FORMULARY UPDATE
The Pharmacy and Therapeutics Committee met March 15, 2011. 5 products were added in the Formulary, and 2 were deleted. 2 products were designated nonformulary and not available; 5 criteria for use were approved, including 3 restrictions and 1 dose-rounding protocol. 2 drugs were designated high-priority nonformulary drugs to facilitate acquisition, if needed.

◆ ADDED
Benzylpenicilloy! Polylysine Skin Test (Pre-Pen® by Alk-Abello)*
Ferrous Sulfate Drops (Generic by Bilard)†
†15 mg elemental iron per mL
Histamine Skin Test (Histatrol® AQ by Alk-Abello)*
Histamine in Glycerin Skin Test (Histatrol® by Alk-Abello)*
*Restricted to Infectious Diseases Approval
Ribavirin Tablet (Generic)

◆ DELETED
Ferrous Sulfate Drops (eg, Enfamil® Fer-In-Sol® Drops)†
†15 mg elemental iron per 0.6 mL; nonformulary and not available
Piperacillin (Generic)§
§Nonformulary and not available

◆ HIGH-PRIORITY NONFORMULARY DRUGS
Factor XIII (13) (Corifact®)
Hydroxyprogesterone Caproate (Makena®)

◆ CRITERIA-FOR-USE CHANGES
Darbepoetin (Aranesp®)*
*Restricted to ESA Order Form.

(continued on next page)

INSIDE THIS ISSUE
◆ Sound alikes

NEWS
What's so special about specialty pharmacies?

Over the past 30 years, specialty pharmacies have emerged from a novel concept to become a fledgling industry. With the biotechnology field growing each day, they have the potential to play a large role in providing patients with access to unconventional medications. Specialty pharmacies filled a niche in the market by enabling patients to obtain medications that historically had barriers to access.

Specialty pharmacies have the potential to play a large role in providing patients with access to unconventional medications. They filled a niche in the market by enabling patients to obtain medications that historically had barriers to access.

Specialty pharmaceuticals are usually expensive injectable medications that may have special preparation or storage requirements and are traditionally used by a small patient population to treat chronic or life-threatening diseases. Examples include tumor necrosis factor-alpha inhibitors, recombinant blood factor products, and growth hormones. Specialty pharmaceuticals typically have intricate distribution and reimbursement systems. The combination of low patient volume, difficult storage, handling, administration, and/or preparation, and complicated reimbursement schemes make specialty agents difficult for conventional community pharmacies to manage.

Specialty pharmacies have the advantage of stocking a low volume of medications, and many are able to work directly with the drug manufac-

(continued on next page)
makes a negative penicillin skin test
penicillin. A negative histamine test
can mount reactions to skin tests, like
controls to document that patients
The penicillin allergy skin test was
with a different antibiotic requires
receive desensitization, or be treated
practitioners. If the condition war
rate or no longer relevant.
of an adverse event when patients
prescribed, there is an increased risk
otic therapy, the patient can receive
immunocompromised patients.
ribavirin are used off-label to treat RSV
and have not been previously treated
virus infections [in combination
with peginterferon alfa-2a] in patients
who have compensated liver disease
with peginterferon alfa-2a] in patients
Hepatitis C virus infections [in combination
Ribavirin tablets have a labeled indica
tion of 15 mg/3 mL elemental iron
for RSV infections in adults, particularly
immunocompromised patients.
Due to its expense (ie, nearly $4000
day and $20,000 for a 5-day course
therapy) and lack of controlled clini
cal trials supporting its efficacy, a sub
of the Anti-Infective Subcommittee
met to develop a protocol on how
best to use inhaled ribavirin therapy at
Shands at UF. Following that review,
a protocol for inhaled/oral ribavirin in
managing both upper and lower respira
tory tract infections associated with
RSV was developed to generate consis
tency in application of this agent. The
protocol categorizes patients by degree
of immunosuppression and severity of
RSV infection and has received the sup
of UF experts in RSV infections.
Inhaled ribavirin is now restricted to
approval by Infectious Diseases. Oral
and inhaled ribavirin were
reviewed because of increased use of
inhaled ribavirin. Ribavirin is an anti
viral. Increased use has been associ
ated with better diagnostic tests that
identify when patients are infected with
respiratory syncytial virus (RSV).
Inhaled ribavirin has a labeled indica
tion for the treatment of infants and
young children with severe lower respira
tory tract infections due to RSV. Ribavirin
tablets have a labeled indication for
the treatment of chronic hepato
titis C virus infections [in combination
with peginterferon alfa-2a] in patients
who have compensated liver disease
and have not been previously treated
with interferon alfa. Inhaled and oral
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Figure 1. Pre-Pen® skin test.
Figure 2. Pre-Pen® skin test.
Figure 3. Pre-Pen® skin test.
Figure 4. Pre-Pen® skin test.
Figure 5. Pre-Pen® skin test.
Figure 6. Pre-Pen® skin test.
Figure 7. Pre-Pen® skin test.
Figure 8. Pre-Pen® skin test.
Figure 9. Pre-Pen® skin test.
Formulary update, from page 2

Therefore, progestrone suppositories will be used for most patients treated at Shands at UF. Compounding pharmacies charged $10 to $20 per injection for hydroxyprogesterone caproate. The cost of Makena® is reported to be as much as $1500 per dose, which would be as much as $30,000 over the course of a pregnancy.

Makena® was designated a high-priority nonformulary drug that will be used at Shands at UF only when a patient could not use progestrone suppositories and when the patient is able to continue therapy as an outpatient.

All erythrocyte-stimulating agents, also known as ESAs (Epogen®, Procrit®, and Aranesp®), require Risk Evaluation and Mitigation Strategies (REMS) for use in patients with cancer. The APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe use of ESAs) Oncology program requires hospitals, healthcare professionals, and patients to undergo this process. The goal of this program is to support informed decisions between patients and healthcare professionals who are considering treatment with an ESA by educating them on the risks of ESAs. ESA have been associated with tumor growth in cancer patients and decreased survival. The APPRISE Oncology program is intended to help mitigate the risks of decreased survival and/or poorer tumor outcomes in patients with cancer. ESAs should only be used in cancer patients in whom their chemotherapy is not curative.

Healthcare professionals who prescribe ESAs in cancer have to complete a training module that covers the use of ESAs. Completion of the training module is required for enrollment in APPRISE. Healthcare providers and patients have to sign an acknowledgement that they understand the risks of ESAs for this indication. If not enrolled in APPRISE, healthcare providers should not prescribe ESAs in cancer.

Hospitals must be enrolled in the APPRISE program in order to dispense ESAs to patients with cancer. Hospitals must have a system in place that ensures that all healthcare providers who prescribe ESAs in the hospital are enrolled and comply with the APPRISE Oncology program. This implies that these agents will have to be restricted in a way that would do this verification. Manufacturers supposedly will stop providing ESAs for ALL indications if this program is not followed. Full compliance with this program is now necessary. Therefore, the use of ESAs is now restricted to use by an ESA Order Form, which forces compliance with the REMS for all oncology uses.

Dexmedetomidine is a relatively selective alpha1-adrenoceptor agonist with centrally mediated sympatholytic, sedative, and analgesic effects. It has a labeled indication for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. The labeling states that dexmedetomidine should be administered by continuous infusion not to exceed 24 hours. Dexmedetomidine has been on the US market since 1999.

When the Shands criteria for use for dexmedetomidine were expanded in September 2008 to include use in patients who are difficult to wean from the ventilator, an order form was created to restrict use to the P&T-approved protocol. This form excluded cardiothoracic attendings. The Dexmedetomidine Order Form was modified to include CT Surgery attendings as prescribers using the previously approved criteria for use.

News, from page 1

drug spend increased by 6.4%. In contrast, during this same period, specialty drug spend increased by 19.5%, and this rate is not expected to slow down any time soon. Moreover, between 30% and 40% of agents currently in the development pipeline are specialty agents. It is estimated that by 2013, generic drugs will account for 50% of the prescription market, but specialty agents will account for 50% of overall drug spend. It is projected that seven of the top ten drugs will be specialty agents by 2014.

With the continued growth of the specialty market, healthcare providers in all types of settings must be prepared to handle the demand of these drugs and help their patients navigate the path for obtaining specialty pharmaceuticals.

Patients under Shands’ employee insurance program are required to obtain specialty pharmaceuticals from any of the Shands-affiliated outpatient pharmacies. The Shands Medical Plaza Pharmacy is charged with handling the most unique agents, and has compounding, clinical services, and the infusion center onsite to aid patients in obtaining and administering many of these specialty agents. These outpatient pharmacies also utilize a mail-order system to provide patients with additional routes of obtaining these medications. Of note, the Shands outpatient pharmacies also offer the same services to patients utilizing other insurance providers, as well as indigent patients.

For patients who wish to have their prescriptions filled elsewhere, most insurance companies contract with one of the large PBMs, many of which have their own branches of specialty pharmacies that patients can use. In some cases, insurance companies may also have contracts with smaller, local specialty pharmacies to allow their patients to use this option instead of mail order from the PBM.

Continuation of care in the hospital setting also presents a problem for these unique, high-cost items. At Shands at UF, some specialty agents are in the Formulary, which makes for the smoothest transition and continuity in care. However, other agents are deemed nonformulary. If this is the case, the pharmacy department may be able to order the item for use in the hospital. Still other agents may be nonformulary and not available, in which case the patient may be able to use their own supply as long as it meets the requirements for patient’s own use. As a whole, patients are not permitted to use their own injectable medications, with a few exceptions including epoprostenu, treprostinil, and insulin when administered via the patient’s own infusion device. Due to the varying degrees of formulary status possible, it is important that providers work together to ensure that patients are able to continue receiving medications that may be critical for optimal outcomes.

From a provider’s viewpoint, it is essential that we educate our patients regarding specialty pharmaceuticals and why they may not be able to have their prescription filled at their neighborhood pharmacy. Additionally, it is important that patients understand why these agents may be different than their typical medications, especially if special monitoring or administration is required. By addressing these issues up front, it is possible to avoid frustrations that could arise from both the patient’s and provider’s perspectives.

by Kathryn Hernando, PharmD

REFERENCES

MEDICATION SAFETY

SALAS: Arista® versus Arixtra®

Sound-alike-look-alike drugs (SALADS) have been a major medication safety initiative...but what about sound-alike-look-alike “stuff” (SALAS)?

Like most places, Shands at UF has a policy on SALAD drugs. Safety measures are taken to use special lettering on labels, separate products on storage shelves, and other safety measures. The ISMP has a published list of Confused Drug Names.1 The U.S. Department of Veterans Affairs also has done a lot in the area of look-alike/sound-alike drugs.2,3

Little emphasis has been given to when non-drug products have similar names to drug names. Recently, there was confusion between Arista® and Arixtra®. Although no harm occurred, this confusion is being discussed to increase awareness.

Arista® AH is a synthetic hemostatic device [not a drug] that includes an absorbable hemostatic powder.4 It is intended to help stop bleeding. Arixtra® is the brand name for the anticoagulant fondaparinux.5 Its therapeutic effect can cause bleeding. It may be difficult to confuse these products, since they are used differently; however, it is possible that these products could both be used in an Operating Room (OR) environment. Awareness of these brand names, which could be confused, could potentially prevent errors.

REFERENCES