone that has been shown to decrease the incidence of preterm births in a large randomized, placebo-controlled trial. Unfortunately, there

(continued on next page)

Formulary update, *from page 4*

is no commercially available hydroxyprogesterone caproate injection. It is only available from compounding pharmacies, which make it from nonsterile ingredients.

In August 2004, the OB-GYN Department agreed to use compounded progesterone suppositories (made at Shands), instead of compounded hydroxyprogesterone caproate injection for most patients. This avoids the potential for more serious complications, need for informed consent, and logistical issues.

However, there have been cases when the OB-GYN Department felt that progesterone suppositories were inadequate. The OB-GYN Department has developed an informed consent for the use of sterile hydroxyprogesterone caproate injection compounded from nonsterile ingredients. Therefore, compounded hydroxyprogesterone caproate injection was designated a high-priority nonformulary drug. Computer entries will be created to explain how to obtain this product with an individual patient prescription from an outside compounding pharmacy.

Peramivir is an injectable neuraminidase inhibitor that the FDA approved recently for use under an Emergency Use Authorization (EUA). This product will replace the use of oseltamivir when patients cannot take an oral medication. Peramivir is no more effective than oseltamivir, and only offers the advantage of route of administration.

Although available, there is considerable paperwork necessary to obtain this product.[d] The paperwork must be completed by the prescriber before obtaining peramivir and while monitoring the use of the product. It will be provided a no cost, but the logistics of acquiring product will be an issue. Peramivir will be handled by the Investigational Drug Service (IDS).

Pharmacy computer entries will be created to explain how it may be obtained and to facilitate availability for those patients who meet the FDA's restrictions. Prescribers will have to be willing to collect and submit data to the FDA in accordance with the Emergency Use Authorization for this investigational drug.

Vigabatrin is an antiepileptic drug approved by the FDA on August 21, 2009. The oral tablets have a labeled indication for the adjunct treatment of refractory complex partial seizures in adults. The oral suspension has a labeled indication for the treatment of infantile spasms.

Vigabatrin is the first drug to be FDA-approved for the treatment of infantile spasms, and it is the first real pharmacologic advancement in the treatment of infantile spasms since the use of ACTH in the late 1950s.

Due to the risk of permanent vision loss, vigabatrin is available only through a restricted-distribution program called SHARE. Patients must use their own supply; Shands cannot purchase and stock vigabatrin.

Therefore, vigabatrin was designated a high-priority nonformulary drug. Pharmacy computer entries will be created that describe the process that would allow patients to use their own supply, if it is needed during a hospitalization.

LINKS

[a] http://www.cdc.gov/h1n1flu/vaccination/acip.htm

[b] https://my.portal.shands.ufl.edu/portal/page/portal/DEPT_CONTENT/Pharmacy/UF/Formulary/TherapeuticInterchange/TI_PDFs/ppi_conversion.pdf

[c] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm190787.htm

[d] http://emergency.cdc.gov/h1n1antivirals/

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Prescribing, from page 1
of the Federal Poverty Level. Patients who are enrolled in the program can access medications for $5 per prescription. Unlike most pharmaceutical company-sponsored programs, patients can remain on the program indefinitely, but they must re-qualify every 6 months.

The enrollment requirements for PAPs are constantly modified. There are a number of centralized resources available to help providers and patients more easily navigate PAPs and better understand enrollment requirements. For more information about PAPs, visit the following websites: *Partnership for Prescription Assistance* (www.pparx.org), *Needy Meds* (www.needymeds.org), and *RxAssist* (www.rxassist.org).

Despite the benefits of PAPs, many disadvantages exist and prescribers complain about the difficulty in using this form of assistance. The application process is often cumbersome, redundant, and time-consuming. Furthermore, there is limited eligibility due to income, long wait times, and the prescription is generally shipped to the provider's office. These programs do not work well for short-term medications, those medications needed immediately, for patients who need temporary assistance due to a recent job loss, or when assistance is needed for more than 1 medication. Because of these many problems, participation in these programs is low and PAPs are a poor option for many patients.

The oldest and possibly most effective strategy for reducing drug cost is prescribing medications that can be substituted with less-expensive generic alternatives. Generic medications are often more than 50% less than the cost of a brand-name counterpart. Major retailers and supermarkets, including Walmart and Target, offer hundreds of generic prescriptions at a significantly discounted price. A 30-day supply can be purchased for around $4, while a 90-day supply will cost just $10. Walgreens' Pharmacy has established a program called the *Prescription Savings Club*. This program offers over 400 generic drugs priced at $12 for a 90-day supply.

Patients can also save money by purchasing over-the-counter (OTC) drugs. Many medications, such as some proton pump inhibitors, that were once available by prescription only are now available without a prescription. These medications can be a convenient and cost-effective alternative for some patients.

Tablet splitting is another strategy that has been used to help patients save without sacrificing drug effectiveness or safety. Some tablets are available at twice the dose and at the same price as lower doses. For example, if a patient needs 10 mg a day of a drug, a prescription can be written for 20 mg to split the pill in half each day. The patient purchases 15 pills a month instead of 30. Note that some tablets should not be split, including time-release tablets.

For Americans struggling to afford prescription drugs, there are many useful strategies available to get drugs at lower prices. Prescription assistance programs may be beneficial for the few who qualify; however, for most Americans, these programs may not be the best option. Therefore, it is critical for healthcare providers to research and understand different cost-saving strategies to help their patients access medications.

by David Guervil, PharmD

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