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Drug Update

Drug Information Updates

Ofev Received New Indication

03/09/2020

The FDA approved the first AB-rated generic to Vyera Pharmaceutical's Daraprim® (pyrimethamine) tablets. Daraprim is known for its controversial high price. Pyrimethamine tablets by Cerovene are indicated for treating toxoplasmosis (*Toxoplasma gondii*) when used in combination with a sulfonamide antibiotic. Toxoplasmosis is a parasite that can cause damage to eyes and other organs when a person consumes contaminated water, infected cat feces or undercooked meat and shellfish. Pyrimethamine will be available in 25mg oral tablets, similar to Daraprim.

Formulary Status: Ofev is a tier 2 preferred brand product on the specialty formulary

New Indication for Opdivo and Yervoy

03/10/2020

Used together, Opdivo® (nivolumab) and Yervoy® (ipilimumab), both made by Bristol Myers Squibb, now are indicated to treat patients who have had prior treatment with Nexavar® (sorafenib – Bayer) for hepatocellular carcinoma (HCC). Combination treatments are given once every three weeks for up to four cycles. If the drugs are tolerated and the cancer does not progress, treatment continues with only Opdivo at 240mg once every two weeks or 480mg once a month. In combination, they are FDA approved to treat some types of colorectal cancer and renal cell carcinoma (RCC).

Formulary Status: Opdivo & Yervoy are both medical drugs due to IV administration and are not covered.

Generic Launched for Zortress

03/10/2020

Hikma Pharmaceuticals has launched the first generics for Zortress® (everolimus – Novartis) tablets, 0.25mg, 0.5mg and 0.75mg. Everolimus is an immunosuppressant used in small doses to prevent organ rejection for adults who are at low to moderate risk after having a kidney transplant. Treatment, which begins immediately after surgery, also includes Simulect® (basiliximab), cyclosporine and a corticosteroid. Doses are taken twice a day beginning at 0.75mg/dose for patients who have had kidney transplants and 1mg/dose for liver transplant recipients. The 1mg tablets of Zortress will remain brand-only for the foreseeable future.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

03/17: Lamotrigine – Eton Pharmaceuticals: A new liquid formulation for the treatment of partial seizures; oral

03/19 – **Patent Expiration:** Qudexy® XR (topiramate extended-release capsules – Upsher-Smith): Under terms of a settlement agreement, Zydus will be permitted to launch its generic capsules; oral

03/20 – **Product Discontinuation:** Prefest® (estradiol/norgestimate – Duramed): The last patent for Prefest will expire and discontinued, but not due to safety or efficacy concerns; oral

GENERAL INFORMATION:

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

For more information on the Coronavirus (COVID-19), visit the CDC website shown on the cover of this newsletter.