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Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met September 16, 2014. 1 drug was deleted from the *Formulary*, 2 drugs were designated non-formulary and not available, and 1 therapeutic interchange was approved.

◆ **DELETED**

Warfarin Injection (generic)

◆ **NON-FORMULARY AND NOT AVAILABLE**

Empagliflozin (Jardiance®)

Sunitinib (Sutent®)

◆ **THERAPEUTIC INTERCHANGE**

Phenobarbital (generic)

◆ **ADDED**

None

◆ **CRITERIA FOR USE CHANGES**

None

◆ **NON-FORMULARY HIGH PRIORITY**

None

Empagliflozin (Jardiance®) is the 3rd approved agent in the sodium-glucose co-transporter 2 inhibitor class. This agent is approved as an adjunct to diet and exercise to improve glycemic control. In August 2013 and March 2014 canagliflozin and dapagliflozin respectively, were designated non-formulary and not available with patients able to take their own medication. The Department of Endocrinology was contacted to determine if this agent could be treated in the

(continued on next page)

MEDICATION SAFETY CORNER

High Alert Medications

The Institute of Safe Medication Practices (ISMP) publishes a list of medications that bear a heightened risk of causing patient harm when used incorrectly.[1] These medications are deemed "high-alert." This list is updated periodically based upon reported errors in the literature and input from practitioners and safety experts. These medications range from those used in daily practice to those that are very uncommonly used, however the consequences of error may be devastating. Examples of high-alert medications include: adrenergic agonists, antithrombotic agents, insulin U-500 and promethazine.

"Our goal is to provide optimal and safe care to all of our patients. We are the first line of defense in preventing medication errors."

A high-alert medication policy (Pharmacy Policy 09-07) has been created at UF Health to identify medications commonly associated with harm as well as describe risk reduction strategies used within the hospital in an attempt to minimize error. Risk-reduction strategies are employed at every level of the medication use process including: prescribing, storage and dispensing of medications, medication administration and monitoring. Examples of specific strategies employed are: dual verification and use of smart infusion pump technology during medication administration, use of standardized concentrations for intravenous medications, use of commercially available medications when available, and the use of ordering instructions in EPIC to guide practice.

The high-alert medication policy may be located on the UF Health portal under 'Core Policies.' Simply login to the portal, click on Core Policies, SUF, and then Pharmacy Services. Or, you may utilize the 'Search' function with the search terms "high alert."

Although a policy exists to address specific medications and medication safety concerns, it is our responsibility to be consistently vigilant when ordering, verifying, dispensing and/or administering medications. In the event an error is made, or a 'near miss' occurs, we encourage reporting via a Patient Safety Report. These reports assist us in identifying trends as well as system vulnerabilities. Once identified, these issues may be addressed to improve patient safety in our facility. Our goal is to provide optimal and safe care to all of our patients. We are the first line of defense in preventing medication errors.

By: Carrie Lagasse, PharmD

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INSIDE THIS ISSUE

Formulary update, *from page 1*

same manner, to which they agreed.

The P&T Committee approved the designation of this agent as non-formulary and not available with patients able to take their own medication.

Phenobarbital is available in multiple strengths with very small variations in dose. Recently, a patient safety report prompted a review of available phenobarbital products. A therapeutic interchange was proposed to align patient dose with the available product at UF Health. All patients should be converted to the 32.4 mg or 64.8 mg tablets as described in the below interchange. The Pharmacy and Therapeutics Committee agreed with this recommendation.

Phenobarbital Formulary Product	Non-Formulary Phenobarbital Dosage Forms
Phenobarbital 32.4 mg	Phenobarbital 30 mg
Phenobarbital 64.8 mg	Phenobarbital 60 mg

Sunitinib (Sutent®) is an oral tyrosine kinase inhibitor indicated for gastrointestinal stromal tumors, neuroendocrine tumors and renal cell carcinoma. Sunitinib is manufactured by Pfizer who recently announced that all oral chemotherapy agents were being moved to Specialty Pharmacies. In the inpatient setting, there has been zero utilization to date. As a result, the Committee voted to designate sunitinib as non-formulary and not available.

Warfarin injection is no longer commercially available. It was proposed to delete warfarin injection from the *Formulary*. The P&T Committee approved this recommendation.

C1 Esterase Inhibitor (Berinert®) is a human plasma-derived C1 esterase inhibitor (C1-INH) indicated for the treatment of acute attacks of hereditary angioedema (HAE). It was last reviewed for the *Formulary* in June 2013 and was added with a restricted treatment algorithm for use in HAE. It was requested by the Department of Anesthesia and Department of Maternal Fetal Medicine for use in Amniotic Fluid Embolism.

Amniotic Fluid Embolism (AFE) is a rare, but devastating complication which is the leading cause of mortality in pregnant women. Although not completely understood, there appears to be a complex activation of proinflammatory cytokines secondary to the introduction of fetal antigens in maternal circulation during delivery. The inflammatory process results in myocardial depression, respiratory distress, and coagulopathy. Diagnosis is often difficult and is based upon clinical observations.

Descriptive reports have postulated that exogenous C1-INH may be useful in amniotic fluid embolism via its ability to inhibit activation of the complement system. In a retrospective analysis of a Japanese AFE registry, it was noted that women with AFE had significantly lower C1-INH serum activity levels than controls. In addition, C1-INH levels were statistically significantly lower in women who died from AFE vs. women who survived AFE. There was concern raised in a letter to the editor that samples in this study were not maintained appropriately and could potentially result in some anomalies reported. However, based on this descriptive evidence, it was proposed that administration of C1-INH may play a role in the treatment of AFE. To date, no human studies have been conducted to assess this. C1-INH has been used in animal models to attenuate inflammation and pulmonary symptoms in other disorders characterized by increased complement activation, including Transfusion Related Acute Lung Injury (TRALI).

Adverse events studied in HAE patients treated with C1-INH were uncommon. Serious adverse events included thromboembolisms and a risk for infectious agent transmission. C1-INH is labeled Pregnancy Category C; however, small observational studies failed to discover any adverse events when used to treat acute HAE attacks in women before, during, and after labor.

Due to a lack of human data, it was recommended that the criteria for use of C1 Esterase inhibitor not be extended to include AFE. Investigational use of this agent may be warranted with IRB approval and manufacturer sponsoring. The Committee agreed with this recommendation and supports pursuit of investigational use of this emerging therapy.

Carboplatin therapy is often dosed via Area under the Curve (AUC). When utilizing this dosing scheme, it is not uncommon for doses to change with very small changes in serum creatinine. Current policy dictates that a 5% margin of dose change is acceptable without having to contact the physician to rewrite the order for chemotherapy. It was proposed to allow for expansion of this to 10% variation in dose in order to limit the need to contact prescribers for carboplatin AUC dosing only. The Committee approved this recommendation.

Crotalidae Polyvalent Immune Fab (Crofab®) was approved by the FDA in October 2000 for the management of patients with crotalid envenomation to prevent clinical deterioration and the occurrence of systemic coagulation abnormalities. Members of the *Crotalidae* family indigenous to Florida include: Diamondback, Canebrake, and Pigmy Rattlesnakes, Cottonmouth and Copperhead Snakes. These pit vipers inject venom which is hemotoxic and destroys red blood cells and the blood vessel walls in victims.

In the past year, 27 patients have received Crofab® at UF Health. In a number of cases, dosing outside current package labeling has occurred. Order sets for pediatric and adult snake bites were presented for approval by the Committee. These order sets were developed by clinical pharmacists in conjunction with medical faculty from hematology, critical care medicine and emergency medicine. These order sets provide guidance to practicing physicians and will create consistency in medication and laboratory monitoring. The Snake Bite Severity Score is incorporated to guide therapy.

The Pharmacy and Therapeutics Committee approved the Order Set. Evaluation of the protocol will occur in 6 months to determine if alterations are necessary.

Pharmacist discontinuation of medications for deceased patients was discussed. Currently, there is a delay in EPIC from the time of patient death to the time when medi-

(continued on next page)

Formulary update, *from page 2*

cations are auto-discontinued by EPIC. Occasionally, this delay has resulted in the compounding and distribution of costly medications. These medications are then wasted at the expense of the institution. A protocol was passed whereby upon documentation and confirmation of patient death, the pharmacist may discontinue medication therapy in the patient record.

Hereditary angioedema (HAE) is a rare autosomal dominant disorder caused by C1 esterase inhibitor deficiency and subsequent dysregulation of complement, contact, fibrinolytic and coagulation systems. This can lead to increased levels of bradykinin which causes vasodilation and increased vascular permeability. HAE is characterized by recurrent, acute episodes of submucosal edema which may affect the skin, gastroinstestinal tract, face, upper airway, or genitals. Attacks are typically self-limiting; however those affecting the larynx may be life-threatening.

Currently, C1 Esterase Inhibitor (Berinert®) is available in the Formulary for the treatment of Type I or Type II HAE. Other agents approved for use in HAE include ecallantide (Kalbitor®), C1 esterase inhibitor (Cinryze®), and icatibant (Firazyr®). Due to the rare and self-limiting nature of HAE, all of these agents are currently designated non-formulary and not available. An amendment was made to the Patient's Own Medication policy to allow for use of a patient's own supply of these nonformulary items. Patients may now provide their own injectable medication for HAE unless the exact branded product is currently available in the *Formulary*.

MEDICATION TECHNOLOGY

Bedside Barcode Medication Administration – Scanning the Horizon

In 1999, the Institute of Medicine reported that medical errors account for as many as 98,000 deaths annually.[1] Of these, up to 7,000 deaths may occur as a result of medication errors. A follow-up report in 2001 suggested that technology may play a role in the reduction of medication errors.[2] In 2002, the Institute of Safe Medication Practices (ISMP) touted barcode technology as one of the most familiar and promising mechanisms for improved patient safety.[3] This white paper urged the FDA to require manufacturers to place barcodes on the backs of all medications, including unit doses, in preparation for Bedside Barcode Medication Administration.

"... medical errors account for as many as 98,000 deaths annually. Of these, up to 7,000 deaths may occur as a result of medication errors."

Bedside Barcode Medication Administration (BCMA) serves to utilize technology to assist in the provision of safe medication administration via verification of the "five rights": Right Patient, Right Medication, Right Dose, Right Route, and Right Time.[3] This is accomplished via a the following workflow: RN scans patient arm band (right patient), RN scans the medication to be administered to determine if an active order exists (right medication, right dose and right route), and finally, the scan checks the timing of administration against the ordered schedule (right time). If at any point, the information scanned does not match the medical record, the RN would be unable to complete the medication administration process with appropriate documentation. The full intent of BCMA aims to improve accuracy and the ability to maintain a retrievable record of medication administration. BCMA is part of Stage 2 of the Centers for Medicare and Medicaid Services (CMS) Meaningful Use Core Measures.[4] In order to be compliant with the intent of the Measure, hospitals must demonstrate a minimum of 10% of all medication orders created in the inpatient or emergency department setting be tracked via eMAR and BCMA technology by the end of September 2014.

UF Health Shands Hospital implemented BCMA in the Emergency Department in early 2014. Expansion of BCMA to inpatient care units of the inpatient North and South towers occurred in late September 2014. Additional units will go-live on BCMA in a stepwise fashion. We are truly excited for this technological advance and know our patients will be benefit from this additional patient safety measure. If you have any questions about BCMA, please reach out to a member of the pharmacy staff who will be happy to assist you.

By: Carrie Lagasse, PharmD

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