P.R.N.

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What's Inside…

FDA Renews Warning On Fentanyl Patches

The FDA has updated its previous warning regarding reports of death and life-threatening adverse events related to the use of fentanyl transdermal systems, such as Duragesic®. Patients and providers should be aware of the following :

Fentanyl patches are indicated for *chronic* pain in *opioid-tolerant* patients *only*. Opioid-tolerant patients are those who have been taking at least 60 mg morphine, 30 mg oxycodone, or 8 mg hydromorphone daily for at least 1 week.

Heat can increase the amount of fentanyl released. Patients should not use heating pads, electric blankets, or saunas. Hot baths and sunbathing should be avoided.

Patches that have been cut, damaged, or changed in any way *should not be used*, as they may expose patients to dangerous levels of fentanyl.

**********RX NEWS**********

Carbamazepine Warning Revised: The FDA has updated the labeling for all products containing **carbamazepine**, which include **Tegretol**, **Carbatrol**, **Equetro**, and generic formulations. The boxed warning will recommend that patients of Asian ancestry be tested for the presence of a particular human leukocyte antigen (HLA) allele, known as HLA-B*1502, which has been associated with an increased risk of developing the serious, potentially fatal, skin reactions Stevens Johnson syndrome and toxic epidermal necrolysis. This allele is believed to occur in at least 10 to 15% of patients from parts of China, Thailand, Malaysia, Indonesia, Taiwan, and the Phillipines. A lesser prevalence, 2 to 4%, appears in South Asian populations, including Indians. There is an even lower frequency, less than 1%, in Japan and Korea. Those who test positive for the allele should not be prescribed any form of carbamazepine unless the benefit clearly outweighs the risk.

New Beta Blocker Approved: Forest Laboratories has received approval to market **Bystolic** (nebivolol), a third-generation beta blocker indicated for use in the treatment of hypertension, either alone or in combination with other antihypertensives. In addition to β-1 selectivity, nebivolol also results in nitric oxide (NO)-mediated vasodilation, which may offer an advantage over older agents in the class. The most common adverse reactions in clinical trials were headache, fatigue, dizziness and diarrhea. Nebivolol may interact with CYP2D6 enzyme inhibitors; **fluoxetine** 20 mg taken daily for 21 days before a single dose of nebivolol led to an 8-fold increase in the AUC of d-nebivolol.[1] The starting dose of nebivolol is 5 mg once daily, with or without food. Dose may be titrated up at 2 week intervals to a maximum of 40 mg daily.

DDAVP Indication Withdrawn: Desmopressin Intranasal formulations (**DDAVP Nasal Spray, DDAVP Rhinal Tube,** and **Stimate**) are no longer indicated for the treatment of primary nocturnal enuresis (PNE). The FDA took this action after reviewing 61 cases of hyponatremic-related seizures, including 2 deaths, associated with desmopressin use. Children treated with intranasal formulations were particularly susceptible to severe hyponatremia and seizures. Desmopressin *tablets* are still indicated for use in PNE, but should not be taken during acute illnesses that may lead to fluid and/or electrolyte imbalances. FDA also recommends that fluid intake be restricted from 1 hour before to 8 hours after administration of desmopressin tablets.

Department of Health and Human Services Updates HIV Guidelines

The U.S. Department of Health and Human Services (DHHS) has issued revised guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. The key changes in the December 1, 2007 update include:

1. **Genotypic Drug Resistance Testing** is recommended for all treatment-naïve patients whether or not treatment is to be initiated

2. **Tropism Assay** should be performed prior to starting therapy with a CCR5 antagonist (i.e. **Selzentry** [maraviroc]). Coreceptor tropism testing should also be considered for any patient exhibiting virologic failure on Selzentry.

3. **Human Leukocyte Antigen Testing** for HLA-B*5701 is recommended before starting **Ziagen** (abacavir sulfate) therapy to reduce the risk of hypersensitivity reaction. Patients testing positive *should not* be prescribed Ziagen and their positive status should be recorded as a Ziagen allergy in their medical record.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Dispensing Enteral Formula for N.Y. State Medicaid Recipients

In order to dispense enteral formula on the Medicaid program, a fiscal order or prescription must be written and a prior authorization must be obtained by the prescriber. Upon receipt of such prescription, the pharmacist must activate the prior authorization (PA) by calling:

1-866-211-1736

and choosing **option 4**. In addition to the PA number, the recipient's Client Identification Number (CIN), the pharmacy's provider ID number and category of service (0441 for retail stores) must be entered. The enteral code for the formula to be dispensed must also be entered (see below). Payment is based not on cans or mLs, but on caloric units, defined as 100 enteral calories. To determine the number of caloric units per can of formula, simply divide the number of calories in each can by 100. For example:

> **Ensure** contains 250 calories per can
> **250 ÷ 100 = 2.5 caloric units**
> A patient requiring 3 cans of Ensure daily will need a PA for
> **2.5 x 3 x 30 = 225 caloric units** per month.

Listed below are the enteral codes for some popular formulas:

BOOST	**B4150**
BOOST PLUS	**B4152**
ELECARE	**B4161**
ENSURE	**B4150**
ENSURE PLUS	**B4152**
GLUCERNA	**B4154**
IMMUNOCAL	**B4155**
JUVEN	**B4155**
KINDERCAL	**B4160**
NEPRO	**B4154**
PEDIASURE	**B4160**
PEPTAMEN	**B4153**
PEPTAMEN JR	**B4161**
SCANDI SHAKE	**B4152**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

DEA Finalizes Rule Change on C-II Prescriptions

The Drug Enforcement Agency (DEA) has finalized a proposed rule change regarding issuance of multiple prescriptions for schedule II controlled substances. Effective December 19, 2007, practitioners are permitted to issue to individual patients multiple prescriptions, to be filled sequentially, for the same schedule II controlled substance, allowing the patient to receive, over time, a 90-day supply of medication.[2] PRN has confirmed with New York's Bureau of Narcotic Enforcement that this rule ***will not apply in New York State***.[3] Current N.Y. State law does not allow practitioners to write multiple controlled substance prescriptions on the same day, nor does it allow pharmacists to fill prescriptions written more than 30 days prior to presentation. A mechanism already exists, however, for practitioners in N.Y. State to provide patients with a 90-day supply of a controlled substance. That mechanism involves the use of ***condition codes,*** as delineated in section 80.67(d)(1) of the Rules and Regulations on Controlled Substances. When a prescription is issued for the treatment of one of several designated conditions (see chart below):

> "**A practitioner may issue a prescription for up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six month supply of an anabolic steroid if used in accordance with the directions for use…."**

The prescriber must indicate either the condition or the code designating that condition (see chart) on the face of the prescription. If the code or condition is missing from a prescription, the pharmacist may add it after consultation with the prescriber (this should be documented on the prescription). Except in the case of schedule II drugs and benzodiazepines, 90-day coded prescriptions may contain one refill. It is important to note that not all controlled substances are indicated for one of the designated conditions; **Ambien** (zolpidem), for example, is indicated for use in insomnia, which is not a designated condition. Therefore, prescriptions for Ambien are limited to a 30-day supply.

CODE	CONDITIONS
A	**Panic disorder**
B	**Attention deficit disorder**
C	**Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity**
D	**Relief of pain in patients suffering from diseases known to be chronic and incurable**
E	**Narcolepsy**
F	**Hormone deficiency states in males; gynecologic conditions that are responsive with anabolic steroids or chorionic gonadotropin; metastatic breast cancer in women; anemia and angioedema**

Feature Article...

MEDICARE ISSUES IN COMMUNITY PHARMACY, PART 1: D vs. B

Medicare. Just a few years back that was a word rarely heard in community pharmacy, except in the context of explaining how "that doesn't cover prescription drugs." But with the advent of Medicare Part D in January, 2006, and with more pharmacies accepting assignment for Medicare Part B, Medicare has become a large part of every pharmacy's workday. In this, the first in a series of two articles on the subject, we will attempt to assist the pharmacist in settling issues involving conflict between a patient's Part D and Part B coverage. In some cases, each part may insist the other part be billed for a particular drug, and the pharmacist is uniquely positioned to help their patients obtain treatments to which they are entitled.

PART B is the part of traditional Medicare that, under certain conditions, will pay for a limited number of drugs in the outpatient setting. There are 13 categories of drugs which are eligible for separate payment by Part B.[4] Of these, there are 6 categories most likely to be encountered in the retail setting (see chart below). Even within those categories for which Part B provides coverage, however, there are often restrictions and specific conditions which must be met to assure payment, such as route of delivery, indication for use, or time frame of therapy. In addition, there are the issues of annual deductibles and co-insurance which must be navigated. In our next issue, we will cover these and other concerns for pharmacists billing claims for Part B prescriptions.

PART D is now entering its third year of existence, and while some of the initial problems have been worked out, there remain numerous coverage issues, including rejections due to Part D vs. Part B conflicts. The chart below will help the pharmacist determine the correct payer in some of the more commonly seen situations. Keep in mind that Part D is a *prescription drug plan*, so that OTC drugs and devices are excluded from coverage, as are prescription vitamins, benzodiazepines, and barbiturates. New for 2008 is the fact that the Centers for Medicare and Medicaid Services (CMS) has directed that Part D plans' formularies must contain all commercially available vaccines (unless excluded due to Part B coverage, such as influenza and pneumococcal vaccines). Most importantly for this patient population, this means that the herpes zoster vaccine (**Zostavax**) will be covered under Part D. Look for details on billing and dispensing Zostavax here in ***PRN*** as they become available.

DRUG CATEGORY	PART B COVERAGE	PART D COVERAGE
Blood Glucose Monitors, Test Strips, Lancets	Medicare pays 80% after deductible is met	Not covered because these items are not Part D drugs
Inhalation Drugs	Covered if used in nebulizer (e.g. Albuterol Nebulizer Sol.)	Covered if used in metered dose inhaler (e.g. Albuterol Inhaler)
Oral Anti-Emetic Drugs	Covered if used within 48 hours of chemotherapy (e.g. Zofran)	Covered under all other circumstances (may require PA)
Oral Anti-Cancer Drugs	Covered if same ingredient or prodrug as injectable (e.g. Xeloda) and used to treat cancer	Covered for all other indications (e.g. methotrexate for arthritis)
Immunosuppressant Drugs	Covered for patients who received a Medicare approved transplant	Covered for all other situations (may require PA)
Insulin	Covered for Insulin Dependent Diabetics when used via infusion pump	Prescription insulin covered if not used via infusion pump

NEXT MONTH: PART 2: PART B CLAIMS

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NATURAL PRODUCTS: SAW PALMETTO

Uses/claimed benefits: The extract of saw palmetto (*Serenoa repens)*, a small fan palm, is commonly used in the treatment benign prostatic hyperplasia (BPH) to relieve the urinary symptoms associated with an enlarged prostate.

Evidence: Many studies over the years have suggested a moderate benefit to the use of saw palmetto in BPH. Recent evidence, however, is conflicting. A 12 month, randomized, double-blind trial published in the New England Journal of Medicine found no benefit for saw palmetto over placebo in BPH[5]. This month's issue of *Current Opinion in Urology* compares that trial to another, also 12 month and randomized, that found a combination of saw palmetto and urtica to be *equal* to therapy with **Flomax** (tamsulosin)[6]. Clearly, more rigorous, placebo-controlled studies are needed to clarify the role of this natural product in the treatment of BPH.

Precautions: Due to antiplatelet effects, saw palmetto should not be taken perioperatively. Due to antiestrogenic and antiandrogenic effects, it is not recommended for woman who are pregnant or nursing (some woman have used this product for hirsuitism or polycystic ovarian syndrome).

Interactions: Saw palmetto may interact with **warfarin, heparin, clopidogrel, aspirin**, and **NSAIDs**, as well as **estrogen-containing contraceptives**.

DID YOU KNOW?

DID YOU KNOW that **Alupent® MDI** (metaproteranol) was, for a few months in early 1983, sold *over the counter?* In October, 1982, the FDA, for the first time, initiated a switch from Rx to OTC status of a drug without support of the manufacturer or of advisory committees. By January, 1983, OTC Alupent was on pharmacy shelves, but did not remain there long. A chorus of objections from physicians and consumer groups led the agency to reverse its decision, and Alupent was prescription-only again by May of 1983. Almost 20 years later, the FDA again made an Rx to OTC switch against the wishes of a drug maker when it responded to a petition by Blue Cross of California and made Claritin the first over-the-counter second generation antihistamine.

PHARMACY FUN

This months puzzle involves *anagrams*, words which contain the exact same letters, but in a different order (e.g., *tablet* and *battle*). There are two commonly used prescription drugs which have generic names that are anagrams of each other. In fact, simply by transposing the first and fifth letters of the name of either drug, you get the name of the other one! What are the names of the two drugs? The first reader to email the correct answer to *askprn@gmail.com* will receive an official P.R.N. binder.

Hint: The *Brand Names* of both drugs contain the letter X

Readers are welcome to submit their own puzzles, games, etc. to PHARMACY FUN. If we use your submission, you will receive a complimentary P.R.N. binder.

Answers to last month's PHARMACY FUN:

1. Efavirenz 2. Theophylline 3. Isoniazid 4. Lactulose 5. Erythromycin 6. Yohimbine 7. Dantrolene 8. Ursodiol *Hidden Word*: YULETIDE

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