

# Drugs & Therapy

B • U • L • L • E • T • I • N

## FORMULARY UPDATE

The Pharmacy and Therapeutics Committee met January 19, 2010. 5 drugs were added in the *Formulary*, and 1 was deleted. 8 products were designated nonformulary and not available with 1 new dose-rounding protocol established. Criteria for use were changed for 4 products.

### ◆ ADDED

**Apraclonidine**  
(Iopidine® by Alcon Laboratories)

**Dronedarone**  
(Multaq® by Sanofi-Aventis)

**Etodolac** (Generic)\*

\*Restricted to Shands Vista/Shands Rehab Hospital

**Meloxicam** (Generic)\*

\*Restricted to Shands Vista/Shands Rehab Hospital

**Povidone-Iodine Ophthalmic**  
(Betadine® by Alcon)

### ◆ DELETED

**Rubella Virus Vaccine**  
(Meruvax® II)†

†Nonformulary and not available

### ◆ NONFORMULARY AND NOT AVAILABLE

**AbobotulinumtoxinA** (Dysport®)

**Hyoscyamine** (Various)

**Measles Virus Vaccine**  
(Attenuvax®)

**Mumps Virus Vaccine**  
(Mumpsvax®)

**OnabotulinumtoxinA**  
(Botox® Cosmetic)

**RimabotulinumtoxinB**  
(Myobloc®)

**Ustekinumab** (Stelara®)

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## NEWS

### New drugs in 2009

There were 26 new unique drugs approved in 2009 (see table on page 5). This was slightly more new drug approvals than last year, but it was a big increase over the period from 2005-2007, when approvals were at all-time lows. It is far below the 1996 record of 53 new drugs, but the mid-twenty number is consistent with historical averages before the 1990s.

There continues to be an increase in the number of new biologicals approved. It appears that the long-awaited wave of biotech drugs is finally arriving.

The trend of approving boutique drugs also continues. For example, 2 drugs were approved for the treatment of hereditary angioedema. A second drug was also approved for the treatment of cryopyrin-associated periodic syndromes (CAPS). When the first drug for this indication was approved, the FDA estimated there were about 300 patients in the U.S. with these conditions.

There were several drugs approved for the treatment or prevention of cancer. Another drug was approved for the treatment of chronic cancer pain. Manufacturers seek approval of drugs used for the treatment of cancer since usually these drugs often are used without consideration of their cost.

Another trend with new drug approvals is the requirement of Risk Evaluation and Mitigation Strategies (REMS). Most of the REMS are required medication guides for new drugs that explain the potential benefits and risks. The medication guides are designed for the outpatient setting and are not required in the hospital setting. A complete list of medication guides can be found at <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>. The Food and Drug Administration Amendments Act of 2007 (FDAAA) granted the FDA the authority to require the submission and implementation of a REMS if the FDA determines a REMS is necessary to ensure that a drug's benefits outweigh its risks. REMS components include medication guides; patient package inserts; a communication plan for

health care providers; and elements to ensure safe use, including requirements for those who prescribe, dispense, or use the drug.

2009 was another big year for first-time generics approvals. Generic versions of blockbuster drugs continue to be marketed as patents expire. Many third-party payers, including Medicare Part D, encourage patients to use generics by requiring much lower co-pays. Some plans now have no co-pays for some generics, and Walmart and many other retailers offer many generics for \$4 for a 1-month supply, and \$10 for 3 months' supply. At least 2/3 of all prescriptions filled are now generic drugs, yet they account for less than 1/4 of all expenses.

Important first-time generic versions of brand name drugs approved in 2009 included generic versions of common drugs used in the ambulatory setting, like Flomax® (tamsulosin), Imitrex® (sumatriptan), and Valtrex® (valacyclovir). Other important generics used in health systems include Cardene® IV (nicardipine injection) and Keppra® (levetiracetam). New generics expected for 2010 include bivalirudin (Angiomax®), ropivacaine (Naropin®), and maybe enoxaparin (Lovenox®).

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.

2010 may finally bring a mechanism for generic biological drugs to come to market. Since biologicals have an increasing importance in the drug therapy arsenal and add to the cost of care, biological generics (also known as biosimilars) would help decrease the costs of many of the older agents whose patents have already expired.

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## ◆ INSIDE THIS ISSUE

- ◆ Brand name drug costs

◆ **INTERCHANGES**

**Calcium and Calcium Carbonate Dose Rounding**

◆ **CRITERIA-FOR-USE CHANGES**

**Albumin** (Various)‡

‡Filtering not required

**Coral Snake Antivenin** (None)§

§Extended stability through October 2010

**Promethazine IV** (Generic)¶

¶Nonformulary and Not Available at Shands Vista/Shands Rehab Hospital

**Romidepsin** (Istodax®)\*\*

\*\*Nonformulary: Must be ordered on a Chemotherapy Order Form

**Apraclonidine** is a relatively selective alpha-adrenergic agonist that is applied topically to the eye. Topically applied apraclonidine decreases intraocular pressure by decreasing aqueous fluid production. It was added in the *Formulary* for use in the Emergency Department to reduce elevated intraocular pressure acutely.

Apraclonidine ophthalmic solution has a labeled indication to control or prevent postsurgical elevations in intraocular pressure that occur in patients after argon laser trabeculoplasty, argon laser iridotomy, or Nd:YAG posterior capsulotomy. It is used off-label to lower any raised intraocular pressure after ophthalmic surgery. It has been used for glaucoma nonresponsive to other therapies and for the diagnosis of Horner's Syndrome. Horner's Syndrome is caused by decreased sympathetic nervous system activity in the eye. It manifests as drooping of the upper eyelid, elevation of the lower eyelid, miosis, dilation lag, and enophthalmos.

Studies that compare apraclonidine and brimonidine show that there is usually no difference in the short-term hypotensive effects on intraocular pressure (IOP) between these agents. The only study that showed superiority for apraclonidine is a Brazilian study.

Apraclonidine is contraindicated for patients receiving monoamine oxidase inhibitors. The primary ocular adverse effects are ocular injection, upper lid elevation, ocular inflammation, conjunctival blanching, burning, discomfort, itching, blurred vision, and mydriasis. The primary systemic adverse effect is dry mouth. Irregular heart rate and nasal congestion have been reported.

**Dronedarone** is an antiarrhythmic medication structurally similar to amiodarone, but it does not contain

iodine. Structural changes to amiodarone were made in an attempt to decrease toxicity and adverse effects on pulmonary and thyroid function.

The antiarrhythmic effect of dronedarone is believed to come from its inhibition of several electrolyte channels. It has qualities of all four Vaughan Williams antiarrhythmic classes.

Dronedarone is dosed twice daily with morning and evening meals, as bioavailability is increased substantially when taken with food. No dosage adjustments are necessary in renal or mild to moderate hepatic impairment.

Dronedarone is metabolized via CYP3A enzymes and exerts an inhibitory effect on CYP3A and CYP2D6 function; thus, dronedarone is contraindicated with strong CYP3A inhibitors (eg, ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, and ritonavir) and should be used cautiously with CYP3A inducers (eg, phenobarbital, carbamazepine, phenytoin, and St. John's wort).

Atrial fibrillation/flutter patients showed a 24% relative risk reduction for cardiovascular hospitalizations/all cause death when using dronedarone compared with placebo. This benefit has only been shown in patients aged 60 years old or greater. The results of the only head-to-head study with amiodarone have not been published; however, a recent press release from the manufacturer states that patients treated with dronedarone have a higher rate of recurrent atrial fibrillation than patients treated with amiodarone. This inferior efficacy may limit the use of dronedarone.

Dronedarone trials revealed several adverse effects, the most common were gastrointestinal (GI) effects, including diarrhea, nausea, and abdominal pain. The unpublished head-to-head trial showed the GI adverse effects of dronedarone to be greater than those of amiodarone. Dronedarone also prolonged the QT interval, caused bradycardia, and increased dermatologic effects compared to placebo. Patients treated with dronedarone had fewer pulmonary and thyrotoxic effects than with amiodarone. However, dronedarone is contraindicated in patients with NYHA class IV heart failure, severe hepatic impairment, bradycardia, QT prolongation, and pregnant patients.

Dronedarone costs nearly 30 times more than amiodarone, which is available as a generic. Thus, dronedarone is not generally considered a first-line agent.

**Etodolac** and **meloxicam** are nonsteroidal anti-inflammatory drugs (NSAIDs) added for use at Shands Vista and Shands Rehab Hospitals only. These older traditional NSAIDs are relatively COX-2 selective and are less

expensive alternatives to celecoxib (Celebrex®). Celebrex® is so expensive that some patients cannot continue treatment after their discharge when they do not have insurance coverage.

Most guidelines state that patients who do not respond to one NSAID may respond to another. These offer additional agents to try. It is important to note that there is no evidence to support the assumption that patients who do not respond to one NSAID will respond to another. This recommendation is based on the assumption that patient variability in NSAID response could be genetic or psychological.

Etodolac and meloxicam have the same risks as all NSAIDs (eg, potential to cause GI ulcers, possible nephrotoxic and hepatotoxic effects, and increased risk for bleeding).

**Ophthalmic povidone-iodine solution** was added for use in the eye examination room in the Emergency Department but could be used anywhere that that an ophthalmologic intervention is done.

Povidone-iodine is a topical broad-spectrum microbicide. It is an iodophor, which consists of iodine complexed with a solubilizing agent (povidone). The spectrum of activity of povidone-iodine is the same as elemental iodine, which includes bacteria, fungi, viruses, protozoa, and spores.

Betadine® 5% Sterile Ophthalmic Prep Solution for the eye has a labeled indication for prepping of the periorbital region (lids, brow, and cheek) and irrigation of the ocular surface (cornea, conjunctiva, and palpebral fornices).

Endophthalmitis is a rare but devastating complication of intraocular surgery that often carries a poor prognosis. A strategy utilized to decrease the incidence of post-operative endophthalmitis is the use of povidone-iodine. Utilization of povidone-iodine as a pre-operative preparation has been associated with a 4-fold reduction of culture-positive endophthalmitis when compared to silver protein solution and improved bacterial clearance versus benzethonium chloride.

Adverse reactions to povidone-iodine ophthalmic solution are rare due to limited systemic absorption, but include local reactions.

Single vaccines containing **measles virus vaccine**, **mumps virus vaccine**, and **rubella virus vaccine** have been discontinued by their manufacturer, and, thus, have been designated nonformulary and not available. Rubella virus vaccine was deleted from the *Formulary*. Based on input from the Advisory Committee on Immunization Practices (ACIP), professional societ-

(continued on next page)

**Formulary update**, from page 2  
ies, scientific leaders, and customers, Merck decided not to resume production of these single vaccines.

In 2008, Merck stopped making these monovalent vaccines due to manufacturing constraints and had announced plans to resume production only if sufficient manufacturing resources were available to do so without compromising supplies of M-M-R® II, which contains each of these components (ie, measles, mumps, and rubella). M-M-R® II is recommended by the ACIP, the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), and is preferred over the monovalent vaccines because it eliminates the need for 3 separate injections and reduces the chance of delays in helping protect against any of these potentially serious diseases.

**AbobotulinumtoxinA** and **rimabotulinumtoxinB** were designated nonformulary and not available. **OnabotulinumtoxinA** (Botox®) is the botulinum toxin listed in the *Formulary*. **Botox® Cosmetic®** brand of onabotulinumtoxinA cannot be used in the inpatient setting.

AbobotulinumtoxinA is a recently approved form of what formerly used to be referred to as botulinum toxin type A. Botox® and later Botox® Cosmetic were the first botulinum toxins and Dysport® is similar, but not identical. Botox®'s generic name was changed from botulinum toxin type A to onabotulinumtoxinA, once more than one "type A" botulinum toxin was approved. All botulinum toxins have new generic names, which differentiate among the various forms of botulinum toxin. These products have different potencies, and the units for these agents are NOT equivalent. Changing generic names is supposed to prevent medication errors.

Botulinum toxins are used for a variety of uses where the "toxin" paralyzes muscle. Since Botox® has been on the market the longest, it has the most labeled and off labeled uses; however, theoretically, any botulinum toxin could be used for these uses as long as the appropriate dose is used. Botox® has labeled indications for blepharospasm, cervical dystonia, facial wrinkles, hyperhidrosis,

and strabismus. Some off-labeled uses include achalasia, neurogenic bladder, sialorrhea, and spasticity. Since Dysport® has recently been approved, it only has labeled indications for cervical dystonia and facial wrinkles.

In 2009, FDA added a boxed warning to botulinum toxins to emphasize the risks of spread of the toxin beyond the site it is injected. FDA has also mandated a Risk Evaluation and Mitigation Strategy (REMS) to explain that botulinum products cannot be interchanged and explain the risk of toxin spread.

**Hyoscyamine** is an anticholinergic medication that inhibits the actions of acetylcholine on structures and smooth muscles innervated by the cholinergic system. This leads to a decrease in cholinergic activities, such as inhibition of gastrointestinal motility, decreased gastric acid secretion, and decreased pharyngeal secretions. Frequently, hyoscyamine has been used nonformulary.

All hyoscyamine products are considered to be "unapproved" by the FDA. They came on the market before FDA approval was required. The drug is used to manage many disorders like controlling gastric secretion, abdominal cramps, treatment of bladder spasms, peptic ulcer disease, irritable bowel syndrome (IBS), and diverticulitis. Since hyoscyamine is mostly used to treat abdominal spasms, it is often referred to as an antispasmodic. Hyoscyamine is available as a sustained-release oral tablet, immediate-release sublingual tablet, and an injectable form that may be administered IV, IM, or SC. The recommended dosing for hyoscyamine varies based on dosage form and indication.

Evidence to support hyoscyamine is limited. Few randomized clinical trials have examined hyoscyamine's efficacy. The studies that have been conducted have failed to show an advantage over placebo. Randomized clinical trials have yet to prove that hyoscyamine provides a statistically significant benefit over placebo for abdominal pain, even pain that is secondary to IBS. Thus, hyoscyamine appears to have similar effectiveness as placebo.

As expected, anticholinergic adverse effects, such as dry mouth, constipation, and difficulty urinating, are the most commonly reported with the use of hyoscyamine. Furthermore, this medication is included in the Beers

Criteria, a list of drugs that should be avoided in the elderly because the older population is more sensitive to the anticholinergic adverse effects, especially when used long-term.

Since hyoscyamine lacks sufficient evidence to support its use and could potentially cause serious adverse effects in the elderly, it was designated nonformulary and not available. Dicyclomine, an antispasmodic that is in the *Formulary* or a pain medication (eg, tramadol) can be used as alternatives for patients experiencing gastrointestinal cramps and spasm.

**Ustekinumab** is an antagonist of human interleukin-12 and -23 with a labeled indication for the treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. As a monoclonal antibody that targets interleukin-12 and -23, it is thought to block the action of 2 proteins that contribute to the overproduction of skin cells and inflammation.

Like other biologicals that suppress the immune system, risk of infection is a major risk with this drug. The FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for ustekinumab that includes a communications plan and a Medication Guide.

Ustekinumab is given subcutaneously (SQ) with a loading dose, a dose 4 weeks later, and then every 12 weeks.

Because of the serious risk of infection (ie, causing infection or prolonging infection), its intermittent dosing schedule (ie, every 12 weeks), its cost per patient dose (ie, \$4500 to \$9000 per dose), and its inventory costs (ie, \$9000), it was designated nonformulary and not available for inpatient use at Shands. When patients are discharged from the hospital (and any infections have completely resolved), it is recommended that (if continued therapy is desired) the every-12-week SQ regimen can be resumed.

Oral **calcium carbonate** is used primarily as a calcium supplement. The prescribed doses of calcium carbonate or nonspecific oral **calcium** orders are a frequent cause for order clarifications. Therefore, the P&T Committee approved the oral calcium carbonate and calcium dose-rounding protocol that follows (below). This protocol does not apply to calcium citrate.

(continued on next page)

## ORAL CALCIUM DOSE ROUNDING

Products available in the *Formulary*

- Calcium carbonate 650-mg tablet (260 mg elemental calcium)
- Calcium carbonate 1250-mg tablet (500 mg elemental calcium)
- Calcium carbonate oral suspension 1250 mg/5 mL (500 mg elemental calcium)

PHYSICIAN'S ORDER	TO BE DISPENSED AS*
Tums® 500 mg (Calcium carbonate 500 mg)	Calcium carbonate 650 mg
Calcium carbonate less than 974 mg	Calcium carbonate 650 mg
Calcium carbonate greater than or equal to 975 mg	Calcium carbonate 1250 mg
Calcium less than 379 mg	Calcium carbonate 650 mg (260 mg elemental calcium)
Calcium 380 mg to 750 mg	Calcium carbonate 1250 mg tablet (500 mg elemental calcium)
Calcium greater than 750 mg/dose	Call MD (The maximum dose of elemental calcium that should be taken at a time is 500 mg)

\*Applies to all adults and children with IBW greater than 50 kg.

**Albumin** is frequently ordered as a colloid volume expander. The P&T Committee endorsed a policy that will allow all albumin products to be used without filtering, regardless of its labeling.

There are no specific FDA recommendations for or against the filtration of albumin during administration. Some products recommend filtering in their labeling, while others do not. Shands at UF uses various suppliers of albumin, so any policy adopted applies, regardless of manufacturer.

The albumin products that recommend filtering come with a 15-micron filter. Unfortunately, the administration sets with the 15-micron filter provided by manufacturers will not work with the new Alaris "smart pumps." The reason for a 15-micron filter is to theoretically remove large protein aggregates (if they exist), not for sterilization.

The FDA was contacted to determine the origins of the differences among albumin products and/or the potential consequences of these protein aggregates. According to the Center for Biologics Evaluation and Research, Federal Law determines what albumin is and determines how it should be processed, tested, and labeled. Nowhere is filtering specifically addressed. Thus, the filtering requirement is established by each manufacturer.

The American Association of Blood Banks (AABB) states, "Albumin and PPF [plasma protein fraction] need not be given through a filter." This statement is from the publication, *Blood Transfusion Therapy: A Physicians Handbook*, which is in compliance with the 25th edition of the AABB Standards for Blood Banks and Transfusion Services.

**Coral snake antivenin** is used to treat patients with a significant envenomation from a coral snake bite. Unfortunately, the manufacturer stopped making this product several years ago, and the final supplies of product were scheduled to expire at the end of October 2008.

Based on stability data submitted to the FDA, the limited supply of coral snake antivenin has again received extended dating until the end of October 2010. Once supplies are exhausted, coral snake antivenin will be designated nonformulary and not available. Unfortunately, there will be no pharmacologic treatment for coral snake bites once supplies are exhausted.

**Promethazine** is a phenothiazine antiemetic that has been used for many years. It provides an effective alternative for patients who do not respond to ondansetron or prochlorperazine.

Unfortunately, it is very irritating to the veins and must be diluted with at least 10 mL of normal saline, given in a large vein, and administered slowly. Promethazine IM and suppositories are alternatives for patients who cannot take oral medications because of their nausea.

Intravenous promethazine use will no longer be permitted at Shands Vista and Shands Rehab Hospitals. This high-alert medication is rarely used in this setting, which could increase the risk of inappropriate administration.

**Romidepsin** is a histone deacetylase inhibitor with a labeled indication for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy. Like other chemotherapy, it is associated with thrombocytopenia, leukopenia, and anemia, and monitoring hematologic parameters is needed. There is also a risk of QT prolongation.

Romidepsin was added in the *Chemotherapy Policy*, which requires that it be ordered on a *Chemotherapy Order Form*. Romidepsin remains a nonformulary drug.

## NEW DRUGS, BIOLOGICALS, & SELECTED DOSAGE FORMS APPROVED BY THE FDA IN 2009

GENERIC NAME	TRADE NAME	INDICATION
AbobotulinumtoxinA <sup>^†¶</sup>	Dysport <sup>®</sup>	Cervical Dystonia
Antithrombin, Recombinant <sup>††¶</sup>	ATryn <sup>®</sup>	Hereditary Antithrombin Deficiency
Artemether <sup>^†</sup> -Lumefantrine	Coartem <sup>®</sup>	Anti-Infective: Malaria
Asenapine <sup>^</sup>	Saphris <sup>®</sup>	Schizophrenia
Benzyl Alcohol Solution <sup>^</sup>	Ulesfia <sup>®</sup>	Anti-Infective: Scabies
Bepotastine Bisilate <sup>^</sup>	Bepreve <sup>®</sup>	Allergic Conjunctivitis
Besifloxacin <sup>^</sup>	Besivance <sup>®</sup>	Anti-Infective: Conjunctivitis
Bromocriptine <sup>§</sup>	Cycloset <sup>®</sup>	Type 2 Diabetes
C1-Esterase Inhibitor <sup>†</sup>	Berinert <sup>®</sup>	Hereditary Angioedema
Canakinumab <sup>^††</sup>	Ilaris <sup>®</sup>	Cryopyrin Associated Periodic Syndromes
Colchicine	Colcrys <sup>®</sup>	Gout & Mediterranean Fever
Dexlansoprazole <sup>¶</sup>	Kapidex <sup>®</sup>	GERD and Erosive Esophagitis
Dronedarone <sup>^*†</sup>	Multaq <sup>®</sup>	Atrial Fibrillation & Flutter
Ecallanotide <sup>^†</sup>	Kalbitor <sup>®</sup>	Hereditary Angioedema
Everolimus <sup>^†</sup>	Afinitor <sup>®</sup>	Cancer: Advanced Kidney Cancer
Febuxostat <sup>^</sup>	Uloric <sup>®</sup>	Gout
Fentanyl Film <sup>§¶</sup>	Onsolis	Cancer Pain
Ferumoxytol	Feraheme <sup>®</sup>	Iron Deficiency Anemia
Fibrinogen Concentrate, Human <sup>††</sup>	RiaSTAP <sup>®</sup>	Afibrinogenemia or Hypofibrinogenemia
Golimumab <sup>^†</sup>	Simponi <sup>®</sup>	Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis
Haemophilus B Conjugate Vaccine <sup>†</sup>	Hiberix <sup>®</sup>	Booster for Haemophilus B
Human Papillomavirus Vaccine <sup>†¶</sup>	Cervarix <sup>®</sup>	Prevention of Cervical Cancer
Ibuprofen Inj <sup>§</sup>	Caldolor <sup>®</sup>	Pain and Fever
Iloperidone <sup>^</sup>	Fanapt <sup>®</sup>	Schizophrenia
Immune Globulin IV <sup>†</sup>	Gammaplex <sup>®</sup>	Primary Immunodeficiency
Influenza A (H1N1) Vaccine <sup>†</sup>	Various	Prevention of "Swine Flu"
Interferon Beta-1b <sup>†</sup>	Extavia <sup>®</sup>	Multiple Sclerosis
Japanese Encephalitis Vaccine <sup>†</sup>	Ixiaro <sup>®</sup>	Prevention of Japanese Encephalitis
Lamotrigine ER <sup>§</sup>	Lamictal <sup>®</sup> XR	Partial Onset Seizures
Milnacipran <sup>^</sup>	Savella <sup>®</sup>	SSNRI for Fibrinomyalgia
Ofatumumab <sup>^††</sup>	Arzerra <sup>®</sup>	Cancer: Chronic Lymphocytic Leukemia
Olanzapine ER Inj <sup>§</sup>	Zyprexa <sup>®</sup> Relprev <sup>®</sup>	Schizophrenia
Pazopanib <sup>^</sup>	Votrient <sup>®</sup>	Cancer: Renal Cell Carcinoma
Pitavastatin <sup>^¶</sup>	Livalo <sup>®</sup>	Statin for Hypercholesterolemia
Pralatrexate <sup>^†</sup>	Foloty <sup>®</sup>	Cancer: Peripheral T-Cell Lymphoma
Prasugrel <sup>^*†</sup>	Effient <sup>®</sup>	Prevention of Thrombosis
Romidepsin <sup>^</sup>	Istodax <sup>®</sup>	Cancer: Cutaneous T-Cell Lymphoma
Saxagliptin <sup>^</sup>	Onglyza <sup>®</sup>	Type 2 Diabetes
Sildenafil Inj <sup>§</sup>	Revatio <sup>®</sup>	Pulmonary Arterial Hypertension
Tadalafil <sup>§</sup>	Adcirca <sup>®</sup>	Pulmonary Arterial Hypertension
Telavancin <sup>^</sup>	Vibativ <sup>®</sup>	Anti-Infective: Gram Positive Skin Infections
Telbivudine <sup>^</sup>	Tyzeka <sup>®</sup>	Anti-Infective: Hepatitis B
Temozolomide Inj <sup>§</sup>	Temodar <sup>®</sup>	Cancer: Glioblastoma Multiforme & Astrocytoma
Tolvaptan <sup>^</sup>	Samsca <sup>®</sup>	Hyponatremia
Tranexamic Acid <sup>§†</sup>	Lysteda <sup>®</sup>	Cyclic Heavy Menstrual Bleeding
Treprostinil Inhaled <sup>§</sup>	Tyvaso <sup>®</sup>	Pulmonary Arterial Hypertension
Ustekinumab <sup>^†</sup>	Stelara <sup>®</sup>	Severe Plaque Psoriasis
Vigabatrin <sup>^†</sup>	Sabril <sup>®</sup>	Infantile Spasms
Zolpidem Sublingual <sup>§¶</sup>	Elduar <sup>®</sup>	Hypnotic

SSNRI = selective serotonin-norepinephrine reuptake inhibitor, GERD = nonerosive gastrointestinal esophageal reflux disease

<sup>^</sup>New Molecular Entities (NMEs)

<sup>\*</sup>Listed in the Formulary

<sup>†</sup>Biological

<sup>†</sup>Priority Review

<sup>§</sup>New Dosage Form or Indication

<sup>¶</sup>Nonformulary and not available

# Drugs & Therapy

B · U · L · L · E · T · I · N

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## NEWS

# Brand name drug prices rise nearly 10%

According to the November 16, 2009, issue of the *New York Times*, wholesale prices of brand-name prescription drugs increased by about 9% last year. It is estimated that over \$300 billion was spent on drugs during this time. The average annual cost of a brand-name drug increased to more than \$2000 per year. This occurred while the consumer price index fell by 1.3%

Brand name manufacturers say they have valid reasons for this major increase (ie, need for research and development as major patents expire), and that the use of these drugs offset other expenses (ie, decreased hospitalization, decreased procedures, and increased productivity). Critics claim that they are trying to establish a higher base price before any healthcare reform legislation occurs. A similar increase in prices was noted before Medicare Part D extended prescription benefits to patients on Medicare.

Rising costs are important to patients who have to pay an increasing share of these costs in rising copays. Many patients could not afford these medications, if they had to pay entirely out of

their pocket. Thus, generic alternatives remain a viable option. More and more drugs have generic alternatives in the same class.

The same *New York Times* article estimates that the price of generic drugs fell about 9% last year. Patients' out-of-pocket expenses can be mini-

mized by accessing the many \$4-per-month (\$10-per-3-months) programs. With the increasing costs of medications, it is more important than ever to ask patients if they have difficulty paying for their medications. High costs can be associated with patients not adhering to their treatment plan.

## Drug information questions?

Contact the Drug Information Service



Call 265-0408



Or submit your question online at  
[www.shands.org/professionals/druginfo/default.asp](http://www.shands.org/professionals/druginfo/default.asp)

- This service is for referring physicians and other healthcare professionals taking care of Shands patients
- Phones are staffed from 9 am to 4:30 pm, Monday – Friday
- All answers are thoroughly researched and referenced

*For emergent questions that do not need thorough research, go to the pharmacy servicing your area.*