MC-Rx

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Drug Information Updates

New Dosage Form and Indication for Tivicay **06/12/2020**

ViiV Healthcare's Tivicay PD (dolutegravir) 5mg tablets for oral suspension was approved. An integrase strand transfer inhibitor (INSTI), it is used in combination with other drugs that treat HIV-1. Tivicay PD is taken once daily by patients who are four weeks or older, who weigh 3kg (about 7 pounds) or more and who have not been given an INSTI previously. The tablets easily dissolve in liquids and doses are based on the child's weight. At the same time, the FDA extended the pediatric indication for Tivicay film-coated tablets, 50mg, to children who weigh 20kg (about 45 pounds) or more. It originally was limited to patients at least six years old and at least 30kg.

Formulary Status: Tivicay PD will be a tier 2 preferred specialty drug on the National Formulary

Gardasil 9 Approved for Head and Neck Cancer **06/12/2020**

Merck's Gardasil® 9 (human papillomavirus vaccine 9-valent, recombinant) was granted a new indication to prevent oropharyngeal (mouth and throat) and head or neck cancers that result from infections with specific strains of human papillomavirus (HPV). Originally FDA approved in 2014 to prevent infections for patients between nine years and 26 years of age, Gardasil 9 provides protection against nine strains of HPV. It does not treat any HPV infection the patient already has, however; and it offers no protection against HPV strains the patient was exposed to before being vaccinated. It is given in a series of two or three intramuscular (IM) injections over six or 12 months, depending on the patient's age.

Formulary Status: Gardisil is a tier 2 preferred specialty drug on the National Formulary

FDA Approves Lyumjev **06/15/2020**

A new rapid-acting insulin, Lyumjev™ (insulin lispro-aabc injection – Eli Lilly) was approved for the treatment of diabetes. Given subcutaneously (SC) immediately before or within 20 minutes of beginning meals, it is indicated to improve blood sugar management for adults who have type 1 or type 2 diabetes. Lyumjev containing a concentration of 100 Units/mL will be available in 10mL, multi-use vials and 3mL cartridges for HumaPen® Luxura® HD insulin delivery device.

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

Juvederm Voluma XC Gains New Indication **06/15/2020**

Voluma™ XC, a cross-linked hyaluronic acid/lidocaine gel implant has approved a second indication to augment the chin area for adult patients. Like all products of its type, it will be injected in the affected areas as several small amounts (0.1mL to 0.2mL) between layers of skin by a cosmetic surgeon or other specifically trained health provider. Some patients experience temporary mild-to-moderate side effects -- mainly bruising, itching, pain, redness or swelling after injections.

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

New Indication for Cosentyx **06/16/2020**

Cosentyx® (secukinumab) injection, an interleukin-17 (IL-17) inhibitor manufactured by Norvartis, was approved for treating *non-radiographic axial spondyloarthritis (nr-axSpA).* An inflammatory arthritis of the spine, nr-axSpA can be treated with a 150mg dose of Cosentyx injected SC once a week for four weeks and then once every four weeks. Some patients may not need the weekly lead-in dosing. Already approved to treat psoriasis, psoriatic arthritis and ankylosing spondylitis, Cosentyx is available as single-use pen devices and single-use prefilled syringes, as well as in vials of powder that must be reconstituted for use.

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

Ilaris Receives New Indication **06/16/2020**

Ilaris® (canakinumab), also was granted an additional indication for the treatment of Still's disease, an inflammatory arthritis associated with fever, joint pain and rash. Since its first approval in 2009, Ilaris has received additional indications for other types of periodic fevers and for SJIA. A monoclonal antibody that inhibits interleukin-1 beta (IL-1β), it is injected SC to decrease inflammation. Recommended dosing for Still's disease is 4mg/kg by SC injection once every four weeks for patients who are at least two years old and who weigh at least 7.5kg (16.5 pounds) with a maximum dose injection of 300mg. It is dispensed in single-use vials containing 180mg of active drug after being mixed with 1mL of sterile preservative-free water.

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

Expanded Pediatric Indication for Mylotarg **06/16/2020**

Wyeth Pharmaceuticals' (Pfizer) Mylotarg™ (gemtuzumab ozogamicin) was approved to treat children as young as one month old for newly-diagnosed, CD33-positive acute myeloid leukemia (AML). A rare and aggressive cancer of the blood and bone marrow, AML is diagnosed for approximately 20,000 patients each year in the United States. Administered by IV infusion, the recommended dose of Mylotarg for babies and children is either 0.1mg/m^2 or 3mg/m^2, depending on body surface area (BSA). Dosing is scheduled by the phase of treatment and by whether other cancer drugs are being used.

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

New Keytruda Indication **06/16/2020**

Keytruda® (pembrolizumab – Merck) was granted another new indication. A PD-1 blocking antibody that is administered as a 30-minute IV infusion, Keytruda has multiple prior indications that include numerous cancers such as some esophageal, head and neck, kidney, lung and stomach cancers; as well as Merkel cell carcinoma (MCL), multiple myeloma and non-Hodgkin lymphoma (NHL). It is used alone or in combination with one of several other oncology drugs. For the new indication, the adult dose is 200mg once every three weeks or 400mg once every six weeks. Pediatric patients will be given 2mg/kg with a maximum of 200mg/dose once every two weeks.

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

Tazverik Gains Additional Indications **06/18/2020**

Tazverik™ (tazemetostat – Epizyme) tablets was approved for the treatment of adults who have one of two separate types of follicular lymphoma (FL). The first new indication is for treatment of patients who have relapsed or refractory FL, whose tumors are positive for a specific enzyme mutation EZH2 and who have received at least two prior systemic therapies. The second is for patients who have relapsed or refractory FL that has no alternative treatment options. The recommended dose of Tazverik is 800mg orally twice daily with or without food until disease progression or unacceptable toxicity.

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

FDA Approves Crysvita for Tumor-Induced Osteomalacia **06/18/2020**

Ultragenyx and Kiowa Kirin's Crysvita® (burosumab-twza) was approved to treat fibroblast growth factor 23 (FGF23)-related hypophosphatemia (low blood levels of phosphate) due to tumor-induced osteomalacia (TIO) that is associated with inoperable or localized phosphaturic mesenchymal tumors. The new approval includes adults and pediatric patients two years of age or older. The pediatric starting dose is 0.4mg/kg, which can be adjusted by rounding to the nearest 10mg, given once every two weeks. Adult doses, which start at 0.5mg/kg once every four weeks, may increase by 2mg/kg and shift to once every two weeks, if needed. Single doses should not exceed 180mg every two weeks for either age group.

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

New Delivery Device for Dupixent **06/18/2020**

Dupixent® (dupilumab) 300mg is now available in a prefilled pen device for injection. An IL-4Rα blocking antibody that disrupts the inflammatory process, Dupixent is injected subcutaneously (SC) and is indicated to treat atopic dermatitis for patients six years old and older, with dosing determined by the patient's weight. For patients as young as 12 years old, it also is approved for treating eosinophilic or oral steroid dependent asthma at a dose of 200mg or 300mg once every two weeks after one larger loading dose. Dupixent's third FDA indication is at 300mg once every two weeks to treat patients aged 18 and older for chronic rhinosinusitis with nasal polyposis. Intended for patients at least 12 years old, the new single-dose auto-injector has both written and spoken directions for use. Its launch is planned for third quarter 2020.

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

Fintepla Approved for Dravet Syndrome **06/19/2020**

Fintepla® (fenfluramine) oral solution by Zogenix was approved for treating patients who have Dravet syndrome (DS), a rare form of epilepsy that typically is diagnosed in infancy. To treat DS, patients at least two years old will be given 0.1mg/kg two times a day. The dose can be increased weekly up to 0.35mg/kg with a daily limit of 26mg, if the patient is not taking other medications for DS. The product will be available as a color free, cherry flavored solution which should be discarded three months after opening. A risk evaluation and mitigation strategy (REMS) is in place to certify prescribers, dispensers and patients. The distribution network has not yet been announced.

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

Gimoti FDA Approved **06/22/2020**

A new formulation, Gimoti™ (metoclopramide – Evoke Pharma) nasal spray, was approved to treat adults who have gastroparesis due to diabetes. Gastroparesis, which can be acute or chronic, is slowed emptying of stomach contents and may be associated with diabetes and other conditions, such as anorexia, infections and stomach surgeries. With women accounting for approximately 80% of patients, diabetes-related gastroparesis is believed to affect as many as 16 million U.S. adults. As the only drug FDA approved to treat gastroparesis, metoclopramide is available in oral solid and liquid forms, as well as injectables and works by promoting muscle contractions but not secretions in the stomach. Gimoti is the first nasal form, which will be dispensed in 9.8mL bottles that contain about 120 sprays each containing 15mg of active drug. Directions are to use one spray one-half hour or more before each meal and at bedtime. Evoke plans a launch in the fourth quarter of 2020.

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

New Xpovio Indication **06/22/2020**

Karyopharm Therapeutics received a second indication for its selective inhibitor of nuclear export (SINE), Xpovio® (selinexor) tablets. The new approval is to treat not-otherwise-specified diffuse large B-cell lymphoma (DLBCL) for adults who have been treated at least twice, but whose cancer recurs or resists previous therapy. To treat DLBCL, Xpovio will be taken on the first and third days of each week. Xpovio works by preventing the transfer of specific growth-promoting and tumor-repressing proteins from cell nuclei.

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

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

06/26: HTX-011 (bupivacaine/meloxicam – Heron Therapeutics): A long-acting, extended-release combination of a local anesthetic and a non-steroidal anti-inflammatory drug (NSAID) for postsurgical local analgesia; instillation into the surgical site

06/26: Mycapssa® (octreotide – Chiasma): A somatostatin analog for the maintenance treatment of adults who have acromegaly; oral

06/30: Breztri Aerosphere™ (budesonide/glycopyrronium/formoterol - AstraZeneca): A new fixed-dose combination of a corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta-2 agonist (LABA) delivered through a single metered-dose hydrofluoroalkane (HFA) device; inhaled

GENERAL INFORMATION:

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