P.R.N.

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What's Inside…

PUBLIC HEALTH ADVISORY

On January 17, 2008, the FDA officially issued a public health advisory recommending that over-the-counter cough and cold products not be used in children under 2 years of age. This warning was first reported last October after the public advisory committee meeting came to the same conclusion and many manufacturers voluntarily removed their products from the market. FDA is currently reviewing the safety of these medicines in children 2 through 12 years of age. Pending completion of that review, the FDA advises parents using cough and cold medicines in children 2 to 12 years old to:

Check the DRUG FACTS label carefully for active ingredients and correct dose

Use only measuring cups or spoons that come with the product or are specially made for measuring drugs

Do not use these products to sedate your child or make children sleepy

NEW DRUG APPROVALS

New HIV Therapy: The FDA has approved Tibotec Therapeutics **Intelence** (etravirine), the first new non-nucleoside reverse transcriptase inhibitor (NNRTI) since the release of **Sustiva** in 1998. Intelence is indicated for use in combination with other antiretrovirals for treatment of HIV-1 in patients who have evidence of viral replication and HIV-1 strains resistant to NNRTIs and other agents. The dose is 200 mg (two 100 mg tablets) twice daily following a meal. Intelence *should not* be used with protease inhibitors administered without **ritonavir**, ritonavir-boosted **Aptivus, Lexiva**, or **Reyataz**, or with any other NNRTI. The most common adverse reactions seen in clinical trials were rash (16.9%) and nausea (13.9%).[1] If a severe rash develops, Intelence should be discontinued and appropriate therapy initiated.

Asthma Maintenance Treatment: A new inhaled corticosteroid for asthma prophylaxis has been approved by the FDA. Nycomed's **Alvesco** (ciclesonide) is a prodrug which is hydrolyzed in the lungs to the active metabolite des-ciclesonide. The metered dose inhaler comes in two strengths, 80 mcg per actuation and 160 mcg per actuation. Both are available in a 60 dose canister and the 160 mcg is also available in a 120 dose canister. The doses for patients 12 years of age and older are:

ALVESCO DOSING CHART

Previous Therapy	Starting Dose	Maximum Dose
Bronchodilators alone	80 mcg BID	160 mcg BID
Inhaled corticosteroids	80 mcg BID	320 mcg BID
Oral corticosteroids	320 mcg BID	320 mcg BID

New Combo Anti-HTN: Novartis has received approval for a new combination antihypertensive, **Tekturna HCT**, which combines their direct rennin inhibitor Tekturna (aliskiren) with the thiazide diuretic hydrochlorothiazide. This new once-daily option for the treatment of hypertension will be available in strengths of 150/12.5 mg, 150/25 mg, 300/12.5 mg, and 300/25 mg. Titration may begin after 2 to 4 weeks of therapy up to a maximum dose of 300/25 mg QD. Tekturna HCT may be taken with or without food, but it is important that patients establish a routine pattern with regard to taking with or without meals in order to obtain consistent blood levels. In clinical trials, the most common adverse effects experienced at a higher incidence than placebo included dizziness, flu-like symptoms, diarrhea, cough, asthenia, and arthralgia.

Extended-Release Amoxicillin: Middle-Brook Pharmaceuticals is marketing an extended-release form of amoxicillin tablets called **Moxatag**. Moxatag is indicated for the treatment of tonsillitis and/or pharyngitis due to *Streptococcus pyogenes* in adults and children 12 years of age and older. In a randomized, double blind study, Moxatag had eradication rates of 85% and 79.7% versus 83.4% and 78% for penicillin VK 250 mg QID.[2] This extended-release formulation consists of 3 components, one immediate-release and two delayed-release. The tablet should not be chewed or crushed. The recommended dose of Moxatag is 775 mg taken once daily, within one hour of finishing a meal, for 10 days. In order to prevent the development of drug-resistant bacteria, the manufacturer recommends that Moxatag only be used to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

New Study Leads to FDA Change in Ortho Evra Label

A recent study conducted by the Boston Collaborative Drug Surveillance Program (BCDSP) concluded that users of the **Ortho Evra** contraceptive patch face a two-fold increase in the risk of venous thromboembolism (VTE) as compared to users of standard oral contraceptives (OC). In light of a previous study which also showed an increase in VTE events in patch users versus OC users, FDA now recommends that women with risk factors for VTE events speak with their physician about available contraceptive options.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Upcoming Changes to the Preferred Drug Program

An update of the Preferred Drug Program (PDP) has been issued and will take effect on **February 21, 2008**. The revisions include 1 new preferred drug and 6 drugs which are now non-preferred:

Preferred Agents

Ciclopirox (lacquer)
(Penlac is *not* covered)

Non-preferred Agents

Lamisil (tablets)
Omnicef (capsules, suspension)
Famvir
Floxin Otic
(generics of above *are* covered)
Kytril (tablets, solution)
Xopenex HFA

The current list of preferred and non-preferred drugs may be accessed on the web at:

https://newyork.fhsc.com

Program Overview

In order to promote the use of less expensive prescription drugs, the Medicaid Preferred Drug Program was implemented in June, 2006 with 6 initial drug categories. Today there are 42 categories covered by the program. Should a practitioner wish to prescribe a non-preferred drug, a prior authorization (PA) must first be obtained. PAs issued for non-preferred drugs will always end in the letter "W." The pharmacist must call the prior authorization phone line at **877-309-9493** to validate the PA written on the prescription. Choose option "2" for pharmacist, then option "1" for non-preferred drugs. PAs are good for the life of the prescription (up to 5 refills in 6 months.) When submitting a claim, the validated PA number must be included in the prior authorization field ***without*** the "W."

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New Requirements for Prescriptions from Exempted Facilities

Effective **February 25, 2008**, all prescriptions issued on regular facility prescription forms by exempted hospitals and their affiliated clinics ***must contain a state-issued serialized authentication label***. The labels measure 2" by 3/4" and may be placed anywhere on the prescription as long as they do not obscure any required prescription information. Each label will contain a scannable bar-code serial number as well as a pharmacist test area. This regulation applies *only* to prescriptions for non-controlled substances written on regular (non-official) prescription blanks by practitioners at health care facilities and their affiliated clinics and health services which have been exempted by the Department of Health from the requirement to use the Official New York State Prescription (ONYSRx). The list of exempted facilities and their associated clinics and health services can be viewed at: *http://www.health.state.ny.us/professionals/narcotic/facilities/exempted_list.htm*
All prescriptions for controlled substances written in New York State *must* be issued on the Official New York State Prescription.

Background

A change in New York's Public Health Law (section 21) required that, by April 16, 2006, all prescriptions written in New York be issued on the ONYSRx. The purpose of the law was to combat prescription fraud. The official prescription contains security features designed to prevent alterations and forgeries that lead to drug diversion. In addition, by requiring pharmacies to submit data for all controlled substance prescriptions, the Department of Health is able to detect the practice of "doctor shopping" and notify practitioners of this illegal activity. A one-year exemption from the requirement to utilize the ONYSRx for non-controlled prescriptions was granted for hospital practitioners. This original exemption expired on April 19, 2007, but was extended for those hospitals and their affiliated clinics and health services which had implemented either an electronic prescription system to transmit prescriptions to pharmacies or a computerized provider order entry system that generates printed prescriptions. These exemptions continue, but as of February 25, 2008 all non-official prescriptions from such facilities must contain the serialized authentication label described above.

Additional Rules for ONYSRx

Practitioners and facilities may use electronic medical record (EMR) systems to print prescriptions on official New York State prescription paper. These printed prescriptions are valid only if they conform to section 6810(6) of the Education Law requiring the phrase "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS THE PRESCRIBER WRITES 'd a w' IN THE BOX BELOW," printed in 8-point upper case type below the signature line, and a 'daw' box measuring 3/4" in length by 1/2" in height. Below the box, the words "Dispense As Written" must appear in 6-point type.

Adhesive stickers or labels containing patient information only may be affixed to ONYSRx's for non-controlled substances. Stickers or labels with drug or patient information are *not allowed* on controlled substance prescriptions as they may interfere with security features of the ONYSRx. A label indicating change of practice address is acceptable for both controlled and non-controlled prescriptions.

Prescriptions issued in New York State for controlled substances must indicate specific directions for use and maximum daily dose. In addition, regulations require that the *quantity of drug* and *number of refills* be written by the prescriber in **both numerical and written word form** in order to prevent alteration of either number by individuals seeking to divert controlled substances.[3]

Feature Article...

MEDICARE ISSUES IN COMMUNITY PHARMACY, PART 2: PART B CLAIMS

Billing Part B claims. In last month's issue we discussed the problem of resolving conflicts between Medicare Part B and Part D in billing prescription claims. This month we focus on the specifics of billing claims to Part B. As previously mentioned, there are several categories of drugs or supplies billable to Part B that are most likely to be encountered in the community pharmacy setting. In the tables below we list the restrictions and conditions applicable to the 4 most common categories, but first let's review the rules that apply to all Part B prescriptions:

1. **A diagnosis code is required for all Medicare Part B prescriptions. This should be indicated on the written prescription by the prescriber.**
2. **The pharmacy must retain a *hard copy* of all Part B prescriptions. Telephone orders must be followed up with a hard copy.**
3. **When dispensing supplies (test strips, lancets) on assignment, a signed Assignment of Benefits form must be obtained and kept on file.**
4. **Directions for use should always be included on Part B prescriptions in order to ensure that frequency limitations are not exceeded.**

DIABETIC TESTING SUPPLIES				
Patient Diagnosis	**Blood Glucose Meter**	**Blood Glucose Test Strips**	**Lancets**	**Diagnosis Codes**
Non-Insulin Dependent	**Allowed 1 meter every 5 years**	**100 strips every 90 days**	**100 lancets every 90 days**	**ICD-9 codes 250.00 - 250.93**
Insulin Dependent	**Allowed 1 meter every 5 years**	**300 strips every 90 days**	**300 lancets every 90 days**	**ICD-9 codes 250.00 - 250.93**

DRUGS USED VIA NEBULIZER			
DRUG CATEGORY	**EXAMPLE DRUG(S)**	**DIAGNOSIS**	**ICD-9 CODE**
Beta Adrenergic Agonist	**Albuterol, Levalbuterol**	**Obstructive Pulmonary Disease**	**491.10 - 508.9**
Anticholinergic	**Ipratropium bromide**	**Obstructive Pulmonary Disease**	**491.10 - 508.9**
Anti-infective	**Tobramycin**	**Cystic Fibrosis**	**277.02**

IMMUNOSUPPRESSANT DRUGS	
COVERED DRUGS	**ICD-9 CODES**
Azathioprine **Cellcept** **Cytoxan** **Cyclosporine** **Methotrexate** **Methylprednisolone** **Prednisolone** **Prednisone** **Prograf** **Rapamune**	**Bone Marrow = V42.81** **Heart = V42.1** **Kidney = V42.0** **Intestines = V42.84** **Liver = V42.7** **Lung = V42.6** **Pancreas = V42.83**

ORAL ANTI-CANCER DRUGS	
COVERED DRUGS	**ICD-9 CODES**
Alkeran **Cytoxan** **Methotrexate** **Myleran** **Temodar** **VePesid** **Xeloda**	**140.0 - 208.91** **230.0 - 239.9** **273.3**

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NATURAL PRODUCTS: CRANBERRY

Uses/claimed benefits: Cranberry is commonly used in the prevention of urinary tract infections (UTIs).

Evidence: There is clinical evidence to support the use of cranberry juice to prevent urinary tract infections. It was previously thought that the mechanism for this effect was acidification of the urine, but research has not substantiated this claim. The current belief is that some constituents of cranberry prevent or inhibit the ability of bacteria to adhere to cells lining the walls of the urinary tract. A review in the June, 2007 issue of *Molecular Nutrition and Food Research* cited a number of well-designed randomized control trials establishing the efficacy of cranberry in reducing the incidence of UTIs in women over a 12-month period.[4] Cranberry juice is preferred to capsules due to lack of standardization of capsule products.

Precautions: Cranberry is generally well tolerated. Gastrointestinal upset and diarrhea may result from consumption of large amounts. Cranberry contains oxalate and may increase urinary oxalate levels and should be avoided by people with a history of calcium oxalate renal stones.

Interactions: Although there are conflicting studies, some case reports have indicated an interaction with **warfarin** leading to increased INR and bleeding episodes. Pending clarification of this interaction, cranberry use should be limited in patients taking wafarin.

DID YOU KNOW?

DID YOU KNOW that Pfizer's **Viagra** (sildenafil citrate) was originally developed as an antihypertensive and antianginal agent? Back in the late 1980's, chemists were searching for ways to increase the activity of the natural vasodilator atrial natriuretic peptide (ANP). At Pfizer, the strategy was to block the breakdown of cyclic guanosine monophosphate (cGMP), which is activated by ANP. They did this by inhibiting the enzyme phosphodiesterase (PDE), specifically PDE-5, with sildenafil. Clinical trials showed little effect on blood pressure, however, and the drug was almost shelved. But then, reports from a clinical trial of sildenafil in Merthyr Tydfil, Wales, mentioned an unusual side-effect.[5] Pfizer investigated, organized new clinical trials, and, in March of 1998, received FDA approval to market Viagra for the treatment of erectile dysfunction.

PHARMACY FUN

This month's puzzle involves finding words *hidden* inside other, unrelated words. Given a clue to one word, answer with the drug name hidden inside that word. For example, if the clue were "Milk Sugar," the correct answer would be "Actos," since the word Actos is found *inside* the word Lactose, which is milk sugar! The first reader to email the correct answers to puzzle@prnnewsletter.com will receive an official P.R.N. binder.

1. **Surrounding, encircling, as in _____ light**
2. **Circumscribed and detached in outlook and experience; narrow or provincial**
3. **A devoted follower or attendant.**
4. **Having a pleasing succession of sounds; melodious.**

Hint: All the correct answers are *Brand Names.*

Answers to last month's **PHARMACY FUN**: Nizatadine and Tizanadine

References:
1. Intelence [package insert]. Raritan, NJ: Tibotec Therapeutics; issued 01/2008.
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3. Title 10 NYCRR 80.69 (b) (3), (5).
4. Jepson RG. A systematic review of the evidence for cranberries and blueberries in UTI prevention. *Mol Nutr Food Res.* 2007 Jun;51(6):738-45
5. Kling J. From hypertension to angina to Viagra. *Modern Drug Discovery*. 1998, 1 (2), 31, 33-34, 36, 38.