Approvals & Updates

May 2022

New Drug Approvals

Camzyos (mavacamten)

Indication: Hypertrophic cardiomyopathy (HCM)

Mechanism of Action: Cardiac myosin inhibitor

Dosage Form(s): Capsules

Comments: Camzyos is FDA-approved for treating symptomatic New York Heart Association (NYHA) class II-III obstructive HCM in adults. Camzyos should be initiated at 5mg by mouth once daily, with subsequent dose titrations individualized based on clinical status and echocardiographic assessment. Camzyos carries a Boxed Warning for risk of heart failure. Thus, it is only available through a Risk Evaluation and Mitigation Strategy (REMS) program, should not be started in patients with a left ventricular ejection fraction (LVEF) <55%, and should not be used in combination with specific CYP450 inhibitors/inducers. Camzyos carries labeled warnings for heart failure, drug interactions leading to heart failure or loss of effectiveness, and embryo-fetal toxicity. Cardiac function should be monitored before and during therapy using echocardiograms of LVEF. Co-administration of Camzyos with weak CYP2C19 inhibitors or moderate CYP3A4 inhibitors may increase the risk of heart failure. Therefore, a reduction in Camzyos dose and additional monitoring should be considered. Co-administration of Camzyos with negative inotropes requires LVEF monitoring and close medical supervision. The most common adverse reactions (>5% and more than placebo) reported with Camzyos were dizziness and syncope.

Vivjoa (oteseconazole)

Indication: Recurrent vulvovaginal candidiasis (RVVC)

Mechanism of Action: Azole antifungal

Dosage Form(s): Capsules

Comments: Vivjoa is FDA-approved for lowering the incidence of RVVC in women without reproductive potential who have a history of RVVC. Vivjoa should be administered by mouth with food. The dosing depends on whether concomitant fluconazole is prescribed (see prescribing information for detailed dosing regimen). Vivjoa carries a labeled warning for embryo-fetal toxicity. Liver function tests and renal function (SCr/BUN) should be monitored throughout therapy. Co-administration of Vivjoa with BCRP substrates (i.e., rosuvastatin) may increase the exposure of the BCRP substrates due to Vivjoa being a BCRP inhibitor. Therefore, a reduction in dose or the lowest possible starting dose of the BCRP substrate should be considered. The most common adverse reactions (>2%) reported with Vivjoa were headache and nausea.

Current Drug Shortages

The following shortages have been recently identified by the FDA:

- Fludarabine phosphate injection
- Iodixanol (Visipaque) injection
- Iohexol (Omnipaque) injection
- Potassium chloride concentrate injection

For additional information on drug shortages, please contact the Center for Drug Information & Evidence-Based Practice.

Recently Approved Drug Combinations, Dosage Forms/Strengths, Indications, and Biosimilars

Brand (Generic)	Indication	Mechanism of Action	Dosage Form	Comments
Alymsys (Bevacizumab-maly)	Cervical cancer, colorectal cancer, lung cancer, ovarian cancer, recurrent glioblastoma, and renal cell carcinoma (see prescribing information for specific indications)	Vascular endothelial growth factor (VEGF) inhibitor	Intravenous (IV) injection	Biosimilar to Avastin
Cuvrior (Trientine tetrahydrochloride)	Wilson's disease	Copper chelator	Tablets	New dosage form
Igalmi (Dexmedetomidine)	Agitation	Alpha-2 adrenergic receptor agonist	Sublingual film	New dosage form
Vijoice (Alpelisib)	PIK3CA-related overgrowth spectrum (PROS)	Phosphatidylinositol-3-kinase (PI3K) inhibitor	Tablets	New indication

Creighton University Center for Drug Information & Evidence-Based Practice

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