

Pharmacy Services

Key Pipeline Updates

November 2020

NEW FDA DRUG APPROVALS

Bamlanivimab The FDA granted an Emergency Use Authorization for Lilly's monoclonal antibody therapy, bamlanivimab, to treat mild to moderate coronavirus infections in adults and children. Bamlanivumab is administered via infusion in a hospital or other health care setting, whereas Veklury (remdesivir) is only indicated to be administered in a hospital setting.

Bronchitol[®] (mannitol) inhalation powder Approved as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis.

Sutab[®] (sodium sulfate, magnesium sulfate, and potassium chloride) Approved as a tablet preparation for colonoscopy, providing an alternative to liquid-based colonoscopy preparations.

NEW FDA INDICATION

Brilinta[®] (ticagrelor) tablet Approved to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤ 5) or high-risk transient ischemic attack (TIA).

Winlevi[®] (clascoterone) For the treatment of acne vulgaris in male and female patients aged 12 years or older. It is expected to be available in the USA in early 2021.

DRUG SAFETY ALERT

Metformin ER has an ongoing recall across metformin ER manufacturers. Nostrum Labs is voluntarily recalling four lots of extended release (ER) metformin because it may contain N-nitrosodimethylamine (NDMA) above the acceptable intake limit. The FDA publishes a [recalled metformin list](#) including details about metformin products that have been recalled. The FDA recommends that health care professionals continue to prescribe metformin when clinically appropriate; FDA testing has not shown NDMA in immediate release (IR) metformin products, which is the most commonly prescribed type of metformin.

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NEW GENERICS LAUNCHED

Zovirax[®] (acyclovir) cream for the treatment of recurrent herpes labialis, or cold sores, in immunocompetent adults and adolescents.

Truvada[®] (emtricitabine-tenofovir disoproxil fumarate) approved in combination with other antiretroviral agents for the treatment of HIV-1 infection and in at-risk patients for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

Vascepa[®] (Icosapent ethyl) to be used as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

Pomalyst[®] (pomalidomide) used in combination with dexamethasone for the treatment of certain adult multiple myelomas as well as AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy or in patients with KS who are HIV-negative.

Tirosint[®] (levothyroxine) for adults and pediatric patients 6 years and older with hypothyroidism and pituitary thyrotropin suppression.

Timoptic-XE[®] (timolol maleate) for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Kerydin[®] (tavaborole topical solution) for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

Finacea[®] (azelaic acid foam) for the topical treatment of the inflammatory papules and pustules of mild to moderate rosacea.

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NEW GENERICS LAUNCHED continued

Monurol® (fosfomycin granules) for the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*.

Tecfidera® (dimethyl fumarate) for the treatment of relapsing forms of multiple sclerosis.

About the EPIC National Pharmacy Practice

The EPIC National Pharmacy Practice's mission is to deliver world class consulting services through innovative pharmacy management solutions with a continuous focus on clinical and savings opportunities so employers can provide a robust and cost-efficient pharmacy program to employees.

If you have any questions please contact your EPIC consultant or submit an email to PharmacyHelp@epicbrokers.com.