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# Drug Information Updates

LIMITED DISTRIBUTION

## Xolair Receives FDA Approval for Additional Indication — 11/30/2020

The FDA approved Genentech's monoclonal antibody, Xolair® (omalizumab), for a third indication on Nov. 30, 2020. The new approval is to treat adults who have nasal polyps that have not responded to nasally inhaled corticosteroid therapy. While steroid therapy continues, Xolair will be administered by a healthcare provider as a subcutaneous (SC) injection once every two weeks or once every four weeks, with dosing based on the patient's weight and IgE blood levels. Injections must be given in a facility staffed and equipped to manage emergencies because Xolair may cause anaphylaxis (severe allergic reactions). Originally indicated to treat patients at least six years old for persistent allergic asthma that resists inhaled corticosteroid treatment, Xolair has an additional FDA approval for patients age 12 and older who have hives due to chronic idiopathic urticaria (CIU) that has not responded adequately to antihistamines.

*Formulary Status*: Xolair is not covered under the pharmacy benefit as it is administered in a healthcare setting.

LIMITED DISTRIBUTION

## Imcivree Approved to Treat Certain Genetic Causes of Obesity — 11/30/2020

The FDA approved Imcivree® (setmelanotide) for chronic weight management (weight loss and maintenance for at least one year) in patients six years and older with obesity due to three rare genetic conditions: pro-opiomelanocortin (POMC) deficiency, proprotein subtilisin/kexin type 1 (PCSK1) deficiency, and leptin receptor (LEPR) deficiency confirmed by genetic testing. Imcivree is the first FDA-approved treatment for these genetic conditions. Imcivree is not approved for other causes of chronic weight conditions. Imcivree works by activating areas in the brain that regulate appetite and fullness, causing patients with these genetic conditions not to eat as much and to lose weight. The drug also increases resting metabolism (the number of calories the body burns at rest), which can contribute to weight loss.

*Formulary Status*: Imcivree will be reviewed at the next P&T Committee meeting

## Hetlioz Receives Additional Indication along with New Dose Form Approval — 12/03/2020

Hetlioz® (tasimelteon – Vanda Pharmaceuticals) has been approved by the FDA as the first drug to treat irregular sleep patterns resulting from Smith-Magenis Syndrome (SMS) on the same day that a new liquid formulation, Hetlioz LQ™ oral suspension, also was approved. SMS generally is caused by spontaneous mutations in the RAI1 gene, occurring in about 1 in every 15,000 to 25,000. To help normalize sleep timing, Hetlioz is weight-based, with all doses given approximately one hour before the patient's bedtime. The two dosage forms are not interchangeable, and children should not take Hetlioz capsules. Release of the oral suspension is expected in the first quarter of 2021. The capsule formulation also has FDA approval to treat Non-24-Hour Wake-Sleep disorder (Non-24), a chronic sleep disturbance that affects most individuals who are totally blind.

*Formulary Status*: Hetlioz is a tier 3 non-preferred brand drug on the National Formulary

LIMITED DISTRIBUTION

## Orladeyo Approved to Prevent Hereditary Angioedema (HAE) — 12/03/2020

Orladeyo™ (berotralstat) capsules were approved by the FDA as the first oral drug indicated to prevent attacks of hereditary angioedema (HAE) for patients who are at least 12 years old. At a recommended daily dose of 150mg, it decreases blood levels of kallikrein, an enzyme involved in promoting pain and swelling caused by HAE. The manufacturer, BioCryst, expects to release Orladeyo in the U.S. before the end of 2020 in cartons of 28 capsules of either 150mg or 110mg.

*Formulary Status*: Orladeyo will be reviewed at the next P&T Committee meeting

## Saxenda Approved for New Age Range — 12/04/2020

Novo Nordisk's glucagon-like peptide 1 (GLP-1) receptor agonist, Saxenda® (liraglutide) subcutaneous (SC) injection, was approved for use by patients as young as 12 years old. It will supplement a reduced-calorie diet and increased exercise for adolescents who weigh 60kg (about 120 pounds) or more, and who are considered to be obese compared to others of the same age and gender. Saxenda can be administered by the patient or a caregiver, with dosing being titrated based on patient age and weight. Saxenda also has been marketed at a lower dose and under the name Victoza® since January 2010 to treat type 2 diabetes, but Saxenda is not FDA approved to treat any type of diabetes.

*Formulary Status*: Saxenda is a tier 2 preferred brand drug on the National Formulary

**Januvia Products Undergo Label Change** **12/04/2020**

In a recent Safety Communication, the FDA authorized labeling changes for Merck's dipeptidyl peptidase-4 (DPP-4) inhibitors, Januvia® (sitagliptin), Janumet® (sitagliptin/metformin) and Janumet® XR (sitagliptin/metformin extended release), against their use in pre-teens and adolescents. All are approved – along with dietary changes and increased activity – to treat adult patients who have type 2 diabetes. However, additional studies did not find effectiveness for any of the drugs in treating type 2 diabetes for patients between the ages of 10 and 18.

*Formulary Status*: Januvia is a tier 2 preferred brand drug on the National Formulary

## IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

***12/10:*** *Patent Expiration:* Saphris® (asenapine – Allergan): One of the patents covering this drug expires, potentially allowing the introduction of a generic for the atypical antipsychotic that treats schizophrenia and bipolar disorder; sublingual

***12/19:*** *FDA Action Date:* margetuximab (MacroGenics): Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2, for the treatment of HER2 (+) breast cancer; IV infusion

*FDA Action Date:* Riabni® (rituximab-arrx – Amgen/Allergan): A biosimilar to Rituxan® (rituximab – Genentech/Biogen), a CD20-directed cytolytic antibody, to treat patients who have non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis, and microscopic polyangiitis; IV infusion

***12/20:*** *FDA Action Date:* roxadustat (FibroGen): An hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) inhibitor for the treatment of chemotherapy-induced renal anemia in pre-dialysis patients who have chronic kidney disease (CKD); oral

*FDA Action Date:* Relumina® (relugolix – Myovant): A once-daily gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of prostate cancer; oral

## GENERAL INFORMATION:

For more information, please either visit FDA.gov or contact your account manager.