MC-Rx

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Drug Information Updates

FDA Approves Zilxi to Treat Rosacea **05/28/2020**

Zilxi™ (minocycline – Foamix, a subsidiary of Menlo Therapeutics) topical foam, was approved as the first minocycline to treat adults who have acne-like inflammatory lesions from rosacea. It will be dispensed in 30gm canisters with directions for once daily application to affected areas of the face. It should be rubbed in gently at about the same time every day — at least one hour before bathing, going to bed, showering or swimming. Even though the risk is less with minocycline topical products, patients still should protect against sunburn from natural or artificial light, such as in tanning beds. A launch is planned by the fourth quarter 2020.

Formulary Status: Zilxi will be reviewed at the next P&T Committee meeting in September

Oriahnn Receives FDA Approval **05/29/2020**

Oriahnn™ (elagolix/estradiol/norethindrone and elagolix) capsules was approved as the first oral drug indicated to reduce heavy menstrual bleeds for women who have uterine fibroids and who have not yet reached menopause. Non-cancerous tumors of the uterus that are worsened by monthly hormone variations, fibroids affect over one-half of women by the time they reach 50 years of age. Although many women have few or no symptoms, about 25% of women who have fibroids experience serious effects such as severe pain that can interfere with usual activities and excessive bleeding that can cause anemia. Patients will take 1 capsule containing all 3 ingredients once each morning and one capsule of just elagolix every evening. It will be dispensed in cartons of 4 blister-packed cards each containing a 7 day supply of the capsules.

Formulary Status: Ohiahnn will be reviewed at the next P&T Committee meeting in September

Brilinta Given New Indication **05/28/2020**

AstraZeneca's antiplatelet drug, Brilinta® (ticagrelor) tablets is now is approved to decrease the risk of an initial major cardiovascular (CV) event, such as a heart attack, a stroke or death, for patients who have coronary artery disease (CAD) that puts them at high risk for a CV event. Dosing is 60mg twice a day along with a single 100mg or lower-dose aspirin.

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

Expanded Indication for Taltz **05/29/2020**

Taltz® (ixekizumab – Eli Lilly and Company) injection is indicated for treating non-radiographic axial spondyloarthritis (nr-xSpA). The Spondylitis Association of America estimates that about 2.7 million Americans have axial spondyloarthritis (axSpA), an inflammatory arthritis of the spine that usually is diagnosed in the late teens to mid-forties for patients who have chronic, severe back pain.

Formulary Status: Taltz is a tier 3 non-preferred brand specialty drug on the National Formulary

New Cyramza Indication **05/29/2020**

Lilly's Cyramza® (ramucirumab) injection was approved as first-line treatment for metastatic non-small cell lung cancer (NSCLC) that has deletions in epidermal growth factor receptor (EGFR) exon 19 or mutations in EGFR exon 21. An inhibitor of new blood vessel formation, Cyramza will be used along with erlotinib (Tarceva® - Genentech/Astellas, generics) tablets, which block EGFR tyrosine kinase. Patients will be verified as having EGFR mutations through diagnostic testing before treatment begins. Cyramza has previous indications for certain colorectal, liver and stomach cancers, as well as for NSCLC in combination with docetaxel.

Formulary Status: Cyramza is currently a tier 2 preferred brand specialty drug on the National Formulary

FDA Approves New Indication for Tecentriq **05/29/2020**

Genentech received approval for Tecentriq® (atezolizumab) injection to now be used in combination with bevacizumab for first-line treatment of patients who have hepatocellular carcinoma (HCC) that has spread or that cannot be removed by surgery. Bevacizumab is available as a branded drug, Avastin® (bevacizumab – Genentech), and two biosimilars, MVASI™ (bevacizumab-awwb – Amgen) and Zirabev™ (bevacizumab-bvzr – Pfizer). For HCC, both drugs will be administered by IV infusion starting with Tecentriq (at 1,200mg) and then bevacizumab (at 15mg/kg) on the first day of 21-day cycles.

Formulary Status: Cyramza is currently a tier 2 preferred brand specialty drug on the National Formulary

Recarbrio Receives New Indication **06/01/2020**

A combination injectable drug made by Merck, Recarbrio® (imipenem/cilastatin/relebactam), is now approved for adult patients who develop pneumonia caused by specific bacteria while they are hospitalized and/or using a ventilator. The recommended dose is one vial (imipenem 500mg/cilastatin 500mg/relebactam 250mg) by IV infusion once every six hours for at least four days, but not more than 14 days. To help prevent antibiotic resistance, Recarbrio should be reserved only for use by patients who have not responded to or who cannot take other treatments.

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

New Dosage Form for Akynzeo **06/01/2020**

The FDA has approved a liquid ready-to-dilute injectable form of Helsinn Healthcare's Akynzeo® (fosnetupitant 235mg/palonosetron 0.25mg) in single-dose vials. A combination of two anti-nausea agents, it is administered along with dexamethasone to prevent cancer chemotherapy (chemo)-induced nausea and vomiting (CINV). Akynzeo also is available as oral capsules and a powdered IV dose form that needs reconstitution before it can be mixed with an IV fluid for administration. Recommended dosage is one vial of either injectable form administered over one-half hour before the start of each chemo treatment.

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

Nyvepria, Fourth Neulasta Biosimilar, Receives FDA Approval **06/11/2020**

Nyvepria™ (pegfilgrastim-apgf), Pfizer's biosimilar to Neulasta® (pegfilgrastim - Amgen), was approved and is indicated to decrease the risk of infections for patients who receive cancer drugs that interfere with the bone marrow's production of blood cells and that are associated with a clinically significant incidence of febrile neutropenia, an adverse effect of some chemotherapy. Pegfilgrastim is a PEGylated form of the granulocyte colony-stimulating factor (G-CSF) analog filgrastim, giving it a longer duration of action, which causes cells in bone marrow to produce more neutrophils. For Nyvepria, the recommended dose is 6mg -- one single-dose prefilled syringe -- injected subcutaneously (SC) administered once during each chemo cycle, at least one day after chemo is completed and 14 days or more before the next treatment.

Formulary Status: Nyvepria will be reviewed at the next P&T Committee meeting in September

FDA Approves Mylan's Insulin Glargine **06/11/2020**

Semglee® (insulin glargine – Mylan/Biocon), a long-acting (basal) insulin, was approved for use by diabetics. Semglee is injected SC at the same time once every day to manage blood sugar levels for adults who have type 1 or type 2 diabetes and for children and teens who have type 1 diabetes. Dosing is individualized according to the patient's blood sugar levels. Semglee is not automatically interchangeable with other insulin glargine products, Lantus® (Sanofi) or Basaglar® (Lilly/Boehringer Ingelheim), even though they have the same amino acid sequences. In addition to Lantus and Basaglar, Semglee will compete with other long-acting insulins, including Levemir® (insulin detemir – Novo Nordisk), Tresiba® (insulin degludec – Novo Nordisk) and Toujeo® (insulin glargine – Sanofi) and will be available in both 10mL multi-dose vials and 3mL disposable prefilled pens that contain 100 units of insulin/mL.

Formulary Status: Semglee will be reviewed at the next P&T Committee meeting in September

Opdivo Approved for New Indication **06/10/2020**

Bristol Myers Squibb's programmed death receptor-1 (PD-1) inhibitor, Opdivo® (nivolumab), was approved and is now indicated for the treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine and platinum-based chemo. A 240mg dose of Opdivo is infused intravenously (IV) every two weeks or a 480mg dose is infused every four weeks until cancer worsens or the patient can no longer tolerate using the drug.

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

Uplinza Approved for NMOSD **06/11/2020**

Viela Bio's Uplizna™ (inebilizumab-cdon) was approved for the treatment of adult patients who have neuromyelitis optica spectrum disorder (NMOSD) and who are anti-aquaporin-4 (AQP4) antibody positive. Uplizna, a humanized CD19-directed monoclonal antibody, is administered as an intravenous (IV) infusion over 90 minutes. Patients should be pretreated with a corticosteroid, an antihistamine and an anti-fever medication to reduce the risk of infusion-related reactions. The recommended initial dose is 300mg followed two weeks later by a second 300mg infusion. Starting six months after the initial infusion, maintenance doses of 300mg by IV infusion should be given every six months. Uplizna will be available exclusively through PantherRx Specialty Pharmacy later this month

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

Warning **05/28/2020**

There were no specific warning issued in the most recent period.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

06/09: Bavencio® (avelumab – Pfizer): A new indication for the fully human anti-PD-L1 IgG1 monoclonal antibody for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma; IV infusion

06/18: Crysvita® (burosumab-twza - Ultragenyx): A new indication for the fibroblast growth factor 23 (FGF23) inhibitor to treat FGF23-related hypophosphatemia associated with phosphaturic mesenchymal tumors; SC

06/18: Tazverik® (tazemetostat – Epizyme): A new indication for the methyltransferase inhibitor for treatment of patients who have relapsed or refractory follicular lymphoma (FL) and who have received at least two prior lines of systemic therapy; oral

06/19: Contepo™ (fosfomycin – Nabriva Therapeutics): An epoxide antibiotic for treatment of urinary tract infections; IV

06/19: Gimoti™ (metoclopramide – Evoke Pharma) nasal spray: A new formulation for the relief of symptoms associated with acute and recurrent diabetic gastroparesis for women who have diabetes; intranasal

GENERAL INFORMATION:

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