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FDA NEWS

FDA Approves New Indication for Humira

The FDA has approved Humira (adalimumab) for the treatment of moderate-to-severe ulcerative colitis in adults. Previously the drug, a tumor necrosis factor blocker which affects inflammatory and immune responses, was approved to treat rheumatoid arthritis (2002), psoriatic arthritis (2005), ankylosing spondylitis (2006), Crohn's disease (2007), plaque psoriasis (2008), and juvenile idiopathic arthritis (2008). In the case of ulcerative colitis, Humira is indicated for use when immunosuppressant drugs such as corticosteroids, azathioprine, and 6-mercaptopurine have not resulted in improvement. The FDA-approved dosing regimen begins with an initial dose of 160 mg, a second dose two weeks later of 80 mg, and a maintenance dose of 40 mg every other week thereafter. Humira should only continue to be used in patients who have shown evidence of clinical remission by eight weeks of therapy.

.....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

STRIBILD (Elvitegravir, Cobicistat, Emtricitabine, and Tenofovir).
Category: Anti-HIV Combination
Initial dose: One tablet taken once daily with food.
MDD: One tablet daily.

The FDA has approved Gilead Science's Stribild, the first four drug combination product for the treatment of HIV-1. Stribild consists of two currently marketed nucleos(t)ide analogs (emtricitabine and tenofovir—the components of Truvada) and two new drugs, elvitegravir and cobicistat. Elvitegravir is an HIV integrase strand transfer inhibitor, and cobicistat is an enzyme inhibitor which prolongs the effects of elvitegravir. Stribild is indicated for the treatment of HIV-1 in patients who have not been treated previously. The product will contain **black box warnings** regarding the possibility of lactic acidosis and severe hepatomegaly with steatosis, and reports of severe acute exacerbations of hepatitis B in co-infected patients discontinuing Stribild. The recommended dose of Stribild is one tablet daily with food. Stribild is a complete regimen for the treatment of HIV-1 and should not be administered with other HIV medications, such as Atripla, Complera, Emtriva, Truvada, Viread, lamivudine, and ritonavir. Stribild should not be taken with drugs which are highly dependent on CYP3A for clearance and for which elevated levels are associated with adverse events, or with drugs which strongly induce CYP3A, which may reduce levels of one or more components of Stribild. According to the manufacturer, Stribild should be dispensed only in the original container.

AUBAGIO (Teriflunamide).
Category: Pyrimidine Synthesis Inhibitor for the treatment of relapsing forms of MS.
Initial dose: 7 mg or 14 mg once daily, with or without food.
MDD: 14 mg once daily.

Sanofi-Aventis has received FDA approval to market Aubagio, a once-daily tablet for the treatment of adults with relapsing forms of multiple sclerosis (MS). Aubagio is a pyrimidine synthesis inhibitor with immunomodulatory and anti-inflammatory properties, and is taken once a day with or without food. The label contains **black box warnings** for hepatotoxicity and teratogenicity. Like its chemical relative leflunamide (Arava), Aubagio is eliminated slowly from plasma, and may persist for up to two years after discontinuation. If necessary, a procedure exists for accelerated elimination using cholestyramine 8 grams every 8 hours for 11 days.

LINZESS (Linaclotide).
Category: Guanylate Cyclase-C Agonist for IBS-C and CIC.
Initial dose: IBS-C: 290 mcg once daily; CIC: 145 mcg once daily. Take on empty stomach at least 30 minutes prior to first meal of the day.
MDD: 290 mcg once daily.

Forest Laboratories has announced FDA approval of Linzess, a new drug indicated for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) and adults with chronic idiopathic constipation (CIC). Linzess will contain a **black box warning** indicating that the drug should not be used in children under 18 years of age due to deaths seen in animal studies.

FDA Warns of Serious Adverse Events Related to OTC Products

The FDA has recently issued two drug safety communications regarding serious illness and injury caused by over-the-counter eye drops and nasal sprays, as well as topical muscle and joint pain relievers.

Eye drops/nasal sprays containing tetrahydrozoline, oxymetazoline, or naphazoline, when accidentally ingested by children 5 years of age or younger, have led to hospitalizations for cardiac and respiratory problems and coma. The agency suggests these products be stored out of reach of children. If a child swallows even a small amount of one of these products, parents should call the Poison Help Line at **1-800-222-1222** or seek immediate medical care.

Topical muscle and joint pain relievers containing menthol, methyl salicylate, or capsaicin have been implicated in rare cases of first- to third-degree burns. The majority of cases occurred with products containing menthol as the single active ingredient and products containing both menthol and methyl salicylate in concentrations greater than 3% menthol and 10% methyl salicylate. If a patient experiences pain, swelling, or blistering of the skin where an OTC muscle and joint pain reliever was applied, advise the patient to discontinue using the product.

Information Regarding the New York State Medicaid Program

Medicaid Coverage of Zostavax

Effective October 16, 2012, the administration of Zostavax (Zoster Live vaccine) by pharmacists will be covered for Medicaid Fee-For-Service non-dual eligible enrollees aged 50 and older. Consistent with Medicaid immunization policy, pharmacies must bill for the administration and cost of the vaccine using specific procedure codes rather than NDC numbers:

90736 Zoster Vaccine

90471 Administration Fee

The amount paid for administration will be \$13.23. No dispensing fee or enrollee co-payment applies. Pharmacies should bill with a quantity of "1" and a days supply of "1". A patient specific order must be presented, and the order must be kept on file at the pharmacy. The ordering prescriber's NPI number is required on the claim for payment.

Drug Utilization Review Update

Effective November 29, 2012, the Medicaid fee-for-service program will implement several new restrictions involving the initial treatment of certain diseases, including the following:

Treatment of Type 2 Diabetes:

- Require a trial with metformin with or without insulin prior to initiating other antidiabetic agents (unless documented contraindication).
- Require a trial of metformin plus another antidiabetic agent prior to a Glucagon-Like Peptide-1 (GLP-1) agonist (Bydureon, Byetta, Victoza). Prior authorization requirement with lack of covered diagnosis in medical history.

Treatment of Diabetic Neuropathy

- Require a trial with a tricyclic antidepressant or gabapentin prior to duloxetine and pregabalin (for treatment of diabetic neuropathy).

Regulatory Issues Affecting Pharmacy in New York State

Pharmacist Immunization Privileges Expanded to Include Zostavax (Zoster Vaccine Live)

Starting on October 16, 2012, pharmacists in New York State will be authorized to administer Zostavax, a live attenuated virus vaccine indicated for the prevention of herpes zoster ("shingles") in individuals 50 years of age and older. Previously, New York pharmacists were limited to providing influenza and pneumococcal vaccines only. The legislation (Assembly bill 6301-D) was signed by Governor Cuomo in July and includes the following provisions:

- **A physician or certified nurse practitioner may prescribe and order a patient specific regimen to a licensed pharmacist, pursuant to regulations promulgated by the commissioner, and consistent with the public health law, for administering immunizations to prevent acute herpes zoster.** (Education Law 6909(7)[a])
- **"Administer", for the purpose of section 6801 of this article, means the direct application of an immunizing agent to adults, whether by injection, ingestion or any other means, pursuant to a) a patient specific order or non-patient specific regimen prescribed or ordered by a physician or certified nurse practitioner, who has a practice site in the county in which the immunization is administered, for immunizations to prevent influenza or pneumococcal disease and medications required for emergency treatment of anaphylaxis or b) A patient specific order prescribed or ordered by a physician or certified nurse practitioner for immunizations to prevent acute herpes zoster.** (Education Law 6802[22])
- **When administering an immunization in a pharmacy, the licensed pharmacist shall provide an area for the immunization that provides for a patient's privacy.** (Education Law 6801[5])

The storage, handling, and administration of Zostavax differs from that of the influenza and pneumococcal vaccines pharmacists are familiar with. A quick primer on the proper use of Zostavax follows below.

Zostavax: Dosage, Administration, and Storage

- ◆ **Recommended Dose:** Administer Zostavax as a single 0.65 mL dose subcutaneously in the deltoid region of the upper arm.
- ◆ **Administration: Subcutaneous administration only.** Do not inject intravascularly or intramuscularly.
- ◆ **Preparation for Administration:** Zostavax is stored frozen and should be reconstituted immediately upon removal from the freezer. When reconstituted, Zostavax is a semi-hazy to translucent, off-white to pale yellow liquid.

Reconstitution:

- Use only the diluents supplied.
 - Withdraw the entire contents of the diluent into a syringe.
 - To avoid excessive foaming, slowly inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly.
 - Withdraw the entire contents of reconstituted vaccine into a syringe and inject the total volume subcutaneously.
 - **ADMINISTER IMMEDIATELY AFTER RECONSTITUTION** to minimize loss of potency. Discard reconstituted vaccine if not used within 30 minutes. Do not freeze reconstituted vaccine.
- ◆ **Storage:** To maintain potency, Zostavax must be stored **frozen** between -58°F and +5°F (-50°C and -15°C). Zostavax may be stored and/or transported at a refrigerator temperature between 36°F and 46°F (2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Vaccine stored in a refrigerator that is not used within 72 hours of removal from +5°F (-15°C) storage should be discarded. The diluent should be stored separately at room temperature (68°F to 77°F, 20°C to 25°C), or in the refrigerator (36°F to 46°F, 2°C to 8°C).

UPDATE ON TIV FOR THE 2012-13 FLU SEASON

Flu Season has arrived, and it is once again time to review the practice and protocols of administering influenza vaccine to our patients. Since most pharmacists deal almost exclusively with Trivalent Inactivated Vaccine (TIV), we have focused on that particular dosage form in our review. Also, because many patients inquire about issues such as mercury content and latex allergy, we have prepared charts detailing the amounts of each in the TIV products available this year.

The Vaccine (TIV)

The 2012-13 influenza vaccine is a trivalent vaccine containing the following 3 antigens:

- **A/California/7/2009 (H1N1)-like**
- **A/Victoria/361/2011 (H3N2)-like**
- **B/Wisconsin/1/2010-like**

The A(H3N2) and B antigens differ from the respective 2010-11 and 2011-12 seasonal vaccine antigens. The A(H1N1) strain is the same one used in 2009, 2010, and 2011. To permit time for production of protective antibody levels, vaccination should optimally occur before the onset of influenza activity in the community. Vaccination should continue to be offered throughout the influenza season (i.e., as long as the virus is circulating in the community)

Dosage, Administration, and Storage (TIV)

The adult dose for TIV is **0.5 mL** given intramuscularly in the deltoid muscle. Vials and prefilled syringes should be shaken before use and a needle of at least **1 inch** should be used to ensure penetration of muscle tissue. The CDC does not recommend the pre-filling of syringes by providers because there are no data on the stability of vaccine stored in syringes filled by providers. However, if pre-filling is done for the purposes of a clinic, no more than 10 doses should be drawn, and any syringes not used by the end of the day should be discarded. TIV should be refrigerated (2° to 8°C) and temperatures should be read and recorded twice a day. Temperature logs should be kept for at least 3 years.

Who Should Get Vaccinated?

The CDC is continuing its recommendation for “universal” flu vaccination, first issued in February, 2010, which states that all persons aged 6 months and older should be vaccinated. For certain people, however, vaccination is especially important because they are at high risk of developing complications. These include:

- **Pregnant women**
- **Children aged 6 months to 4 years (59 months)**
- **People 50 years of age and older**
- **People who live in nursing homes**
- **American Indians/Alaska Natives**
- **Morbidly obese persons (BMI 40 or greater)**
- **Healthcare personnel**
- **Immunosuppressed patients and those with chronic diseases**
- **People who live with or care for those at high risk, and household contacts and caregivers of children less than 6 months of age**

Mercury Content (mcg per 0.5 mL dose) of TIV Vaccines

Vaccine Trade Name	Multidose Vial	Prefilled Syringe
FLUZONE	25.0	0.0
AFLURIA	24.5	0.0
FLUVIRIN	25.0	≤ 1
FLUARIX		0.0
FLULAVAL	< 25.0	
AGRIFLU		0.0
FLUZONE HIGH-DOSE		0.0
FLUZONE INTRADERMAL		0.0 (per 0.1 mL)

Latex Content of TIV Vaccines

Vaccine Trade Name	Contains Latex?
FLUZONE	NO
AFLURIA	NO
FLUVIRIN	YES - In Syringe Tip Cap
FLUARIX	YES - In Syringe Tip Cap
FLULAVAL	NO
AGRIFLU	YES - In Syringe Tip Cap
FLUZONE HIGH-DOSE	NO
FLUZONE INTRADERMAL	NO



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Our pharmacy periodically receives inquiries from physicians who wish to prescribe a 90-day supply of Ambien (zolpidem) for their patients. Is there a condition code which would allow for the dispensing of such a prescription?

No. The Rules and Regulations on Controlled Substances in New York State (Part 80) allow for the prescribing of a 90-day supply of a controlled substance (180-day supply in the case of anabolic steroids) provided the prescription has been issued for the treatment of certain specific conditions, which include panic disorder, ADHD, convulsive disorders, pain, and narcolepsy. Ambien is indicated for the treatment of insomnia, which is *not* one of the specified conditions. The condition or its designated letter code must be written on the prescription, or may be added by the pharmacist after consultation with the prescriber. The current list of condition codes is as follows:

- A. Panic disorders.
- B. ADHD.
- 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 conditions known to be chronic or incurable.
- E. Narcolepsy.
- F. Hormone deficiency states in males, gynecological conditions responsive to anabolic steroids or HCG, metastatic breast cancer in women, anemia, and angioedema.

GOT QUESTIONS? WE HAVE ANSWERS!
 Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the word *influenza* was imported from the Italian language and originally referred to disease spread through the air via the influence of the cosmos?¹ The Latin root, *influentia* was an astrological term referring to an ethereal fluid emanating from the stars with the power to affect humans. Similar to the miasma, or “bad air” theory of disease, it was discredited when the likes of Pasteur and Koch developed the germ theory. The ancients weren’t completely off the mark however, since it is believed that the flu, or influenza, is primarily spread *through the air* by infected droplets expelled when people suffering from the disease cough, sneeze, or talk!

PHARMACY FUN

Welcome to our fifth annual back-to-school quiz, a once-a-year chance to find out how much, or how little, you remember from your days in academia. For this edition, we will test your knowledge of common pharmacy acronyms. For each of the following, spell out in full what each letter of the acronym stands for (e.g., ASA is *acetyl salicylic acid*). The first reader to submit the correct answers to puzzle@prnnewsletter.com will receive a custom-printed PRN binder.

1. APAP	6. KOW
2. 5-ASA	7. NPH
3. AZT	8. PRN
4. BCG	9. QS
5. INH	10. SSKI

Answers to last month's **PHARMACY FUN**:
 1. Diovan 2. Corgard 3. Zocor 4. Prevacid 5. Avodart 6. Zolofit 7. Videx 8. Zantac
 9. Levitra

References:
 1. Dave Wilton. "Influenza: an origin in the stars." May 6, 2009 article accessed at:
www.examiner.com/article/influenza-an-origin-the-stars