MC-Rx

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Drug Information Updates

Second Rituxan Biosimilar Now Available

01/23/2020

Ruxience™ (rituximab-pvvr), Pfizer's biosimilar to Rituxan® (rituximab – Celgene), is indicated to treat adults who have non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL) or granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). Administered as intravenous (IV) infusions, it has to be given by a healthcare professional in a facility equipped to handle emergency treatment of serious side effects that it may cause. Ruxience is not interchangeable with Rituxan or with Rituxan's other biosimilar, Truxima® (rituximab-abbs – Celltrion/Teva), but is available at a 24% discount to the price of Rituxan.

Formulary Status: Ruxience will be under a medical benefit and not covered under our pharmacy benefit

Tazverik™ Approved for Epithelioid Sarcoma

01/24/2020

The FDA announced approval of Tazverik™ (tazemetostat – Epizyme) tablets, the first drug in a new class of drugs that block the activity of an enzyme, *enhancer of zeste homolog 2* (EZH2) methyltransferase. It is approved to treat patients 16 years of age and older who have epithelioid sarcoma that has metastasized or spread locally and that cannot be removed by surgery. Its recommended dose is 800mg (four tablets) taken twice a day. Epizyme plans to launch Tazverik by mid-February at a WAC of $15,500 for a one-month supply.

Formulary Status: Tazverik will be reviewed at our next P&T Committee meeting in March

Trijardy™ XR Approved to Treat Diabetes

01/27/2020

The FDA approved Trijardy™ XR extended-release tablets for managing diabetes, a three-drug combination of metformin, Jardiance® (empagliflozin), an SGLT2 inhibitor, and Tradjenta® (linagliptin), a DPP4 inhibitor. Marketed jointly by Eli Lilly and Boehringer Ingelheim, all three branded drugs are indicated for the treatment of adults who have type 2 diabetes (Metformin reduces production of glucose and lessens its absorption and improves insulin sensitivity, SGLT2s blocks reabsorption of glucose by the kidneys to increase glucose excretion in the urine and DPP-4s decrease the activity of an enzyme that breaks down hormones that help to maintain blood glucose control). Including all three in one tablet taken once daily is more convenient for patients who need more than one drug to control blood sugar. No launch or pricing plans are available.

Formulary Status: Trijardy XR will be reviewed at our next P&T Committee meeting in March

FDA Approves Monoferric to Treat Iron Deficiency Anemia

01/16/2020

Monoferric® (ferric derisomaltose – Pharmacosmos Therapeutics) injection was approved and is indicated to replenish iron for adults who have iron deficiency anemia, but who cannot take an oral iron product, who haven't improved while taking iron orally or who have chronic kidney disease (CKD) that does not require dialysis. It will be administered as one intravenous (IV) infusion for patients based on who weigh 50 kg (110 pounds) or more. Treatments will be given a healthcare facility that is staffed and equipped to manage severe hypersensitivity responses sometimes associated with IV iron.

Formulary Status: Monoferric will be under a medical benefit and not covered under our pharmacy benefit

Auto-Injector Approved for Ajovy

01/27/2020

Teva Pharmaceuticals USA received FDA approval for an auto-injector device for its calcitonin gene-related peptide (CGRP) inhibitor, Ajovy® (fremanezumab-vfrm). One of three injectable CGRP inhibitors that are FDA approved, Ajovy is used to prevent migraine headaches for adult patients. Auto-injectors containing 225mg of Ajovy are expected to launch soon. Its recommended dosing is one subcutaneous (SC) injection (225mg) every month or three injections (675mg) all at the same time once every three months. Prefilled 225mg syringes remain available, as well.

Formulary Status: Ajovy auto-injectors are a line extension and will be preferred brand on our National Formulary

Palforzia Approved for Prevention of Severe Peanut Allergies

01/31/2020

Palforzia™ [peanut (*Arachis hypogaea*) allergen powder-dnfp] capsules and sachets from Aimmune Therapeutics has been approved by the FDA. Palforzia is an immunotherapy to be taken orally for preventing severe allergic reactions (anaphylaxis) to peanuts for children ages four to 17 who have diagnosed peanut allergies. Patients still will have to avoid eating or being around products that contain peanuts and keep emergency treatments at hand, but using Palforzia may help prevent or decrease reactions if peanuts are encountered accidentally.

Treatment is in three stages – on the first day, 13mg is administered in gradually larger amounts, then doses are increased progressively over several months from 3mg/day to a maintenance dose of 300mg per day – about the same amount of protein as in one peanut. Capsules and sachets contain peanut powder that should be sprinkled onto cold, soft food, such as applesauce or yogurt, and consumed immediately. The first doses at each increasing dose level will be given in a healthcare facility staffed and equipped to manage severe allergic reactions. A boxed warning on the labeling cautions that Palforzia, itself, could trigger anaphylaxis. Launch is projected late in 1st quarter 2020.

Formulary Status: Palforzia will be reviewed at our next P&T Committee meeting in March

New Dosage Form and Extended Indication for Dificid

01/24/2020

The FDA approved an oral suspension formulation and an extended indication for the tablet form of Dificid® (fidaxomicin - Merck). An antibiotic that is absorbed only minimally into the body, Dificid is indicated only to treat *Clostridioides difficile* (C diff)-associated diarrhea for patients at least six months old. C diff is a bacterium that infects the colon, particularly for the 500,000 patients each year who have used different antibiotics for other infections. Dificid will be administered as two doses per day for 10 days, as one 200mg tablet a weight based dosing for those who cannot swallow tablets

Formulary Status: Dificid Solution is a line extension and will be a preferred brand on our National Formulary

Clozapine – Important Information!

01/28/2020

An updated safety communication for clozapine, which is used for treating schizophrenia. Clozapine is available as a generic drug and as the brand names (Clozaril® tablets and Versacloz® Oral Suspension). The FDA is intensifying its previous warning that constipation often associated with taking clozapine may cause rare bowel blockages and other severe bowel problems. Although constipation is a common side effect of taking clozapine, some patients needed to be hospitalized, had to have surgery or died due to infections or blockages they developed while taking it.

Most seriously affected patients were taking higher doses of clozapine and many were using other medications, such as opioid pain relievers and overactive bladder drugs that also slow down activity in the intestines. Prescribers should consider recommending a laxative to their patients when prescribing with clozapine, while patients with signs of constipation should any major changes in bowel habits to their doctors.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

Rykindo® (risperidone, extended-release microspheres for injection – Luye Pharma): new formulation to treat schizophrenia and bipolar disorder, given once every two weeks [intramuscular]

LMIS (leuprolide mesylate, 50 mg depot injection – Foresee Pharmaceuticals): A ready-to-use, sustained-release, six-month synthetic gonadotropin-releasing hormone for palliative treatment of advanced prostate cancer [sub-cutaneous]

GENERAL INFORMATION:

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