MC-Rx

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Drug Information Updates

Twirla (New Contraceptive Patch) Approved **02/14/2020**

Agile Therapeutics received FDA approval for Twirla® (levonorgestrel/ethinyl estradiol) transdermal system. Each Twirla patch releases a low daily dose of an estrogen and a progestin to provide contraception. One patch is applied to clean, dry skin of the abdomen, back, buttocks or lower chest once each week for three weeks and then no patch is needed for the fourth week. Twirla is not approved for women who have a body mass index (BMI) over 30kg/m^2 and its effectiveness may be limited for women whose BMI is between 25kg/m^2 and 30kg/m^2. An additional boxed warning specifies that its risk of causing blood clots means it should not be used by women who are older than 35 years of age and who smoke. Agile plans to begin distributing Twirla in the fourth quarter of 2020.

Formulary Status: Twirla was placed on formulary as a tier 3 non-preferred brand.

FDA Approves Anjeso **02/20/2020**

Anjeso™ (meloxicam injection – Baudax Bio) was approved by the FDA. Anjeso a non-steroidal anti-inflammatory drug (NSAID) indicated to treat moderate-to-severe pain for adults. Although oral formulations of meloxicam have been available in the U.S. for about 20 years, Anjeso is the first injectable form to be FDA approved. It can be used by itself, but it does not begin to work immediately. Dosage is one vial (30mg) given as an intravenous (IV) per day. It should be used only as long as the patient needs relief for severe pain, not moderate pain.

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

Additional Biosimilar to Herceptin Launched **02/15/2020**

Trazimera™ (trastuzumab-qyyp), a biosimilar for Herceptin® (trastuzumab - Genentech) was recently launched by Pfizer. It is used to treat breast cancers and metastatic stomach cancers (gastric or gastroesophageal junction adenocarcinomas) that overexpress the HER2 gene (HER2+). Mainly given as 30-minute IV infusions after an initial 90-minute infusion, doses vary on schedules that also differ according to the type of the cancer being treated. All trastuzumab products have boxed warnings that they may cause birth defects, heart failure, respiratory distress or severe allergic reactions. In addition to sharing the market with Herceptin, Trazimera will compete with Kanjinti™, and Ogivri™. None of the biosimilars are interchangeable with Herceptin or with each other.

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

New Dosage Form Approved for Procysbi **02/14/2020**

Procysbi® (cysteamine bitartrate – Horizon Therapeutics) delayed-release oral granules was recently approved by the FDA. Procysbi is used for treating patients who have nephropathic cystinosis, an orphan condition affecting only around 500 U.S. patients. If untreated, few patients who have it survive into their teens. Procysbi is taken once every 12 hours on a weight-based dosage scale beginning with amounts as small as 25mg each and gradually increasing over four to six weeks to maintenance doses of as much as 1,000mg each. Previously, Procysbi was available only as 25mg and 75mg oral capsules, which can be swallowed whole or their contents can be sprinkled onto soft foods or into small amounts of a drink and consumed right away. The granules are available in packets containing 75mg or 300mg, which may be easier to transport and open for patients, especially those taking higher doses of Procysbi.

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

Three Products Switched to Non-Prescription Status **02/14/2020**

The FDA granted the manufacturers of three prescription drug products permission to sell the drugs without prescriptions (OTC). All were shown to be safe for patients to use without diagnosis or supervision from a health professional.

1. GlaxoSmithKline's **Voltaren Arthritis Pain** (diclofenac) topical gel, 1% is an NSAID indicated for adults. Rubbed onto the skin, it helps to lessen joint pain caused by arthritis. Directions are to apply it four times a day, keeping total daily doses to 32gm or less. Patients should not use it for more than three weeks at a time. The OTC product is expected to be in stores in the spring of 2020.
2. Also switched to OTCs were **Pataday Twice Daily Relief®** (olopatadine ophthalmic solution, 0.1%) and **Pataday Once Daily Relief®** (olopatadine ophthalmic solution, 0.2%), made by Alcon. Both eye drops contain a mast cell stabilizer that helps to control allergy symptoms in the eyes and reduces eye redness. Patients should be careful not to touch the eye dropper tips or to use the eye drops while wearing contact lenses. Alcon will launch both products in March, 2020.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

02/21: Bempedoic acid (Nexletol - Esperion): An adenosine triphosphate (ATP) citrate lyase (ACL) inhibitor/5'-adenosine monophosphate-activated protein kinase (AMPK) activator, for once-daily treatment of patients who have elevated LDL cholesterol and who need additional LDL-C lowering despite the use of current therapies; oral --UPDATE: Approved 02/21/2020

02/21: Eptinezumab (Lundbeck): A calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraines; IV

02/26: Bempedoic acid/ezetimibe (Nexlizet - Esperion): A new inhibitor of ATP citrate lyase (ACL) and activator of 5'-adenosine monophosphate-activated protein kinase (AMPK), combined with an 2-azetidinone that limits cholesterol absorption, to treat patients who have elevated LDL cholesterol and who need additional LDL-C lowering despite the use of current therapies; oral

02/26: Barhemsys® (amisulpride – Acacia Pharma): A selective dopamine antagonist for management of post-operative nausea and vomiting (PONV); IV

GENERAL INFORMATION:

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