MC-Rx

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Drug Information Updates

Xalkori Receives New FDA Indication **01/15/2021**

The FDA granted a new indication to Pfizer's tyrosine kinase inhibitor (TKI), Xalkori® (crizotinib) capsules. Initially, it was FDA approved to treat patients who have advanced or metastatic, non-small cell lung cancer (NSCLC) that tests positive for anaplastic lymphoma kinase (ALK). It gained an additional indication for the treatment of patients who have c-ros oncogene 1 (ROS1)-positive metastatic NSCLC. Xalkori's most recent approval is for treating children as young as 1 year old, teens and young adults who have ALK-positive systemic anaplastic large-cell lymphoma (ALCL), that has recurred or become resistant after other drug therapy. Recommended twice-daily dosing ranges between 200mg/dose and 500mg/dose based on the patient's body surface area (BSA).

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

New Indication for Darzalex Faspro **01/15/2021**

Darzalex Faspro™ (daratumumab/hyaluronidase-fihj), the subcutaneous (SC) dosage form of Janssen's CD38-directed antibody, received an additional indication to treat adults who have light chain (AL) amyloidosis along with bortezomib, cyclophosphamide, and dexamethasone. AL amyloidosis is a rare disorder affecting between 3,000 and 4,000 new U.S. patients each year, is caused when light-weight proteins in immunoglobulins fold incorrectly, and the resulting fiber deposits damage body organs. Recommended dosing for AL amyloidosis is one vial (1,800mg daratumumab/30,000units hyaluronidase) injected SC into the patient's abdomen, given on 28-day schedules with the first eight doses once a week, the next eight once every two weeks, and then one every four weeks for up to a total of two years.

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

Enhertu Awarded New Indication **01/16/2021**

Daiichi Sankyo's antibody-drug conjugate, Enhertu® (fam-trastuzumab deruxtecan-nxki) was given an additional indication to treat adults who have locally advanced or metastatic human epidermal growth factor receptor 2-positive (HER2+) gastric or gastroesophageal junction (GEJ) adenocarcinoma that previously was treated with trastuzumab. The average overall survival (OS) time for patients treated with Enhertu was 11.3 months vs 3.9 months for the patients on chemo. Its recommended dose for gastric cancers is weight-based at 6.4mg/kg given as an intravenous (IV) infusion once every three weeks. It originally was FDA approved in December 2019 to treat HER2+ metastatic breast cancer that cannot be removed by surgery, or that has metastasized further after at least two previous treatments with anti-HER2 drugs.

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

Verquvo Approved to Reduce CV Risk & Heart Failure **01/18/2021**

Merck received approval for its soluble guanylate cyclase (sGC) stimulator, Verquvo® (vericiguat), and is indicated to reduce the risk of cardiovascular (CV) death and heart failure (HF) hospitalization following, either a hospitalization for HF or the need for outpatient intravenous (IV) diuretics, in adults who have symptomatic chronic HF and ejection fraction less than 45%. Patients who suffer from HF may have heart or vascular abnormalities leading to reduced activity of soluble guanylate cyclase (sGC) and synthesis of nitric oxide (NO), which contribute to decreased levels of cyclic guanosine monophosphate (cGMP), a key messenger for heart muscle functioning. Verquvo will be available as 2.5mg, 5mg, and 10mg tablets in 1st quarter 2021. Patients should start with 2.5mg orally once a day with food, and the dose may be doubled every two weeks until a dose of 10mg orally once daily is achieved.

Formulary Status: Verquvo will be reviewed at the next P&T Committee meeting

Cabenuva Combination Drug Injection Approved for HIV-1 **01/21/2021**

Cabenuva (cabotegravir extended-release injection/rilpivirine extended-release injection) from ViiV Healthcare, is the first long-acting drug combination approved for treating HIV-1. Indicated as an alternate to oral therapy, it will be used for adult patients who have had no previous treatment failures, and whose viral load is less than 50 copies of HIV-1 RNA/mL due to a current stable anti-HIV-1 regimen. One single-dose vial injection each of cabotegravir and rilpivirine, will be given as intramuscular (IM) injections once monthly, by a health professional in a healthcare setting. The first dose will contain 600mg of cabotegravir and 900mg of rilpivirine on the last day of oral lead-in dosing. Subsequent doses will be 400mg and 600mg, respectively.

Formulary Status: Cabenuva will be covered as a medical benefit as it requires administration in a healthcare setting

LIMITED DISTRIBUTION

Vocabria Approved for HIV-1 for Short Term Use **01/21/2021**

Vocabria (cabotegravir) tablets, also from ViiV Healthcare, is a new oral integrase strand transfer inhibitor (INSTI) that is approved for short-term use as patients switch to Cabenuva injections from an oral HIV drug regimen. To determine the patient's tolerability for cabotegravir, one Vocabria tablet will be taken on a daily basis, along with one Edurant® (rilpivirine - Janssen) tablet, for about one month before Cabenuva is initiated. Vocabria also can be used to maintain therapy for patients who miss a Cabenuva injection. Launch is expected in 1st quarter.

Formulary Status: Vocabria will be reviewed at the next P&T Committee meeting

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

01/20: *FDA Action:* vericiguat (Bayer/Merck): A soluble guanylate cyclase (sGC) stimulator to be used in combination with other heart failure therapies for reducing the risk of cardiovascular (CV) death and hospitalization for heart failure (HF) following a worsening HF event in patients who have symptomatic chronic HF with reduced ejection fraction (HFrEF); oral

01/22: *FDA Action:* voclosporin (Aurinia Pharmaceuticals): A calcineurin inhibitor immunosuppressant cyclosporine analog for the treatment of lupus nephritis; oral

***01/28*:** *FDA Action:* Nplate® (romiplostim - Amgen): A new indication for the treatment of hematopoietic syndrome of acute radiation syndrome; SC

***01/29*:** *FDA Action*: Bijuva® (estradiol, 0.5mg/progesterone, 100mg – TherapeuticsMD): A lower-dose, daily treatment for moderate-to-severe vasomotor symptoms of menopause for women who have an intact uterus: oral

CORPORATE UPDATE:

It is with great pleasure that we announce the expansion of our brand, MC-Rx, to our clients in Puerto Rico.

MC-Rx, used on the mainland since 2019, has solidified the growth and transformation of our company under one name. Continued integration of our services has assured us that it was time for this evolution. We are also pleased to announce that our offices in Puerto Rico will operate as the business hub for **MC-Rx** for our clients in Puerto Rico. While many of the mainland and island teams have already merged, our clients will continue to see the highest level of service from the team with whom you currently interact.

MC-Rx is now a global brand, ready to take on greater leadership status in the healthcare industry due to its extensive range of products and services. As our role as one of the preeminent PBM/PBA providers for commercial, Medicaid and Medicare clients on both Puerto Rico and in the United States, **MC-Rx** is designed to exceed existing expectations of the original brands, while also continuing to meet new challenges presented by the healthcare industry today and tomorrow.

If you have any questions, please don't hesitate to contact your account manager.

GENERAL INFORMATION:

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