

INSIGHT



VOLUME 2 ISSUE 3

THE VALUE OF PHARMACISTS AS PART OF A COMPREHENSIVE HEALTH TEAM

A pharmacist can add significant value as part of a comprehensive health plan for patients. The pharmacist's value has been accepted in general terms by the health care professionals and patients alike. However, in order to provide concrete evidence, the trial described below was conducted to show their value in a specific situation. In controlling blood pressure, various small trials of different designs have provided the hypothesis for this trial that the addition of a clinical pharmacist can significantly improve a patient's chance of achieving goals.

A randomized trial led by Barry L. Carter, Pharm.D, of the University of Iowa, evaluated whether a physician and pharmacist collaborative model in community-based medical offices could improve blood pressure control. The trial enrolled 402 patients at six Iowa medical offices and was performed over six months. All pharmacists who were engaged in the study held doctor of pharmacy (Pharm.D.) degrees and completed pharmacy residencies in primary care. Clinical pharmacists recommended drug

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therapy to physicians based on national guidelines, while research nurses conducted BP readings and 24-hour BP observations. The study established that the intervention pharmacists made 771 recommendations, of which 742 (96.2%) were accepted by physicians.¹

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SUMMER SUN SAFETY



Summer is one of the most energetic times of the year with most people spending a significantly greater amount of time outdoors. Popular summer activities include gardening, swimming, biking, and hiking. The increased time spent outside reinforces the need for sun safety. The Sun can have a variety of effects on the skin including suntan, sunburn, and sun damage. Many visible skin changes commonly attributed to aging are actually caused by the Sun.¹ Sun exposure can also be associated with more serious problems, such as skin

cancer. The Skin Cancer Foundation reports that more than 1 million skin cancers are diagnosed each year making it the most common form of cancer in the United States.¹ Approximately 20% of Americans will develop skin cancer during their lifetime.¹

Despite these ominous statistics, some precautions can help protect against the harmful effects of the Sun. One of the simplest steps is to avoid the Sun during

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SUMMER SUN SAFETY

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the middle of the day. The Sun's energy is greatest between the hours of 10 a.m. and 4 p.m. so staying out of the Sun during these hours can reduce the Sun's harmful effects.² Another simple precaution is to cover your skin while outdoors. A hat and sunglasses can help protect the head, face, and eyes and light-colored clothing can help protect the body.

Sunscreen is another way to help protect the skin. Broad-spectrum sunscreens that block both ultraviolet A and ultraviolet B rays can provide the best protection. Sunscreens are available in a large variety of preparations that can vary in the application (lotion, gel, cream, or spray) and Sun Protection Factor (SPF). The SPF is a number that indicates the length of time a person can spend in the sun without risk of burning.² For example an SPF of 15 means that a fair-skinned person who normally burns in 20 minutes of midday Sun exposure may tolerate 15 times 20 minutes (300 minutes) without burning.² The higher the SPF number the greater the protection provided.³ The American Academy of Dermatology recommends applying sunscreen 30 minutes before sun exposure and reapplying it every two hours, even on cloudy days.³ Sunscreen may need to be reapplied more often if swimming or excessive sweating occurs. It is always very important to follow the product's specific instructions since individual products may have different directions for use.

As you spend time outdoors this summer, take a few extra minutes to ensure that your skin is protected from the sun. Following a few simple precautions can help keep your skin healthy and reduce your chance of sun damage.

References:

1. Skin Cancer Foundation website. Available at www.skincancer.org Viewed June 1, 2010.
2. American Academy of Dermatology [sun protection for children] Available at www.aad.org/public/publications/pamphlets/sun_sunprotection.html. Viewed June 1, 2010.
3. American Academy of Dermatology [sunscreens/sunblocks] Available at www.aad.org/public/publications/pamphlets/sun_sunscreens.html. Viewed June 1, 2010.

THE VALUE OF PHARMACISTS AS PART OF A COMPREHENSIVE HEALTH TEAM

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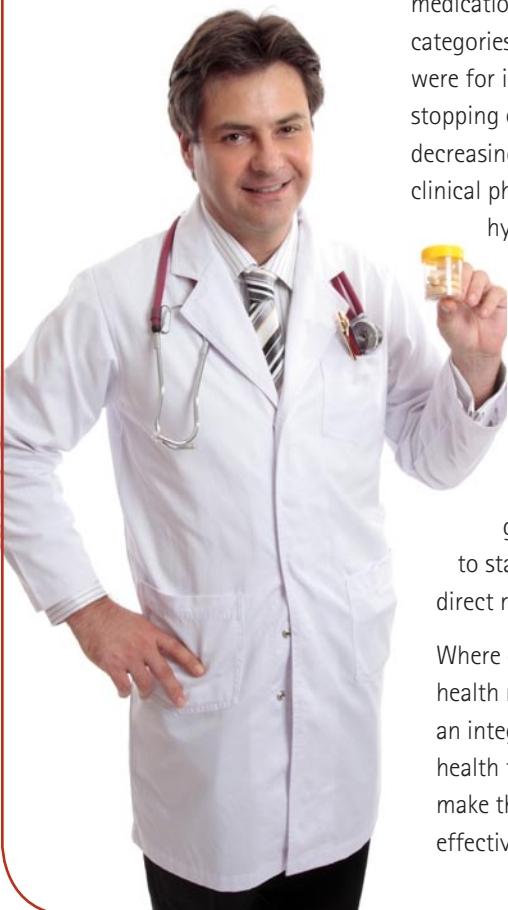
The result was 1,139 documented antihypertensive medication changes broken down into the following categories: 49.3% were for new therapy, 29.2% were for increasing dosages, 17.1% were for stopping current therapy, and 4.3% were for decreasing drug dosages. The recommendations of clinical pharmacists for patients with uncontrolled hypertension resulted in controlled blood pressure for 63.9% of intervention group patients, compared to 29.9% of control group patients. Hence, this approach more than doubled the number of patients with improved hypertension, compared with monotherapy by traditional family medicine. The research group that conducted this trial went on to state that pharmacists should have a more direct role in patient care.

Where drug therapy is an integral part of patient's health management, a pharmacist needs to be an integral part of that patient's comprehensive health team. Pharmacists' years of training make them "walking encyclopedias" on drug effectiveness, side effects, and interactions.²

"In terms of the number of hours spent studying drug effectiveness, pharmacists are better trained than physicians," says Julie Donohue, an associate professor of health policy and management at the University of Pittsburgh. Furthermore, pharmacists can help patients to get the most from their medications, to better handle side effects, to avoid interactions, and even to save money. While the model involving physicians and pharmacists cannot be formally conducted in many settings, it can be developed as the physician educates his or her patients about the importance of including a pharmacist in patient care. Similarly, pharmacists can make themselves available as a valuable tool in comprehensive health care by developing a relationship with both patients and providers. When clinical teamwork includes physicians, pharmacists, and open lines of communication, the results can be better overall health care for the patient.

References:

1. Carter BL, Ardery G, Dawson JD, et al. "Physician and pharmacist collaboration to improve blood pressure control," *Arch Intern Med.* 2009; 169:1996-2002.
2. Ravn, Karen. "Pharmacists an under-used part of health care," *Chicago Tribune*, January 31, 2010, <www.chicagotribune.com/health/sc-health-0127-pharmacist-20100129,0,3384978,full.story>.



PROPER DISPOSAL OF PRESCRIPTION DRUGS: IS FLUSHING SAFE?



Pharmaceuticals play an essential role in treating health conditions and diseases; however, they may cause harm if used by individuals other than the intended patient.¹ Most drugs can be disposed of in household trash, but the U.S. Food and Drug Administration (FDA) says that consumers should take precautions when doing so. The White House Office on National Drug Control Policy, in collaboration with the FDA, has developed guidelines that provide recommendations for discarding medications.²

Check the drug labeling and patient information accompanying the medication for specific disposal instructions. Drugs should be flushed down toilets only if recommended in these instructions.² This disposal method is prohibited for most pharmaceuticals. The chart at right from the FDA lists drugs that may be poured down the sink or toilet to prevent danger to people in the home. The FDA continually evaluates medications for safety risks and will update this list as needed.¹

About a dozen drugs, mainly powerful narcotic pain relievers and other controlled substances, have instructions for flushing to reduce the risk of accidental ingestion. Despite the safety reasons for flushing drugs, some question the practice due to trace levels of pharmaceuticals found in the water system. Raanan Bloom, Ph.D., an environmental assessment expert at the FDA's Center for Drug Evaluation and Research, explains that the majority of medicines found in water systems are a result of people naturally passing them through their bodies. In addition, according to the Environmental Protection Agency, scientists have found no evidence of harmful human health effects from drugs in the environment.² The FDA has determined that the drugs it deems safe for flushing pose little human and environmental risk compared to the benefit of preventing accidental ingestion.¹

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MEDICATIONS RECOMMENDED FOR DISPOSAL BY FLUSHING

MEDICINE	ACTIVE INGREDIENT
Actiq , oral transmucosal lozenge	fentanyl citrate
Avinza , capsules (extended release)	morphine sulfate
Daytrana , transdermal patch system	methylphenidate
Demerol , tablets*	meperidine hydrochloride
Demerol , oral solution*	meperidine hydrochloride
Diastat/Diastat AcuDial , rectal gel	diazepam
Dilaudid , tablets*	hydromorphone hydrochloride
Dilaudid , oral liquid*	hydromorphone hydrochloride
Dolophine hydrochloride , tablets*	methadone hydrochloride
Duragesic , patch (extended release)*	fentanyl
Embeda , capsules (extended release)	morphine sulfate; naltrexone hydrochloride
Fentora , tablets (buccal)	fentanyl citrate
Kadian , capsules (extended release)	morphine sulfate
Methadone hydrochloride , oral solution*	methadone hydrochloride
Methadose , tablets*	methadone hydrochloride
Morphine sulfate , tablets (immediate release)*	morphine sulfate
Morphine sulfate , oral solution*	morphine sulfate
MS Contin , tablets (extended release)*	morphine sulfate
Onsolis , soluble film (buccal)	fentanyl citrate
Opana , tablets (immediate release)	oxymorphone hydrochloride
Opana ER , tablets (extended release)	oxymorphone hydrochloride
Oramorph SR , tablets (sustained release)	morphine sulfate
Oxycontin , tablets (extended release)*	oxycodone hydrochloride
Percocet , tablets*	acetaminophen; oxycodone hydrochloride
Percodan , tablets*	aspirin; oxycodone hydrochloride
Xyrem , oral solution	sodium oxybate

*These medicines have generic versions available or are available only in generic formulations. List revised: August 2009

FUTURESCRIPTS CLIENT CORNER

As your pharmacy benefits manager (PBM), FutureScripts is committed to helping you effectively manage your prescription drug spending while ensuring clinical safety for your employees. We'd like to take this opportunity in the FutureScripts Client Corner to highlight the benefit of some of the value-added programs we offer you and your employees.

PRIOR AUTHORIZATION

Ensuring clinical safety

Prior authorization is a management tool that helps ensure that the drug being prescribed for your employee is medically necessary and appropriate, is being prescribed according to U. S. Food and Drug Administration guidelines, and is being prescribed with the approval of the FutureScripts Pharmacy & Therapeutics Committee. Using these criteria, clinical pharmacists evaluate requests for certain drugs based on clinical data, on information submitted by the member's prescribing physician, and on the member's available prescription drug therapy history. Their review also considers drug interactions or contraindications; whether the dose and length of therapy are appropriate; and, if other drug therapies were utilized, if necessary.

The prior authorization process may take up to two business days, which may span a weekend. For this reason, a 96-hour temporary supply is available for most medications that require prior authorization. Some medications are not eligible due to packaging or other limitations, such as age limits and/or quantity level limits.

VALUE-BASED PRESCRIPTION DRUG PLANS

Improving health outcomes for high-risk members

Value-based prescription drug (Rx) plans either waive or reduce the copayment on generic prescriptions used to treat chronic diseases, with the goal of increasing medication compliance and reducing overall medical costs. Value-based drug plans are becoming more popular among employers and more prevalent across the PBM marketplace. Value-based drug plans are designed to make prescription drugs more affordable for members with chronic health conditions. By lowering the members' out-of-pocket costs and making more affordable maintenance medications available, members are more likely to adhere to their prescription drug protocols for their specific chronic health conditions. Common conditions we target include:

- asthma/COPD
- diabetes
- cardiovascular/heart disease
- depression

As medication compliance increases, health outcomes should improve, and preventable hospitalizations associated with these conditions, especially emergency room visits, should decrease, reducing overall health care costs.

FUTURESCRIPTS DIRECT SHIP SPECIALTY PHARMACY

Added convenience plus 24/7 clinical support

Specialty Pharmacy refers to a pharmacy that provides self-injectables and certain oral specialty medications that can be administered at home or in a physician's office. These complex and costly medications usually require special storage and handling, and may not be readily available at the member's local drugstore. With the FutureScripts Direct Ship Specialty Pharmacy Program, your employees' specialty medications are delivered to their homes or physicians' offices. Members have 24/7 access to our clinical staff, who are available to answer any questions about specialty medications the member is taking. With the FutureScripts Direct Ship Specialty Pharmacy Program, your employees have easy access to the following benefits:

- 24/7 medication counseling;
- educational materials;
- confidential and convenient order and delivery;
- refill reminder service.

The FutureScripts Direct Ship Specialty Pharmacy Program offers your employees a single, reliable source for their specialty medication needs and helps decrease the overall expense associated with these high-cost medications.

As always, we welcome your ideas and suggestions for programs that will help you and your employees get the most out of your FutureScripts prescription drug coverage. Contact your FutureScripts client manager with your suggestions.

NEW GENERIC DRUGS RECENTLY APPROVED BY THE FDA

OCTOBER 2009

Buprenorphine hydrochloride sublingual tablets

Approved: October 8, 2009
Generic manufacturer: Roxane Laboratories, Inc.
Generic for: Suboxone®

NOVEMBER 2009

Ketorolac tromethamine ophthalmic solution 0.5%

Approved: November 5, 2009
Generic manufacturer: Akorn Inc.; Sun Pharma Global, Inc.
Generic for: ACULAR® ophthalmic solution

Ketorolac tromethamine ophthalmic solution 0.4%

Approved: November 5, 2009
Generic manufacturer: Apotex Inc.; Alcon Inc.; Akorn Inc.
Generic for: ACULAR LS® ophthalmic solution

Norethindrone acetate and ethinyl estradiol tablets USP, 1 mg/0.005 mg

Approved: November 6, 2009
Generic manufacturer: Barr Laboratories, Inc.
Generic for: Femhrt® tablets 1 mg/0.005 mg

Lansoprazole delayed-release capsules USP, 15 mg and 30 mg

Approved: November 10, 2009
Generic manufacturer: Teva Pharmaceuticals USA; Matrix Laboratories Limited
Generic for: PREVACID® delayed-release capsules

Perindopril erbumine tablets 2 mg, 4 mg, and 8 mg

Approved: November 10, 2009
Generic manufacturer: Aurobindo Pharma Limited; Roxane Laboratories, Inc.; IVAX Pharmaceuticals, Inc.
Generic for: ACEON® tablets

Tramadol hydrochloride extended-release tablets, 100 mg and 200 mg

Approved: November 13, 2009
Generic manufacturer: Par Pharmaceutical, Inc.
Generic for: ULTRAM® ER tablets, 100 mg and 200 mg

Nizatidine oral solution 15 mg/mL

Approved: November 18, 2009
Generic manufacturer: Amneal Pharmaceuticals
Generic for: AXID® oral solution

DECEMBER 2009

Donepezil hydrochloride orally disintegrating tablets 5 mg and 10 mg

Approved: December 11, 2009
Generic manufacturer: URL Pharma, Inc.
Generic for: ARICEPT® ODT

FEBRUARY 2010

Desloratadine tablets, 5 mg

Approved: February 19, 2010
Generic manufacturer: Orchid Healthcare
Generic for: CLARINEX®

Imiquimod cream 5%

Approved: February 25, 2010
Generic manufacturer: Nycomed US, INC.
Generic for: Aldara® cream

PROPER DISPOSAL OF PRESCRIPTION DRUGS: IS FLUSHING SAFE?

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Unused or expired medications that cannot be flushed down the toilet should be disposed of in household trash. Such drugs should be removed from packaging and mixed with an undesirable substance such as used coffee grounds or kitty litter, which make the medication less appealing and recognizable. This mixture should then be placed in a sealable bag or a small, lidded can to prevent leakage while in the garbage.²

Another secure way of removing unused or expired medicines from the home is to bring them to community drug take-back programs.³ These programs collect drugs from the public at a central location for appropriate disposal.² Contact city or county government household trash and recycling services for details about local drug take-back programs.³

FDA Director of Pharmacy Affairs Ilisa Bernstein, Pharm.D., J.D., provides additional tips for medication disposal, including

scratching out all identifying information on prescription labeling before disposal in order to protect a patient's health information. She advises patients against sharing medications with their friends, and cautions that a drug safely prescribed for one person may be dangerous to someone else. Finally, Bernstein recommends asking a pharmacist any remaining questions about proper disposal methods.²

References:

1. Food and Drug Administration, "Disposal by Flushing of Certain Unused Medicines: What You Should Know," <<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>>, viewed on February 12, 2010.
2. Food and Drug Administration, "How to Dispose of Unused Medications," <<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm#GuidelinesforDrugDisposal>>, viewed on February 12, 2010.
3. Office of National Drug Control Policy, "Proper Disposal of Prescription Drugs". Available at: <www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf>, viewed on February 16, 2010.

NEW BRAND DRUGS RECENTLY APPROVED BY THE FDA

Folotyn™ (pralatrexate) injection

Date of approval: September 24, 2009

Company: Allos Therapeutics, Inc.

Description: A folate analogue metabolic inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)

STELARA™ (ustekinumab) injection

Date of approval: September 25, 2009

Company: Centocor Ortho Biotech Inc.

Description: A human monoclonal antibody for the treatment of moderate to severe plaque psoriasis

TWYNSTA® (telmisartan and amlodipine) tablets

Date of approval: October 16, 2009

Company: Boehringer Ingelheim Pharmaceuticals Inc.

Description: An angiotensin II receptor blocker (ARB) and a dihydropyridine calcium channel blocker (DHP-CCB) combination product indicated for use alone or with other antihypertensive agents for treatment of hypertension

Votrient™ (pazopanib) tablets

Date of approval: October 19, 2009

Company: GlaxoSmithKline

Description: A kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma

ARZERRA™ (ofatumumab) injection

Date of approval: October 26, 2009

Company: GlaxoSmithKline

Description: A CD20-directed cytolytic monoclonal antibody indicated for the treatment of patients with chronic lymphocytic leukemia

Pennsaid® (diclofenac sodium) topical solution

Date of approval: November 4, 2009

Company: Nuvo Research Inc.

Description: A topical non-steroidal anti-inflammatory drug (NSAID) used for the treatment of signs and symptoms of osteoarthritis of the knee

ISTODAX® (romidepsin) for injection

Date of approval: November 5, 2009

Company: Gloucester Pharmaceuticals

Description: A histone deacetylase (HDAC) inhibitor indicated for the treatment of cutaneous T-cell lymphoma

LYSTEDA™ (tranexamic acid) tablets

Date of approval: November 13, 2009

Company: Xanodyne Pharmaceuticals, Inc.

Description: An antifibrinolytic agent for the treatment of women with menorrhagia, heavy menstrual bleeding, and its accompanying symptoms

Qutenza® (capsaicin) transdermal patch

Date of approval: November 16, 2009

Company: NeurogesX, Inc.

Description: A capsaicin transdermal patch for the management of pain due to postherpetic neuralgia

Revatio™ (sildenafil citrate) injection

Date of approval: November 18, 2009

Company: Pfizer Inc.

Description: Only FDA-approved phosphodiesterase-5 (PDE5) inhibitor available in both tablet and intravenous formulations indicated for the treatment of adult patients with pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening

AGRIFLU® (influenza virus vaccine, inactivated) injection

Date of approval: November 27, 2009

Company: Novartis Vaccines and Diagnostics, Inc.

Description: A vaccine indicated for the active immunization of adults 18 and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine

ZEGERID OTC™ (omeprazole and sodium bicarbonate) capsules

Date of approval: December 1, 2009

Company: Merck & Co. and Santarus Inc.

Description: Zegerid OTC (omeprazole and sodium bicarbonate) is an over-the-counter version of the prescription heartburn drug Zegerid

KALBITOR® (ecallantide) injection

Date of approval: December 1, 2009

Company: Dyax Corp.

Description: A plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema in patients 16 and older

Wilate® (von Willebrand Factor/Coagulation Factor VIII Complex (Human)) injection

Date of approval: December 4, 2009

Company: Octapharma USA

Description: A von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease

Zyprexa® Relprevv™ (olanzapine) for extended-release injectable suspension

Date of approval: December 11, 2009

Company: Eli Lilly and Company

Description: A long-acting atypical antipsychotic for intramuscular injection indicated for the treatment of schizophrenia

ACTEMRA® (tocilizumab) injection

Date of approval: January 8, 2010

Company: Genentech USA, Inc.

Description: A humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment of moderate to severe rheumatoid arthritis in adults

NEW BRAND DRUGS RECENTLY APPROVED BY THE FDA

AMPYRA™ (dalfampridine) extended-release tablets

Date of approval: January 22, 2010

Company: Acorda Therapeutics, Inc.

Description: An oral potassium channel blocker indicated to improve walking ability in people with multiple sclerosis

Victoza® (liraglutide) injection

Date of approval: January 25, 2010

Company: Novo Nordisk A/S

Description: A glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

OLEPTRO™ (trazodone) extended-release tablets

Date of approval: February 2, 2010

Company: Labopharm Inc.

Description: A once-daily serotonin antagonist reuptake inhibitor (SARI) formulation for the treatment of major depressive disorder (MDD) in adults

XIAFLEX™ (collagenase clostridium histolyticum)

Date of approval: February 3, 2010

Company: BioSpecifics Technologies Corp.

Description: A collagenase product for the treatment of Dupuytren's contracture, a condition that affects the connective tissue that lies beneath the skin in the palm

MIRAPEX® (pramipexole dihydrochloride)

Date of approval: February 19, 2010

Company: Boehringer Ingelheim Pharmaceuticals, Inc.

Description: A new once-daily treatment option for the signs and symptoms of early idiopathic Parkinson's disease

Menveo® (meningococcal conjugate vaccine)

Date of approval: February 19, 2010

Company: Novartis Vaccines and Diagnostics

Description: A vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135

Cayston® (aztreonam lysine) inhalation solution

Date of approval: February 22, 2010

Company: Gilead Sciences, Inc.

Description: An inhaled anti-pseudomonal therapy for people with cystic fibrosis who have pulmonary *Pseudomonas aeruginosa* infection

Pevnar 13™ (pneumococcal 13-valent conjugate vaccine)

Date of approval: February 24, 2010

Company: Wyeth Pharmaceuticals Inc.

Description: A vaccine indicated for active immunization against invasive pneumococcal disease in infants and young children

VPRIV™ (velaglucerase alfa) for injection

Date of approval: February 26, 2010

Company: Shire plc

Description: A hydrolytic lysosomal glucocerebrosidase-specific enzyme indicated for long-term enzyme replacement therapy for pediatric and adult patients with Type 1 Gaucher disease

EXALGO™ (hydromorphone) extended-release tablets

Date of approval: March 1, 2010

Company: Covidien

Description: A once-a-day, extended-release opioid formulation for the management of moderate to severe pain in opioid-tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time

Hizentra™ (immune globulin subcutaneous (human))

Date of approval: March 4, 2010

Company: CSL Behring

Description: An immune globulin subcutaneous (human), 20% liquid indicated for the treatment of primary immunodeficiency

NEW FDA INDICATIONS FOR EXISTING DRUGS

Mirena® (levonorgestrel)

Description: Mirena was approved as a contraceptive by the U.S. Food and Drug Administration (FDA) in 2000. It is a small, flexible hormone-releasing device inserted into the uterus by a trained health care professional to prevent pregnancy.

New indication approved: October 1, 2009

New indication: The FDA approved Mirena (levonorgestrel intrauterine system) to treat heavy menstrual bleeding in women who use intrauterine contraception as their method of pregnancy prevention. This is the first intrauterine device approved by the FDA for this additional indication.

WelChol® (colesevelam HCl)

Description: WelChol is indicated as an adjunct to diet and exercise to improve both glycemic control in adults with type 2 diabetes mellitus and to reduce elevated LDL cholesterol in adults with primary hyperlipidemia (Fredrickson Type IIa), alone or in combination with a statin.

New indication approved: October 2, 2009

New indication: Received FDA approval to lower LDL cholesterol in pediatric patients with heterozygous familial hypercholesterolemia.

Crestor® (rosuvastatin calcium)

Description: Crestor is indicated as an adjunct to diet to reduce elevated Total-C, LDL-C, ApoB, non-HDL-C, and TG levels and to increase HDL-C in patients with primary hyperlipidemia and mixed dyslipidemia.

New indication approved: October 15, 2009

New indication: The FDA approved Crestor (rosuvastatin calcium) for use in pediatric patients 10 to 17 with heterozygous familial hypercholesterolemia (HeFH) when diet therapy fails to reduce elevated cholesterol.

Gardasil® (human papillomavirus quadrivalent (types 6, 11, 16, and 18) vaccine, recombinant)

Description: Astepro (azelastine) is a nasal antihistamine for the treatment of seasonal and perennial allergic rhinitis.

New indication approved: October 16, 2009

New indication: The FDA has approved Gardasil [human papillomavirus quadrivalent (Types 6, 11, 16, and 18) vaccine, recombinant] for use in boys and men 9 to 26 years of age for the prevention of genital warts caused by human papillomavirus (HPV) types 6 and 11.

Elitek® (rasburicase)

Description: A recombinant urate oxidase enzyme, Elitek was initially approved by U.S. Food and Drug Administration (FDA) in 2002 to manage PUA levels in pediatric patients receiving anti-cancer treatment and at risk for tumor lysis syndrome (TLS).

New indication approved: October 16, 2009

New indication: The FDA has granted marketing approval for Elitek (rasburicase) to be used for the initial management of plasma uric acid (PUA) levels in adult patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in TLS and subsequent elevations of plasma uric acid.

Micardis® (telmisartan)

Description: Micardis is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

New indication approved: October 16, 2009

New indication: The FDA approved angiotensin II receptor blocker (ARB), Micardis (telmisartan) 80 mg tablets for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 or older at high risk of developing major cardiovascular events and who are unable to take angiotensin-converting enzyme (ACE) inhibitors.

Colcryls® (colchicine)

Description: Colcryls is an oral, branded form of colchicine that has been formulated for optimal efficacy and tolerability. It was first approved by the FDA on July 30, 2009, for the treatment of acute gout flares when taken at the first sign of a flare.

New indication approved: October 19, 2009

New indication: The FDA has approved Colcryls (colchicine, USP) for the prophylaxis (prevention) of gout flares.

Byetta® (exenatide)

Description: Glucagon-like peptide-1 (GLP-1) receptor agonist with approval for use only in patients who were also taking other common diabetes medications and had not achieved adequate glycemic control.

New indication approved: November 2, 2009

New indication: Byetta is now approved for use as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes.

Influenza A (H1N1) 2009 Monovalent Vaccine (H1N1 influenza virus vaccine)

Description: This vaccine was previously approved only for use in adults, 18 and older.

New indication approved: November 2, 2009

New indication: The FDA has approved the use of the CSL Limited's 2009 H1N1 influenza vaccine to include children 6 months and older.

Abilify® (aripiprazole)

Description: Abilify is indicated for bipolar disorder, schizophrenia, and major depressive disorder.

New indication approved: November 19, 2009

New indication: The FDA has approved Abilify (aripiprazole) for the treatment of irritability associated with autistic disorder in pediatric patients 6 to 17 years of age. Included are symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods.

NEW FDA INDICATIONS FOR EXISTING DRUGS

Cymbalta® (duloxetine)

Description: Cymbalta is approved for the acute and maintenance treatment of major depressive disorder, the management of diabetic peripheral neuropathic pain and fibromyalgia, and the acute treatment of generalized anxiety disorder.

New indication approved: November 30, 2009

New indication: The FDA has approved Cymbalta (duloxetine HCl) for the maintenance treatment of generalized anxiety disorder (GAD) in adults.

Seroquel XR® (quetiapine)

Description: Seroquel XR, a once-daily, extended-release formulation of quetiapine fumarate, was approved in the US in 2007 for the treatment of schizophrenia in adult patients and in October 2008 for the acute treatment of the depressive episodes associated with bipolar disorder, the manic and mixed episodes associated with bipolar I disorder, and the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex.

New indication approved: December 2, 2009

New indication: The FDA has approved once-daily Seroquel XR (quetiapine fumarate) Extended Release Tablets as adjunctive (add-on) treatment to antidepressants in adults with Major Depressive Disorder (MDD).

Zyprexa® (olanzapine)

Description: Zyprexa is indicated in adults in the United States for the treatment of schizophrenia, acute treatment of mixed and manic episodes of bipolar I disorder, and maintenance treatment of bipolar I disorder.

New indication approved: December 14, 2009

New indication: Zyprexa (olanzapine) in tablet form received approval as an option for the treatment of schizophrenia and manic or mixed episodes associated with bipolar I disorder in adolescents 13 to 17 years of age.

Spiriva® HandiHaler® (tiotropium bromide)

Description: Spiriva HandiHaler is already approved by the FDA as a once-daily maintenance treatment for breathing problems associated with COPD, which includes chronic bronchitis, emphysema, or both.

New indication approved: December 17, 2009

New indication: The FDA approved Spiriva HandiHaler (tiotropium bromide inhalation powder) for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Tykerb® (lapatinib ditosylate)

Description: Tykerb was already indicated in combination with Xeloda (capecitabine) for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.

New indication approved: January 29, 2010

New indication: Tykerb is now indicated in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor and for whom hormonal therapy is indicated.

Crestor® (rosuvastatin calcium)

Description: Crestor is indicated as an adjunct to diet to reduce elevated Total-C, LDL-C, ApoB, non-HDL-C, and TG levels and to increase HDL-C in patients with primary hyperlipidemia and mixed dyslipidemia. Crestor is also indicated as an adjunct to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C.

New indication approved: February 8, 2010

New indication: The FDA has approved Crestor (rosuvastatin calcium) to reduce the risk of stroke, myocardial infarction (heart attack) and arterial revascularization procedures in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease.

Benicar® (olmesartan medoxomil)

Description: Benicar is a member of the ARB class of antihypertensive medications that help lower blood pressure and was approved in 2002 for the treatment of hypertension in adults.

New indication approved: February 4, 2010

New indication: The FDA has approved the hypertension treatment Benicar (olmesartan medoxomil) for use in children and adolescents 6 to 16 years of age.

Rituxan® (rituximab)

Description: Rituxan is a monoclonal antibody and binds to the surface of cancer cells, making it easier for the patient's immune system to attack the cancer cell as if it were a foreign pathogen. It has indications to treat Non-Hodgkin's Lymphoma (NHL) and rheumatoid arthritis (RA).

New indication approved: February 18, 2010

New indication: Rituxan (rituximab) received approval to treat certain patients with chronic lymphocytic leukemia (CLL), a slowly progressing blood and bone marrow cancer.

Botox® (onabotulinumtoxinA)

Description: Botox is a prescription-only medical product that contains tiny amounts of highly purified botulinum toxin protein refined from the bacterium *Clostridium botulinum* and has received 21 different indications in approximately 80 countries.

New indication approved: March 10, 2010

New indication: The FDA has approved Botox (onabotulinumtoxinA) for the treatment of increased muscle stiffness in the elbow, wrist, and fingers in adults with upper limb spasticity.

PRESCRIPTION DRUG ABUSE ON THE RISE

Pain medications encompass a wide variety of drugs, including morphine, oxycodone, hydromorphone, methadone, and hydrocodone. When used properly, they can provide pain relief for many patients, including those suffering from rheumatoid arthritis, cancer, and traumatic injuries. When used improperly or abused, however, these medications can be extremely dangerous and can result in overdoses, hospitalizations, and death. The national use of prescription painkillers has increased dramatically over the past several years with the number of overdoses also increasing. Between 1999 and 2006, the number of poisoning deaths in the United States nearly doubled, from approximately 20,000 to 37,000, largely because of overdose deaths involving prescription opioid painkillers.¹

The abuse of pain medications is a growing problem among all age groups, including children. A survey funded by the National Institute on Drug Abuse reported that approximately 1 in 10 high school seniors reported nonmedical use of Vicodin® (hydrocodone/apap) within the past year and that 1 in 20 abused Oxycontin® (oxycodone ER). Another study showed that the number of individuals 12 and older who

abused prescription pain medications for the first time was roughly even with the use of marijuana.²

Individuals can obtain these medications from many sources, including friends, family members, and drug dealers. For example, the National Institute on Drug Abuse found that 12th graders who abused drugs often got the drugs from a friend or relative. In fact, more than half of all instances of abuse involved a friend or relative supplying the drugs.³

The abuse of pain medications is a concern that needs to be kept on the radar of patients, prescribers, pharmacists, and other health care professionals. Here are several precautions that can help minimize the risk of drug abuse:

- Medications should never be shared with or given to individuals for whom they have not been prescribed.
- Pain medications should be kept in a safe location out of the reach of children or kept in a lock box to prevent theft or unauthorized use.
- "Opioid contracts" may be implemented between a provider and a patient for

whom pain medications are prescribed. Opioid contracts are intended to improve care and may provide specific rules and regulations surrounding a patient's behavior, such as limiting patients from seeing other prescribers or using multiple pharmacies.⁴ Opioid contracts may also require patients to submit to random drug tests.

Although prescription medication abuse is a major concern, it is important to know that there are options for individuals who are abusing medications. Individuals can always speak with their physician or pharmacist to discuss the situation. Treatment centers are also available to help individuals who are abusing medications. Treatment centers can be located at the Substance Abuse and Mental Health Services Administration website at <http://findtreatment.samhsa.gov/>.⁵

References:

1. Centers for Disease Control, <www.cdc.gov>, viewed on February 4, 2010.
2. Colten M., "Opioid contracts and random drug testing for people with chronic pain – Think twice," *Journal of Law Medicine and Ethics*, Winter 2009, 841-845.
3. Facts and Comparisons <www.factsandcomparisons.com>, viewed on February 4, 2010.
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