

Drugs & Therapy

B • U • L • L • E • T • I • N

FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met January 20, 2009. 2 drugs were added in the *Formulary*, and no drugs were deleted from the *Formulary*. 3 drugs were designated nonformulary and not available, 2 drugs were evaluated, but not added, and 1 interchange was approved. 1 drug was restricted.

◆ ADDED

Methylnaltrexone
(Relistor® by Wyeth)*

*Restricted to labeled indication by *Methylnaltrexone Order Form*.

Olmесartan
(Benicar® by Daiichi Sankyo)

◆ DELETED

None

◆ NONFORMULARY AND NOT AVAILABLE

Alvimopan
(Entereg® by GlaxoSmithKline)

Cefpodoxime (Generic)

Levocetirizine
(Xyzal® by Sanofi-Aventis)†

†Interchanged to *Loratadine*.

◆ EVALUATED BUT NOT ADDED

C1-Esterase Inhibitor, Human
(Cinryze® by VivoPharma)‡

‡Restricted Distribution Program (*Cinryze Solutions Program*)

Eltrombopag (Promacta® by GlaxoSmithKline)§

§Restricted Distribution Program (*PROMACTA Cares*)

◆ INTERCHANGES

Loratadine (Generic) for
Levocetirizine (Xyzal®)†

†Loratadine 10 mg = Levocetirizine 5 mg

(continued on next page)

POLICIES AND PROCEDURES

Don't get stuck not knowing about postexposure prophylaxis

Bloodborne pathogen exposure is an issue of vital importance and concern to thousands of healthcare workers who care for patients.¹ Prevention of exposure to blood and body fluids is the primary means of preventing occupationally acquired bloodborne

1%.³ According to the Centers for Disease Control (CDC), a surveillance of healthcare personnel conducted in 2002 reported that 57 healthcare workers in the US had documented seroconversion to HIV following occupational exposure.⁵ Of the adults reported with AIDS in the United States, 24,844 had a history of employment in healthcare and represented 5.1% of AIDS cases reported to the CDC for whom occupational information was known. Exposure to bloodborne pathogens through a contaminated needlestick or cut is the most frequent mode of transmission in healthcare workers.¹ Exposure can also occur with exposure to nonintact skin (eg, chapped, abraded, infected, or cut skin). Human bites are another potential means for bloodborne pathogen transmission, although this has been infrequently documented.

Bloodborne pathogens, including HIV, are found at highest concentrations in blood or body fluids.⁴ The greatest risk for transmission to healthcare workers, occurs from exposure to blood and bloody secretions, while exposure to infected fluids or tissues remains a lower risk. Body fluids, which may be potentially infected with HIV, include cerebrospinal fluid, amniotic fluid, or any body fluid visibly contaminated with blood. Urine, feces, saliva, sputum, sweat, vomitus, and tears are considered to have low infectious potential unless visibly contaminated with blood.

Initiation of postexposure prophylaxis (PEP) should occur as soon as
(continued on page 4)

Occupational exposures should be considered urgent medical concerns to ensure timely post-exposure management. Appropriate postexposure management is an important element of workplace safety, and an essential component to preventing infection following bloodborne pathogen exposure.

pathogens infections including human immunodeficiency virus (HIV) infections.² Occupational exposures should be considered urgent medical concerns to ensure timely postexposure management. Appropriate postexposure management is an important element of workplace safety, and an essential component to preventing infection following bloodborne pathogen exposure.

Healthcare workers are at an increased risk for contracting HIV through contact with contaminated needles or sharp objects or a splash to mucous membranes (ie, eyes, nose, or mouth).¹ According to the World Health Organization, the risk of transmission of HIV from an infected patient through a needlestick where the skin is punctured by a sharp is less than

INSIDE THIS ISSUE

- ◆ New drugs in 2008
- ◆ Override medications

◆ CRITERIA-FOR-USE CHANGES

Methylene Blue (Generic)**

***Restricted: Cannot be used in tube feedings*

Methylnaltrexone and **alvimopan** are the first peripheral mu-opioid-receptor antagonists. Both agents were reviewed proactively because of their potential for off-label misuse, potential safety issues, and high costs.

Methylnaltrexone is an injectable peripheral mu-opioid-receptor antagonist with a labeled indication for the treatment of opioid-induced constipation when laxatives have failed. It is intended for palliative care patients receiving large doses of opioids for chronic pain. Methylnaltrexone is given subcutaneously every other day. The dosage has to be reduced with renal dysfunction, and it should not be used in patients with severe hepatic disease or bowel obstruction.

Methylnaltrexone was shown to be effective at producing rescue-free laxation within 4 hours compared with placebo. Patients received their regular laxative treatments for at least 3 days prior to methylnaltrexone treatment. It should be noted that 9% to 14% of patients in the placebo group had a bowel movement within 4 hours of "treatment."

Gastrointestinal effects are the most common adverse effects (ie, diarrhea, abdominal pain, flatus, and nausea). Dizziness is also a common effect. The mechanism for dizziness is unclear since methylnaltrexone does not cross the blood-brain barrier. An indirect effect may be the cause. Few patients have been exposed to methylnaltrexone, so its safety is not well described.

Methylnaltrexone was added in the *Formulary* but was restricted to use for its labeled indication. This restriction will be enforced by a *Methylnaltrexone Order Form*. The indication for use, contraindications, and dosage must be specified on the form. Methylnaltrexone will automatically be stopped once the patient has a bowel movement.

Alvimopan is an oral peripheral mu-opioid-receptor antagonist with a labeled indication for the prevention of post-operative ileus. Alvimopan was approved by FDA despite concerns about cardiovascular toxicity, and therefore, it is available only via a restricted drug distribution program that limits its use to hospitals and only for 7 days and 15 doses (ie, the Entereg Access Support & Education Program or EASE Program).

Alvimopan appears to be effective compared to placebo as measured by

the GI-2, which measures the time to patients taking oral food post-operatively or when the patient has their first bowel movement. Also, it decreases length-of-stay (LOS), but the effect is small, and it is unclear if decreased LOS will be realized in a practice setting. Chewing gum (sugar-free) has been shown to have a greater effect on post-operative ileus and LOS by a Cochrane review, but this is not a direct comparison to alvimopan. A direct comparison between alvimopan and chewing gum would be interesting.

Gastrointestinal effects are the common adverse effects. Few patients have been exposed to alvimopan, so safety is not well described. As previously noted, a higher rate of myocardial infarctions was noted in a long-term study of alvimopan for the reversal of constipation in patients with chronic pain receiving opioids. This is not an approved use for alvimopan.

Alvimopan was reviewed proactively because of the potential for misuse and because it cannot be used until (or if) Shands at UF signs the EASE agreement, which puts strict limitations on its use. Alvimopan costs \$62 per capsule and an entire prophylactic course could cost near \$1000 per patient.

Currently, use to prevent post-operative ileus after colon resection surgery is the only approved use for alvimopan, and off-label use is prohibited. This, along with the current safety concerns, led to the nonformulary and not available designation.

Olmesartan is 1 of 7 FDA-approved angiotensin receptor blockers (ARBs); 3 (losartan, irbesartan, and valsartan) have been listed in the Shands at UF *Formulary*. However, olmesartan was frequently ordered through the nonformulary process. There is limited information to support the preferential use of 1 ARB over another.

Olmesartan has labeled indications for the treatment of hypertension, either alone or in combination with other antihypertensive agents. Treatment is initiated at lower doses (ie, 5 mg to 10 mg daily) in patients who are volume-depleted. There are no recommended dosage adjustments for elderly patients or patients with moderate to marked renal or hepatic dysfunction.

Data from studies provide inconclusive results; it appears that olmesartan is comparable in efficacy to other ARBs. However, no conclusions may be made about its comparative efficacy with other agents because of methodological flaws in the published studies.

Adverse effects of olmesartan are the same as expected for other ARBs. There are no significant differences in the incidence of adverse events observed between ARBs in comparative trials. Therefore, no single ARB appears to confer any safety benefit. No ARB should be

used in the second and third trimester of pregnancy. Caution is needed in severe heart failure or in patients with renal artery stenosis. Concomitant use with drugs that increase serum potassium may lead to hyperkalemia.

The acquisition cost of olmesartan is comparable to the other available ARBs. Olmesartan was added in the *Formulary* pending a proposal for a therapeutic interchange among the available ARBs.

Cefpodoxime was evaluated because of high volume of nonformulary use. A review of the charts of the patients receiving cefpodoxime revealed that it was used for the treatment of community-acquired pneumonia (CAP).

CAP remains a common and serious illness, in spite of the availability of potent new antimicrobials and effective vaccines. Initial therapy for CAP is empirical and based on the more commonly seen pathogens (ie, *Streptococcus pneumoniae*, *Haemophilus influenzae*, and atypical organisms). A goal of therapy when treating CAP is the utilization of oral antimicrobials. Switching patients from parenteral therapy to oral therapy as soon as the patient is deemed clinically stable is crucial in decreasing lengths of hospital stay and costs.

Cefpodoxime has a labeled indication for use in community-acquired pneumonia. It mainly covers gram-negative organisms, but it is effective against some gram-positive organisms. Other labeled indications for cefpodoxime include acute bacterial exacerbation of chronic bronchitis, acute uncomplicated gonorrhea, uncomplicated skin and skin structure infections, acute otitis media, pharyngitis or tonsillitis, and uncomplicated urinary tract infections.

The results from 3 studies and 1 meta-analysis demonstrate that step-down therapy with cefpodoxime is a safe and effective option for the treatment of CAP. Early conversion to oral therapy from parenteral therapy in inpatients with CAP not only improves the quality of care for hospitalized patients but can often prevent the complications and associated costs of IV therapy (ie, phlebitis, cellulitis, and bacteremias), while at the same time allowing patients to become more mobile and permitting them to leave the hospital.

The most frequently reported adverse effects for cefpodoxime are diarrhea and nausea. Cefpodoxime is contraindicated in patients with a known allergy to cefpodoxime or to the cephalosporin group of antibiotics. It should be used with caution in patients with a known penicillin allergy (ie, IgE mediated reactions). Cross hypersensitivity among beta-lactam antibiotics

(continued on next page)

Formulary update, from page 2

may occur in patients with a history of penicillin allergy. Cefpodoxime is best absorbed in an acidic environment and may interact with medications that increase the gastric pH (ie, antacids and H2 antagonists), lowering the effectiveness of cefpodoxime.

Cefuroxime is an alternative oral option to cefpodoxime in the *Formulary* that is nearly 1/4 the cost for the treatment of CAP. Although cefpodoxime may be used in the treatment of CAP, there is no clinical or financial benefit of using it over the second generation cephalosporin cefuroxime for step-down therapy. Due to cefpodoxime's broad-spectrum of activity, it increases the risk for the development of antibiotic resistance (ie, greater "collateral damage"). Therefore, the Anti-Infective Subcommittee (AIS) recommended that cefpodoxime be designated nonformulary and not available.

Levocetirizine is a recently-marketed prescription non-sedating antihistamine. It is the active enantiomer of cetirizine, which is widely available as a generic nonprescription product.

Levocetirizine is twice as potent on a mg-per-mg basis as cetirizine; it is considerably more expensive. Cetirizine is not currently listed in the *Formulary* and is automatically interchanged to loratadine. Therefore, loratadine will be automatically dispensed for levocetirizine using the following ratios: loratadine 5 mg for levocetirizine 2.5 mg, and loratadine 10 mg for levocetirizine 5 mg.

Human C1-esterase inhibitor is the first marketed drug with a labeled indication for treatment of hereditary angioedema (HAE), a rare and potentially life-threatening genetic disorder that affects about 6,000 to 10,000 people in the US. This plasma-derived product regulates clotting and inflammatory reactions that, when impaired, can lead to local tissue swelling. C1-esterase inhibitor does not function in patients with HAE, and plasma-derived human C1-esterase inhibitor replaces the nonfunctioning or missing protein. It is administered parenterally every 3 to 4 days (chronically).

Cinryze® is available in the community setting only via the Cinryze® Solutions Program (877-945-1000) from 2 specialty pharmacies (Caremark and Curascript) on a patient-specific basis. Drug is shipped to the site of care, which could be the patient's home, a physician's office, a clinic, or a hospital, depending on where the patient's therapy is being administered. Shands at UF cannot purchase and stock a nonpatient-specific supply of Cinryze®. Therefore, it cannot be listed in the *Formulary*.

Human C1-esterase inhibitor was designated a high-priority nonformu-

lary drug, which creates a process to inform prescribers about how to acquire Cinryze® for inpatient use, if a patient is admitted. Patients can receive this drug in the inpatient setting only if they use their own supply. This will be an exception to the *Patients Own Medications* policy, which generally prohibits the use of a patient's supply of injectable products. However, in this case, there is no other method of continuing therapy.

Eltrombopag is an oral nonpeptide thrombopoietin-receptor agonist approved by the FDA with a labeled indication for the treatment of idiopathic thrombocytopenic purpura (ITP) in patients who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Eltrombopag is available only through a restricted-distribution program called *PROMACTA Cares*; prescribers, pharmacies, and patients must register in the program to prescribe, dispense, or receive eltrombopag (877-9-PROMACTA or 877-977-6622).

Eltrombopag has the potential to be used off-label for the treatment of thrombocytopenia from other causes, including chemotherapy-induced thrombocytopenia and nonchemotherapy-induced thrombocytopenia (eg, patients with hepatitis C virus receiving interferon and ribavirin therapy). These other indications are currently being studied. It is unclear whether these uses would be allowed in the restricted-distribution program. It is doubtful that patients could be enrolled in the restricted-distribution program for off-labeled uses.

The major warnings for eltrombopag concern its risk of hepatotoxicity. Alanine transferase (ALT) and bilirubin must be measured at baseline and every 2 weeks during the dose adjustment phase and monthly once the dosage is stabilized. There are guidelines for additional monitoring and discontinuation of therapy if ALTs or bilirubins increase.

At this point, neither UF prescribers nor Shands at UF are registered for the restricted-distribution program. A high-priority nonformulary designation assures that prescribers will understand the options for managing these patients during their hospitalization (eg, use of the patient's own supply of medication or use of an alternative).

Methylene blue is a water-soluble dye used to diagnose suspected gastrointestinal fistulas or for the treatment of methemoglobinemia from cyanide toxicity or drug-induced methemoglobinemia. Methylene blue has been used for other uses, including coloring enteral feedings for the diagnosis of aspiration. However, a 2003 FDA Health Advisory warned of deaths associated with tube feedings tinted with blue dyes. The FDA concluded that dyes do not offer significant benefit for the diagnosis of aspiration. Dyes may increase gastrointestinal per-

meability, which has been associated with adverse events (eg, sepsis and deaths).

An alternative method of aspiration detection involves using glucose oxidase test strips to monitor for elevations in glucose concentrations of endotracheal secretions. Endotracheal secretions normally contain low glucose concentrations; thus, any elevation would likely indicate aspiration of glucose-rich enteral formulas. This method has been shown to be superior in detecting aspiration in comparison to the blue food dye method. A 5% false-positive rate has been reported for the detection of aspiration with glucose oxidase strip testing, as compared with a 33% false-positive rate of detection of aspiration with the blue food dye method. However, additional studies have found elevated endotracheal glucose concentrations in both enterally and nonenterally fed patients. Additional concerns with the method include false-positives from blood contamination and low sensitivity when enteral formulas containing lower concentrations of glucose are used. While glucose oxidase may be superior to the blue dyes, its multiple problems preclude it from being recommended as a reliable, safe method of aspiration detection.

Another method of aspiration detection is monitoring of gastric residual volumes (GRV) during enteral feeding. While a 2002 consensus statement recommended withholding tube feeds and reassessing tolerance if GRV is greater than 500 mL, they recommended careful bedside evaluation and an algorithmic approach to management throughout various levels of GRV. However, attempts to validate the use of GRV found no appropriate designated GRV level to identify aspiration could be derived because of poor sensitivity over a wide range of GRVs.

Ultimately, radiographic evidence of pulmonary infiltrates along with clinical manifestations of pulmonary insults remain the most accurate and reliable ways to document, as well as to assess for, significant aspiration in critically ill patients. Due to the lack of reliable bedside methods of aspiration detection in enterally fed patients, the focus should be on prevention techniques, such as proper feeding-tube placement, proper head-of-bed positioning at 30 to 45 degrees, optimization of oral health, etc.

Therefore, the use of methylene blue in enteral feedings is now prohibited. The use of glucose strips, gastric residual volumes, and radiographic methods should be considered as alternative bedside methods of detecting aspiration in enterally fed patients.

Policy and procedures, from page 1 possible — within hours rather than days of exposure.¹ Early PEP is thought to inhibit HIV replication.⁴ Studies have shown systemic infection does not occur immediately; and, therefore, a short window of opportunity exists to prevent viral replication. Currently, antiretrovirals from 5 classes of drugs are available to treat HIV infection.² Determining which PEP to use is mainly empirical. The recommendations from the US Public Health Service provide guidance using 2 or more PEP drug regimens on the basis of the level of risk for HIV transmission. These recommendations apply to situations in which the health care provider has been exposed to a source person who either has confirmed HIV infection or whom is considered to be at high risk of HIV infection. HIV PEP is built upon the level of exposure, which is dependent upon severity and amount of exposure to blood or body fluids. Persons receiving PEP should complete a 4-week regimen; although, the optimum length of therapy has not been determined.

HIV status of the source individual is useful, but not necessary. Healthcare workers who have been exposed to blood or body fluids need to treat the incident as though the

patient is infected with a bloodborne pathogen.² If the source individual has a known HIV status, then information about the stage of infection should be made available to those assisting the exposed healthcare worker. Known or suspected resistance of the source virus to antiretroviral agents, particularly those that could be included in a PEP regimen, is a concern and should be offered when possible.

Shands at UF has an established protocol for employees exposed to HIV. Employees can access the protocol via the Pharmacy Services-UF Website or by accessing the following link: https://my.portal.shands.ufl.edu/portal/page/portal/DEPT_CONTENT/Pharmacy/UF/Department-Tools/PDFs/HIV-PEP.pdf. Employees are instructed to go to Occupational Health Services (OHS) as soon as possible after the exposure, preferably within 1 to 2 hours. Exposures occurring during evening, night, or weekend hours will be triaged by the nursing coordinator who will make referrals to the Emergency Department (ED), if necessary. The ED attending may prescribe a 72-hour course of PEP following the protocol. The ED will administer the first dose(s) of PEP medications, and then write a prescription for the remaining medications. The exposed employee will then fill the prescription at a local pharmacy.

The employee should contact OHS the next business day for follow-up. UF faculty, staff, resident house-staff, and students who experience exposures to bloodborne pathogens should contact the Needle Stick Hotline at 866-477-6824.

Bloodborne pathogen exposure remains a significant occupational hazard to all healthcare professionals. Prevention of exposure to blood and body fluids is the primary means of preventing occupationally acquired bloodborne pathogens. In the event of exposure, PEP should be initiated as quickly as possible. Employees should be aware of PEP practices and keep up-to-date about the latest strategies for the management of bloodborne pathogen exposure.

by Morgan L. Mace, PharmD

REFERENCES

1. Twitchell KT. Bloodborne pathogens: what you need to know-part I. AAOHN J 2003;51:38-45.
2. Panlilio AL, Cardo DM, Grohskopf LA, et al. Updated U.S. Public Health Service Guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR Recomm Rep 2005;54(RR-9):1-17.
3. Anon. WHO post exposure prophylaxis. Available at <http://www.who.int/hiv/topics/prophylaxis/en/>. Accessed 12/2/08.
4. Twitchell KT. Bloodborne pathogens: what you need to know-part II. AAOHN J 2003;51:89-97.
5. Anon. Surveillance of Healthcare Personnel with HIV/AIDS, as of December 2002. Available at http://www.cdc.gov/ncidod/dhqp/bp_hiv_hp_with.html#. Accessed 12/17/08.

NEWS

New drugs in 2008...and looking forward

In a reversal of trends over the last 3 years, more new molecular entities (NMEs) and biologicals were approved in 2008 (see table on page 5). The most new drugs approved in 1 year occurred more than 10 years ago in 1996 when 53 new drugs were approved. There has been a steady decline since then. The 24 new drugs (21 if you count only NMEs) approved in 2008 is in line with historical averages. 9 of the drugs approved in 2008 were "priority review" drugs, which are supposed to be reviewed by the FDA within 6 months of their application.

Many of the drugs and biologicals will not be widely marketed, and there were few potential blockbuster drugs approved. Only 40% of the drugs approved in 2008 were first-in-class agents, represented a significant therapeutic advance, or addressed a disease not previously treated. Several drugs approved are for rare disorders and diagnostic procedures. Only 3 drugs were approved for the treatment of cancer, which is lower than in previous years.

2008 was another big year for first-time generic approvals. Generic versions of drugs continue to be marketed as patents expire. Many third-party

payers, including Medicare Part D plans, encourage patients to use generics by assessing much lower co-pays.

◆

2008 was another big year for first-time generic approvals. Generic versions of drugs continue to be marketed as patents expire. The growing arsenal of generics makes it easier to find a less expensive option in many therapeutic categories. After generics have been on the market for several months, the cost to health systems can drop by as much as 70% or more.

Important first-time generic versions of brand name drugs approved in 2008 include generic versions of common drugs used in the ambulatory setting, like Effexor[®] XR (venlafaxine extended-

release), Risperdal[®] (risperidone), Fosamax[®] (alendronate), Imitrex[®] tablets (sumatriptan), and Zyrtec[®] (cetirizine). Other important generics used in health systems include Flolan[®] (epoprostenol) and Camptosar[®] (irinotecan).

The growing arsenal of generics makes it easier to find a less expensive option in many therapeutic categories. After generics have been on the market for several months, the cost to health systems can drop by as much as 70% or more.

Although difficult to predict, generic versions are expected in 2009 for Adderall[®] XR (amphetamine-dextroamphetamine extended-release), Clarinex[®] (desloratadine), Depakote[®] XR (divalproex extended-release), Flomax[®] (tamsulosin), Lamictal[®] (lamotrigine), Prevacid (lansoprazole), Topamax[®] (topiramate), and Valtrex[®] (valacyclovir). Many of these are blockbuster drugs accounting for over a billion dollars in sales (based on 2007 sales). Prevacid[®] (3.3 billion), Topamax[®] (1.8 billion), Lamictal[®] (1.7 billion), Valtrex[®] (1.4 billion), Adderall[®] XR (1.3 billion), Flomax[®] (1 billion), and Imitrex[®] (1 billion) account for more than 10 billion dollars in prescription sales.

NEW DRUGS & SELECTED BIOLOGICALS APPROVED BY THE FDA IN 2008

GENERIC NAME	TRADE NAME	INDICATION
Alvimopan [◊]	Entereg [®]	Post-Operative Ileus Prevention
Antihemophilic Factor, Recombinant [†]	Xyntha [®]	Hemophilia
Bendamustine [‡]	Treanda [®]	Cancer, Chronic Lymphocytic Leukemia
C1-Esterase Inhibitor, Human [†]	Cinryze [®]	Hereditary Angioedema
Certolizumab pegol [†]	Cimzia [®]	Crohn's Disease
Clevidipine	Cleviprex [®]	Hypertension
Degarelix	Pending	Prostate Cancer
Desvenlafaxine	Pristiq [®]	Depression
Difluprednate [‡]	Durezol [®]	Inflammation/Pain Ocular Surgery
DTaP-IPV ^{†◊}	Kinrix [®]	Childhood Vaccine
DTaP-IPV/Hib ^{†◊}	Pentacel [®]	Childhood Vaccine
Eltrombopag [‡]	Promacta [®]	Immune Thrombocytopenia Purpura (ITP), Chronic
Etravirine [‡]	Intelence [®]	HIV Infection
Ferric Hexacyanoferrate	Radiogardase [®]	Antidote for Radioactivity Exposure
Festoterodine	Toviaz [®]	Overactive Bladder
Fibrin Sealant, Human [†]	Artiss [®]	Adhesive for Burn Skin Grafts
Fospropofol	Lusedra [®]	Anesthesia Sedation
Gadoxetate	Eovist [®]	MRI Contrast Media
Gadofosveset	Vasovist [®]	MRI Contrast Media
Iobenguane I 123 [‡]	AdreView [®]	Diagnostic Radiopharmaceutical
Lacosamide	Vimpat [®]	Seizure Disorder
Methylnaltrexone [*]	Relistor [®]	Opioid-Induced Constipation
Plerixafor [‡]	Mozobil [®]	Mobilization of Hematopoietic Stem Cells for Bone Marrow Transplantation
Regadenoson [*]	Lexiscan [®]	Pharmacologic Cardiac Stress Testing
Rilonacept ^{†‡}	Arcalyst [®]	Cryopyrin-Associated Periodic Syndromes
Romiplostim ^{†‡*}	Nplate [®]	Immune Thrombocytopenia Purpura (ITP), Chronic
Rotavirus Vaccine ^{†◊}	Rotarix [®]	Prevent Rotavirus Infections
Rufinamide	Banzel [®]	Seizure Disorder
Silodosin	Rapaflo [®]	Benign Prostatic Hyperplasia (BPH)
Tapentadol	Pending	Moderate/Severe Pain
Tetrabenazine [‡]	Xenazine [®]	Huntington's Chorea
Thrombin, Topical, Recombinant [†]	Recothrom [®]	Surgical Hemostasis

DTaP = Diphtheria-Tetanus-acellular Pertussis; Hib = Haemophilus influenza B; IPV = Inactivated Polio Vaccine

New Molecular Entities (NMEs) shown in bold

*Listed in the Shands at UF *Formulary*

†Biological

‡Priority Review

§Only available through the CDC's Strategic National Stockpile and military personnel.

¶Not currently being marketed for legal reasons.

◊Nonformulary and not available

Volume 23, No. 2 February 2009
This publication is produced by the Drug Information and Pharmacy Resource Center under the direction of the Department of Pharmacy Services and the Pharmacy and Therapeutics Committee.

**EDITOR,
DRUGS & THERAPY BULLETIN**

Randy C. Hatton, PharmD

**DIRECTOR,
PHARMACY SERVICES**

Alan Knudsen, MS, RPh

**CHAIRMAN,
PHARMACY & THERAPEUTICS
COMMITTEE**

Ricardo Gonzalez-Rothi, MD

EDITING, DESIGN, & PRODUCTION

Shands HealthCare's Publication Svcs.
© Copyright 2009. All rights reserved.
No portion of the *Drugs & Therapy Bulletin* may be reproduced without the written consent of its editor.

**FOR MORE INFORMATION,
VISIT US ONLINE**

<http://shands.org/professionals/druginfo/bulletin.asp>

SHANDS

**Shands at the University of Florida
DRUG INFORMATION SERVICE**

PO Box 100316
Gainesville, FL 32610-0316

NON-PROFIT ORG.
U.S. POSTAGE
PAID
GAINESVILLE, FL
PERMIT NO. 94

POLICIES AND PROCEDURES

Override medications in automated dispensing cabinets

The policy regarding the availability of “override medications” from Omnicell® automated dispensing cabinets has been revised. Override medications are those that are available from the Omnicell® without a pharmacist’s review of the order. Whenever a medication is removed from the dispensing cabinet via override, the person removing the drug assumes the responsibility of the pharmacist (ie, checks for allergies, other contraindications, appropriate dosing, etc). The purpose of this revision was to comply with The Joint Commission standards for medication safety, which state that all orders should be reviewed for appropriateness before administration to the patient.

The 2 criteria used in determining what are appropriate override medications are that a delay for pharmacist review of the order would result in immediate patient harm or that a licensed independent practitioner will be at the bedside during administration of the drug. Medications ordered “Stat” do not meet these criteria; “Stat” meds are needed within 15 minutes, which allows time for pharmacist review. The revision of this policy dramatically de-

creases the number of drugs available by override. For example, instead of all narcotics being available, transdermal patches and sustained-released products have been removed since they do not provide immediate relief. Now a procedure determines which drugs can

be added to the list of override medications based on criteria listed in the policy (see table). The complete policy is available on the Portal as *Override Medications in Automated Dispensing Cabinets*.

by Candice T. Morris, PharmD

AGENTS THAT CANNOT BE OVERRIDE MEDICATIONS

- Any nonformulary medication
- Sustained-released medications
- Transdermal dosage forms
- Topical medications (except those listed in inclusions)
- Any oral dosage form except those listed as “inclusions” – these include narcotics, non-opioid pain relievers (eg, acetaminophen, NSAIDs, tramadol), antiemetics, antiinfectives, anticonvulsants, hypnotics, anxiolytics, antihypertensives, and steroids.
- IV antiinfectives (except those listed in inclusions (ie, ampicillin, cefazolin, cefepime, and vancomycin).
- Inhalers (except albuterol)
- Albumin (except on Unit 24)
- Insulins (except regular insulin on Unit 24)
- Anabolic steroids
- Acetylcysteine
- Local anesthetics (except those listed in inclusions)
- IV heparin
- Marinol
- Mannitol vials