MC-Rx

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Drug Information Updates

Nexlizet Approved as New Cholesterol Lowering Agent **02/26/2020**

The FDA approved Esperion's Nexlizet™ (bempedoic acid and ezetimibe) tablet, the first once-daily, non-statin, LDL cholesterol lowering combination. It is indicated for use in adults who have heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) and who are on a statin, but who require further lowering of LDL cholesterol (LDL-C). Bempedoic acid, an ATP Citrate Lysase (ACL) inhibitor, was approved as a single drug earlier in February under the trade name Nexletol™. Ezetimibe, available as a generic, works by blocking absorption of cholesterol in the small intestine. Compared to placebo, Nexlizet lowered LDL-C by an average of 38% in clinical trials. Notable drug interactions include simvastatin in daily doses of 20mg or higher and pravastatin at 40mg or more. Patients should be monitored when taking cyclosporine, which could affect blood levels of both drugs, and fibrates, which could cause gallstones if taken together. Nexlizet is planned for launch in July 2020.

Formulary Status: Nexlizet is scheduled for clinical review at the next P&T Committee meeting in June.

Vyepti Approved for Migraine Prevention **02/21/2020**

Lundbeck's Vyepti™ (eptinezumab-jjmr) is the first intravenous (IV) prevention treatment for migraine in adult patients. Vyepti, a humanized monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), is given by IV infusion at a recommended dose of 100mg over 30 minutes once every three months. Some patients may need to increase the dose to 300mg if relief is not adequate. Vyepti's label advises about some relatively mild hypersensitivity reactions that led to discontinuation of treatment by a few patients in trials. To be introduced in April 2020, Vyepti, which does require dilution before administration, will be available in 100mg/mL single use vials.

Formulary Status: Vyepti has been deemed a medical drug due to IV administration and is not covered.

Nurtec-ODT Approved for Acute Migraine **02/27/2020**

An oral CGRP antagonist, Nurtec™ ODT (rimegepant orally-disintegrating tablets), is indicated to treat adults who have acute migraine headaches, but not to prevent migraines. The recommended dose is one 75mg tablet, dissolve on or under the tongue, once a headache starts or once the patients has signs that a migraine is about to begin. Only one tablet should be used per day and using more than 15 tablets per month has not been proven safe. Beginning next month, the manufacturer, Biohaven Pharmaceuticals, will market cartons containing eight blister-packed tablets.

Formulary Status: Nurtec-ODT is scheduled for clinical review at the next P&T Committee meeting in June.

Barhemsys Approved **02/26/2020**

Acacia Pharma Group was granted FDA approval for Barhemsys® (amisulpride) injection, an IV antiemetic indicated to prevent post-operative nausea and vomiting either alone or along with another anti-nausea drug, such as ondansetron. The recommended dose before a surgical procedure is 5mg infused over one to two minutes. The dose is 10mg, administered over one to two minutes, for the treatment post operation. Barhemsys is not approved for use in pediatric patients. Beginning in the second half of 2020, it will be available as single-dose vials containing 5mg/2mL.

Formulary Status: Barhemsys has been deemed a medical drug due to IV administration and is not covered.

FDA Approves ArmonAir Digihaler **02/24/2020**

The FDA approved Teva's ArmonAir® Digihaler™ (fluticasone propionate) inhalation powder administered for one inhalation twice each day. ArmonAir Digihaler is indicated for use as a maintenance therapy of asthma in patients at least 12 years of age but not used as rescue treatment for acute bronchospasms. Each digihaler includes digital components that can transmit information to an app for keeping track of usage or sharing with a health professional. ArmonAir Digihaler will be marketed in 55mcg, 113mcg and 232mcg strengths although the costs and launch date have not been disclosed.

Formulary Status: ArmonAir Digihaler is a line extension and is a tier 3 non-preferred brand product on the formulary.

Fluad Quadrivalent Approved **02/21/2020**

The FDA approved Fluad® Quadrivalent (influenza vaccine, adjuvanted - Seqirus) to prevent flu for patients who are 65 years old and older. Although Fluad has been available in a trivalent version for several years, the new form is the first version to be active against four strains of flu viruses. Fluad Quadrivalent also contains an adjuvant (an immune booster) that not only improves its effectiveness, but prolongs it as well. Like most other flu vaccines currently on the market, Fluad Quadrivalent will be given as one dose of 0.5mL in an intramuscular (IM) injection, ideally by the start of each year's flu season.

Formulary Status: Fluad Quadrivalent, like all flu vaccines, are tier 2 preferred brand products on the formulary.

Expanded indication for Trulicity **02/21/2020**

Trulicity® (dulaglutide), Eli Lilly's long-acting GLP-1 agonist, got a new indication from the FDA. Self-administered once-weekly as a subcutaneous (SC) injection, Trulicity can now be used to decrease the likelihood of cardiovascular (CV) events, such as heart attacks and strokes, in adult patients with type 2 diabetes who have established cardiovascular disease or multiple cardiovascular risk factors. All GLP-1 drugs carry a boxed warning that tumors of the thyroid gland (thyroid C-cell tumors) have occurred in laboratory animals.

Formulary Status: Trulicity is a tier 2 preferred brand drug on the formulary.

Riomet ER Launched **02/21/2020**

Sun Pharma's Riomet ER™ (metformin for extended-release oral suspension) now is available in the U.S. Riomet ER is indicated along with diet and exercise for treating patients at least 10 years old with type 2 diabetes who have some degree of difficulty swallowing tablets or capsules. It is taken with the last meal of the day. All medications that contain metformin have a boxed warning that taking it may cause lactic acidosis, the buildup of excessive acid in the blood.

Formulary Status: Riomet & Riomet ER have a 100% copay assigned on the formulary.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

None listed.

GENERAL INFORMATION:

More information will be provided as it becomes available. Visit FDA.gov for more information.

Coronavirus Alert

Stay informed about the COVID-19 situation.

- Visit the CDC website to get up-to-date information about COVID-19.