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Drug Update

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Drug Information Updates

FDA Approves Fensolvi **05/01/2020**

The FDA approved Fensolvi® (leuprolide acetate) from Tolmar Pharmaceuticals, a gonadotropin releasing hormone (GnRH) agonist used to treat pediatric patients two years of age and older who have central precocious puberty (CPP). Fensolvi needs reconstitution prior to administration, it will be available in kits containing 45mg of leuprolide and is injected subcutaneously (SC) every six months by a healthcare professional. Fensolvi is not substitutable with generic and brand alternative options of injectable leuprolide that are available. Fensolvi's launch is planned in the next couple of months.

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

Darzalex Faspro Receives FDA Approval **05/01/2020**

Darzalex Faspro™ (daratumumab/hyaluronidase-fihj) was approved as a subcutaneous (SC) dosage form of Janssen's intravenous (IV) Darzalex® (daratumumab). Darzalex Faspro has indications, either alone or along with other cancer drugs, to treat adults who have multiple myeloma. Dosing schedules differ according to the type and stage of multiple melanoma, the patient's prior treatment status and the other drugs being used. The new SC form showed comparable effectiveness to the original form, but it can be administered in only a few minutes as compared to several hours for an IV dose. Both forms require pre-treatment and post-treatment with other drugs, though; and both forms must be given by a healthcare provider in a facility equipped to manage severe reactions that may occur.

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

New Dosage Form for Celecoxib **05/05/2020**

Dr. Reddy's Laboratories received FDA approval for Elyxyb™ (celecoxib oral solution). The first liquid COX-2 formulation inhibiting NSAID, it is indicated to treat adults who have migraine headaches but does not prevent migraines from occurring. The recommended dose is 120mg (one bottle) after a migraine has started with no more than one dose taken per day. Elyxyb will be dispensed in boxes containing nine individual, one-dose bottles. All NSAIDs, including celecoxib, have boxed warnings that using them can raise the chances of blood clots, which could result in cardiovascular (CV) events such as a heart attack and may be associated with gastrointestinal (GI) side effects.

Formulary Status: Elyxyb will be reviewed at the next P&T Committee meeting in June

New Indication for Farxiga **05/05/2020**

AstraZeneca announced that a new indication was FDA approved for Farxiga® (dapagliflozin) tablets to reduce the risk of cardiovascular (CV) death and hospitalization in adults who have heart failure (NYHA class II to IV) with reduced ejection fraction with and without type 2 diabetes (DM2). NYHA classifies heart failure based on limitations of physical activity. Heart failure occurs when the heart loses the ability to pump blood adequately throughout the body. Farxiga is a sodium-glucose cotransporter 2 (SGLT2) inhibitor first approved for blood sugar control, in addition to diet and exercise, for patients with DM2. Although other SGLT2 inhibitors have CV indications, Farxiga is the first approved to treat reduced ejection fraction in heart failure.

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

Imbruvica Indication Extended **04/20/2020**

Imbruvica® (ibrutinib – Pharmacyclics) was approved by the FDA to be used in combination with rituximab for initial treatment of adult patients less than 70 years old who are newly diagnosed with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). Rituximab, an IV monoclonal antibody, is available as the brand, Rituxan® (Genentech) and two biosimilars, Ruxience™ (rituximab-pvvr – Pfizer) and Truxima® (rituximab-abbs – Celltrion/Teva). Since its first FDA approval to treat mantle cell lymphoma (MCL) in November 2013, Imbruvica also has gotten additional approvals for treating chronic graft-versus-host disease (cGvHD) and other cancers. Whether or not it is used alone, recommended dosing is 420mg once daily with water.

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

New Indication for Lynparza **05/08/2020**

AstraZeneca's PARP inhibitor, Lynparza® (olaparib) tablets was approved to be used as initial maintenance therapy, in combination with bevacizumab, for advanced ovarian, fallopian tube or primary peritoneal cancers that are positive for homologous recombination deficiency (HRD). An estimated 50% of the cancers covered by the new indication have an HRD, which must be verified by a diagnostic test for deleterious BRCA mutation, suspected BRCA mutations or genemonic instability before treatment begins. The recommended Lynparza dose for its new indication is 300mg twice a day for up to two years. Treatment stops, however, if the cancer progresses or the patient can no longer stand drug side effects. Bevacizumab is available as the brand-name, Avastin® (bevacizumab – Genentech), and two biosimilars, MVASI™ (bevacizumab-awwb – Amgen) and Zirabev™ (bevacizumab-bvzr – Pfizer).

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

Pomalyst Approved for Kaposi Sarcoma **05/14/2020**

Pomalyst® (pomalidomide – Celgene/Bristol Myers Squibb) capsules was to treat adults who have Kaposi sarcoma (KS). Although it can be used whether or not the condition is related to AIDS, treatment with highly active antiretroviral therapy, which usually manages both AIDS and KS, will have to have stopped controlling KS before Pomalyst can be considered for patients living with AIDS. HAART still must be continued. The recommended dose of Pomalyst for KS is 5mg/day for the first 21 days of each 28-day cycle. Due to potential for serious side effects a REMS program has been implemented that restricts its dispensing to limited quantities through certified prescribers and pharmacies.

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

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

*05/*14 Dasotraline (Sunovion): A dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) for treating moderate-to-severe binge-eating disorder; oral

*05/*15: Rubraca® (rucaparib – Clovis oncology): A new indication to treat patients who have BRCA1/2-mutant recurrent, metastatic castrate-resistant prostate cancer; oral

*05/*21: Opdivo® (nivolumab)/Yervoy® (ipilimumab): A new indication for the PD-1 inhibitor (Opdivo) and low-dose CTLA4 inhibitor (Yervoy) in previously-untreated NSCLC patients whose tumors do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations; IV

*05/*21: Lynparza® (olaparib): A new indication to treat patients who have metastatic castration-resistant prostate cancer (mCRPC) that has deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, and that has progressed following prior treatment with a new hormonal agent; oral

*05/*21: apomorphine sublingual film (Sunovion): To treat motor fluctuations (OFF episodes) experienced by people who are living with Parkinson's disease (PD); Sub-Lingual

Top Projected Drug Approvals for Remainder of 2020

Ozanimod (Bristol Myers) – S1P for Multiple Sclerosis

Inclisiran (Novartis) – PCSK9 for high cholesterol

Roxadustat (FibroGen) – HI Factor for Anemia

Sacituzumab Govitecan (ImmunoMedics) – Breast Cancer

Filgotinib (Gilead) – Rheumatoid Arthritis

Palforzia (Aimmune) – Peanut Allergies

Valoctocogene Roxaparvovec (BioMarin) – Hemphilia A

Rimegepant (Biohaven) – Migraines (*approved*)

Risdiplam (Roche) – Spinal Muscular Atrophy

GENERAL INFORMATION:

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