2015 Fall Medication App

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Employers Health is pleased to provide this seasonal medication update! The goal of this piece is to inform our members about the latest pharmaceutical industry news relevant to employers while providing analyses and strategies to best manage these trends. Please send any questions or comments to our clinical pharmacist, Matthew Harman, at mharman@employershealthco.com.

First PCSK9 Inhibitors for High Cholesterol Approved

Two of three highly anticipated PCSK9 inhibitors were launched this summer for the treatment of certain types of hypercholesterolemia for patients at high risk of cardiovascular events. The PCSK9 inhibitors – Praluent (alirocumab) and Repatha (evolocumab) – are approved in combination with diet and a maximally tolerated statin as a result of a 45-60 percent reduction in LDL-cholesterol (LDL-C) observed in clinical trials. Thus, plan sponsors may expect to **cover an estimated four members per 1,000 commercially insured lives** with proper utilization management strategies (step therapy, days' supply limits, etc.) in place.

Due to efficacy and safety similarities in both PCSK9 inhibitors, PBMs will implement individual exclusion strategies by selecting either Praluent or Repatha, which will drive better pricing terms. Employers that have their proposed options clinically reviewed will be in the best position to manage the PCSK9 inhibitors' impact on trend, which can range from $3-$12 PMPM based on the Employers Health PCSK9 inhibitors modeling tool for our purchasing members.

The third PCSK9 inhibitor, yet to be named by Pfizer, will hit the market in 2016. Expect broader use of PCSK9 inhibitors if the future studies show positive cardiovascular outcomes in 2017-2018. Perhaps more important than efficacy, the unknown long-term impact on safety by reducing LDL-C must be determined before expanding the use to anyone with high cholesterol. It is for this reason that plan sponsors, even those that typically take a hands-off approach to drug management, have utilization controls to reflect the approved indication in order to protect their employees from off-label usage.

One final note: the package inserts for PCSK9 inhibitors recommend testing LDL-C at four to eight weeks to determine effectiveness of the self-injectable medications. Depending on the LDL-C level after initiating treatment, the patient may be better off discontinuing therapy or switched to the higher dose. This provides an opportunity to have proper protocols in the plan to reduce waste, and thereby unnecessary costs, for the $1,000 per month self-injectable pens. These protocols can take the form of days' supply limitations and/or increasing the frequency of prior authorization review.

Female Libido Drug Raises Questions about Benefits versus Risks

Third time's a charm for a drug known as Addyi (flibanserin). It's the first approved medication from the Food and Drug Administration (FDA) for the sudden and unexplained loss of libido for premenopausal women. The "pink pill" is making headlines and sparking controversy over its questionable efficacy, concerning side effects, and serious interactions with alcohol and hormonal contraceptives.

If the real world results are anything like the clinical trials, formulary decision makers should have great pause when you consider only about 8-13 percent of women, on average,

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experienced 0.5 more "sexually satisfying events" per month compared to a placebo, while 8 percent more women had a moderate to severe adverse drug reaction on Addyi.

Since the drug works a certain way on brain neurotransmitters, Addyi needs to be taken nightly for two to four weeks to see an effect. Additionally, the data show only one in 10 women perceive a benefit from this medication.

The FDA had rejected the medication twice before (in 2010 and 2013) due to the concerns, but as a result of a powerful marketing and advocacy campaign by the drug manufacturer and women's groups, Addyi was approved even though no new beneficial evidence was presented. To maneuver these issues, the FDA approved the medication for daily use at bedtime and requires prescribers to undergo specially certified training to ensure women will permanently abstain from alcohol while on Addyi. Still, the potential for off-label use is there.

Since this is a lifestyle drug, plan sponsors should expect it to have parity coverage to erectile dysfunction (ED). Thus, if you cover ED drugs, then Addyi will likely be covered, and vice versa. If possible, Employers Health recommends not covering this medication due to the lack of efficacy and questionable safety, which can be exacerbated with the use of alcohol and birth control. For those that must cover Addyi, limiting the initial approved quantity to eight weeks then evaluating for symptom improvement is a sound utilization strategy.

Because this drug exclusively affects women, plan sponsors should be cognizant of sex discrimination implications. A full article discussing this dynamic can be found on our website under Staff Articles.

New Cystic Fibrosis Drug May Quadruple Treatable Population

More than 30,000 Americans live with cystic fibrosis (CF), which is a rare, life-threatening genetic disorder characterized by a buildup of thick mucus in the lungs, pancreas and other organs. Within CF, multitudes of genetic variations comprise the illness, and the latest specialty drug now can treat roughly 8,500 CF patients ages 12 and older, compared to past CF drugs that could only treat approximately 2,000 patients.

Costs for CF treatments are approximately $240,000 per year. Employers Health purchasing members are monitored on a weekly basis for high-cost medications, such as Orkambi (lumacaftor/ivacaftor), to provide a real-time awareness about pharmacy claims for budgeting purposes.

First Generic Version of Copaxone Launched

Copaxone (glatiramer acetate), the brand name drug for Multiple Sclerosis (MS), now has a generic substitute known as Glatopa. As an attempt to minimize the market share losses to Glatopa (glatiramer acetate), the Copaxone manufacturer has created a 40 milligram version that is injected every other day, as opposed to 20 milligrams of Glatopa each day.

Currently, the Copaxone manufacturer was able to get approximately 60 percent of patients on the every-other-day formulation. This being the case, it might be disruptive to patients if they switch back to daily administration with Glatopa.

However, adherence to a daily regimen may be higher for patients, as opposed to remembering to inject Copaxone every other day. Glatopa currently costs 25 percent less than the Copaxone 20 milligram with similar efficacy and safety. Plan sponsors should have a basic step therapy criteria in place for newly prescribed MS patients to try Glatopa first while grandfathering current Copaxone users. If the cost difference grows substantially larger than 25 percent, expect formulary decision makers to exclude Copaxone from the formulary in favor of universal Glatopa usage.