MAGELLAN PHARMACY SOLUTIONS | MAGELLAN MEDICAID ADMINISTRATION

Kentucky UNBRIDLED SPIRIT

Pharmacy Quarterly

September 2012 Volume 8, Number 3

The Numbers Listed Below Are For Fee-For Service Support

Pharmacy Support Center

1-800-432-7005

24 hours per day/7 days per week
For claim assistance, early refill overrides, and lock-in overrides

Clinical Support Center

Prior Authorizations

1-800-477-3071

24 hours per day/7 days per week

Diabetic Supply Questions

Prior Authorization

1-800-477-3071

Claim Inquiry

1-800-432-7005

Please Note: Questions regarding claims prior to October 5, 2010, should be directed to 1-800-807-1232.

Provider Services

1-877-838-5085

M–F, 10:30 a.m.–4:30 p.m. (ET)

Providers should contact Provider Services for inquiries regarding enrollment and changes.

Member Services

1-800-635-2570

M–F, 8:00 a.m.–5:00 p.m. (ET)

Recipients should contact Member Services for medication replacement requests and benefit information.

Web Sites

Kentucky Department for Medicaid Services
http://chfs.ky.gov/dms/Pharmacy.htm

Magellan Medicaid Administration
https://kentucky.fhsc.com/

Onsite Provider Education

For onsite education presentations, please contact Kasie Purvis at 1-314-387-4792, M–F 8:30 a.m.–5:00 p.m. This education is free of charge.

Getting to Know Kentucky Medicaid Providers

Sheldon's Express Pharmacy has been a part of the Bowling Green community for almost 25 years. During this time, Sheldon's Express Pharmacy has expanded to three locations. One branch alone fills over 1,000 scripts a day including compounded medications. They staff around 6 pharmacists and 40 technicians. You can also find diabetic supplies and immunization services at Sheldon's Express Pharmacy. Please visit http://www.sheldonsexpresspharmacy.com/index.cgi for additional information about each pharmacy location and the additional services that are offered.

If you would like to see your pharmacy highlighted, please contact Kasie Purvis at KLPurvis@magellanhealth.com.

Upcoming Changes

Preferred Drug List (PDL) Changes Effective October 30, 2012

New Drugs to Market: Jentadueto™, Janumet®, Kalydeco™, Inlyta®, Erivedge™, Bydureon®, Zioptan®, Qnasl™, Potiga™, and Omontys®.

PDL Changes Effective November 1, 2012

- Xolair® clinical criteria, Liptotropics: High Potency Statins, Agents for Pulmonary Hypertension, Sildenafil and Tadalafil clinical criteria, Proton Pump Inhibitors, Sedative Hypnotic Agents, Antibiotics: Quinolones, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and Topical diclofenac clinical criteria.
- Narcotics: Short Acting, fentanyl transdermal clinical criteria, Butrans™ clinical criteria, Topical Immunomodulators, Dermatologics: Antibiotic Agents, Ophthalmic Mast Cell Stabilizers, Ophthalmic Sympathomimetics, and Ophthalmic Prostaglandin Agonists.

PDL Changes Effective November 8, 2012

Alpha blockers for BPH, Otic Anti-Infective and Anesthetic, GI Antibiotics, Xifaxan clinical criteria, and Oral Anti-Arrhythmics.

These changes can be viewed at https://kentucky.magellanmedicaid.com/Providers/Bulletins.asp, in the Fee-For-Service Pharmacy Provider Notice #153 – July 19, 2012 PTAC PDL Changes – effective beginning June 6, 2012.

CLINICAL NEWS[1]

INFLUENZA (FLU) VACCINE

The 2012–2013 flu vaccine formulation for all six manufacturers licensed to produce and distribute the vaccines in the United States has received Food and Drug Administration (FDA) approval. The flu vaccine brand names and the licensed manufacturers for the upcoming flu season are

- Afluria, by CSL Limited;
- Fluarix, by GlaxoSmithKline Biologicals;
- FluLaval, by ID Biomedical Corporation;
- FluMist, by MedImmune Vaccines Inc.;
- Fluvirin, by Novartis Vaccines and Diagnostics Limited; and
- Fluzone, Fluzone High-Dose, and Fluzone Intradermal, by Sanofi Pasteur.

Based on recommendations of the FDA's Vaccines and Related Biological Products Advisory Committee, the 2012–2013 flu vaccine strains are A/California/7/2009 (H1N1)-like virus, A/Victoria/361/2011 (H3N2)-like virus, and B/Wisconsin/1/2010-like virus. The H1N1 virus is the same as what was included in the 2011–2012 flu vaccine. However, this season's influenza H3N2 and B viruses differ from last year. The Centers for Disease Control and Prevention (CDC) reports between 5 to 20 percent of the US population develops influenza annually, leading to over 200,000 hospitalizations. The CDC's Advisory Committee on Immunization Practices (ACIP), recommends that everyone six months of age and older receive an annual influenza vaccine.

CODEINE SAFETY

In December 2011, a patient with multiple sclerosis (MS) in the United States died within 24 hours of taking the first dose of the oral MS agent fingolimod (Gilenya). Although the cause of death remains unexplained, the drug label has been strengthened. The product, which did not originally carry any contraindications, now carries four new contraindications. Fingolimod is now contraindicated in patients with a history or occurrence of certain cardiovascular conditions, including myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure within the last six months. It is also contraindicated in second degree or third degree atrioventricular (AV) block or sick sinus syndrome, unless the patient has a pacemaker, in other serious cardiac rhythm disturbances, and in treatment with select anti-arrhythmic drugs. Prior to the label change, it was recommended that all patients be observed for six hours post first dose for signs and symptoms of bradycardia. The current label provides specific guidance to health care professionals for first-dose monitoring in a medical setting. The label now recommends observing all patients for signs and symptoms of bradycardia for at least six hours after first dose with hourly pulse and blood pressure measurement. An electrocardiogram (ECG) must be obtained prior to initial dosing and at the end of the observation period. In the following situations, additional observation should be started until the finding has resolved:

- The heart rate six hours post-dose is <45 bpm
- The heart rate six hours post-dose is at the lowest value post-dose (suggesting that the maximum pharmacodynamic effect on the heart may not have occurred)
- The ECG six hours post-dose shows new onset second degree or higher AV block.

In patients experiencing post-dose symptomatic bradycardia, continuous ECG monitoring is recommended until the symptoms have resolved. If pharmacological intervention is required to treat bradycardia, continuous ECG monitoring should continue overnight in a medical facility, and a first-dose monitoring strategy should be repeated for the second dose. The new label also provides guidance for re-initiation of fingolimod. In an unrelated event, an MS patient who had been treated with natalizumab (Tysabri®) for approximately three and a half years prior to initiating fingolimod was recently hospitalized. The patient is positive for JCV and has confirmed progressive multifocal leukoencephalopathy (PML). There were about six weeks between natalizumab and fingolimod treatments.

Unstable Angina (UA)/Non-ST-Elevation Myocardial Infarction (NSTEMI) Clinical Guidelines

The American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) have updated their Unstable Angina/Non St-Elevation Myocardial Infarction (UA/NSTEMI) guidelines and added ticagrelor (Brilinta®) with a class I recommendation. Patients with definite UA/NSTEMI at medium or high risk and in whom an initial invasive strategy is selected should receive dual antiplatelet therapy on presentation (Level of Evidence [LOE]: A). In addition to aspirin (LOE: A), the choice of a second antiplatelet therapy before percutaneous cardiac intervention (PCI) includes clopidogrel, ticagrelor (both LOE:B), or IV GP IIb/IIIa inhibitor (LOE: A). At the time of PCI, in addition to aspirin, the recommendations are clopidogrel (LOE: A) or prasugrel or ticagrelor (both LOE: B) or IV GP IIb/IIIa inhibitor (LOE: A).

Gonorrhea Evidence-Based Practice Guidelines

Recent data from the CDC's Gonococcal Isolate Surveillance Project have shown the development of resistance for *Neisseria gonorrhoeae* ('gonorrhea') to the oral antibiotic cefixime. As a result, the CDC has revised its 2010 Sexually Transmitted Diseases (STD) guidelines. The revised guidelines no longer recommend cefixime as an effective oral treatment for gonorrhea. The new guidance recommends combination therapy with ceftriaxone, 250 mg intramuscularly, and either azithromycin, 1 g orally as a single dose, or doxycycline, 100 mg orally twice daily for seven days. This may delay emergence and spread of resistance to other cephalosporins. There are approximately 300,000 new cases of gonorrhea reported annually.

Hydroxyprogesterone Caproate

A hearing was held in a US District Court on August 7, 2012, in the lawsuit filed by KV Pharmaceuticals (KV) versus the FDA and HHS (collectively FDA) over hydroxyprogesterone caproate (Makena™) exclusivity. KV claims the FDA has violated its rights under the Food, Drug, and Cosmetic Act and the Orphan Drug Act. The manufacturer wants the FDA to take enforcement action against compounding pharmacies that compound unapproved generic versions of the drug at substantially lower cost. The FDA wants the court to dismiss KV's lawsuit. The court decision is expected in the near future.

Drug Information[1]

Stribild®

Gilead has received approval for Stribild®, a once-daily single-tablet quad regimen for HIV-1 infection for treatment-naïve adults. The tablet contains elvitegravir 150 mg, an integrase inhibitor; cobicistat 150 mg, a pharmacoenhancing agent; emtricitabine 200 mg, a reverse transcriptase inhibitor; and tenofovir disoproxil fumarate 300 mg, a reverse transcriptase and polymerase inhibitor. The approval was based on two 48-week Phase 3 trials where the quad tablet showed non-inferiority compared to efavirenz/emtricitabine/tenofovir disoproxil fumarate (Atripla®), and to a regimen containing ritonavir-boosted atazanavir, plus emtricitabine/tenofovir disoproxil fumarate (Truvada®). Between 88 and 90 percent of patients treated with Stribild demonstrated undetectable blood levels of HIV, compared with 84 percent treated with Atripla and 87 percent treated with Truvada plus atazanavir and ritonavir. The label contains Boxed Warnings of lactic acidosis/severe hepatomegaly with steatosis, and post-treatment acute exacerbation of hepatitis B. The launch is planned for the end of August 2012.

Ipratropium bromide/albuterol (Combivent® Respimat®)

Boehringer Ingelheim is introducing ipratropium bromide/albuterol (Combivent® Respimat®) inhalation spray CFC-free formulation to replace ipratropium bromide/albuterol sulfate inhalation aerosol (Combivent®). The manufacturer is expected to phase out Combivent® in May 2013. The dosing for Combivent® Respimat® is one inhalation four times daily versus two inhalations four times daily for Combivent®.

[1] Magellan Medicaid Administration, Inc. Clinical Alert. September 2012. Available at www.MagellanMedicaid.com/news/ClinicalAlerts.asp.