November 23, 2020

COM-2020-087

Dear provider of healthcare-related services,

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. The EUA defines high risk for progressing to severe COVID-19 and/or hospitalization as compliance with one of the following criteria:

- diabetes
- immunosuppressive disease
- receiving immunosuppressive treatment
- chronic kidney disease (CKD)
- body mass index (BMI) ≥ 35
- age ≥65 years
- age ≥55 years with cardiovascular disease, hypertension, or respiratory diseases,
- age 12-17 years with asthma or other respiratory diseases, medical-related technological dependence, congenital or acquired heart disease, neurodevelopmental disease disorders, sickle cell disease, or BMI ≥85th percentile for their age and gender (based on the Centers for Disease Control and Prevention [CDC] growth charts).

Bamlanivimab is a monoclonal antibody that blocks viral attachment and entry into human cells with the aim of limiting viral replication.

Key points for appropriate use of bamlanivimab:	
Setting of administration	To be administered only in a setting where healthcare providers have immediate access to medications to treat severe infusion reactions and the ability to activate the emergency medical system (EMS).
Target population	Authorized for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40

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Key points for appropriate use of bamlanivimab:	
	kilograms, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
Dosing	To be administered as a single dose of 700mg intravenous (IV) infusion over 60 minutes.
Timely administration	To be administered as soon as possible after positive viral testing for SARS-CoV-2 and within 10 days of symptom onset.
Patient isolation	Patients treated with bamlanivimab should continue to self-isolate and use infection control measures according to CDC guidelines.
Limitations of use	Bamlanivimab is not authorized for patients hospitalized due to COVID-19 or who require oxygen therapy or who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. Based on the results of the clinical trial ACTIV-3, bamlanivimab is unlikely to help hospitalized COVID-19 patients recover from a more advanced stage of the disease.

Additional information can be found on the American Pharmacist Association (APhA), the U.S. Department of HHS, and the FDA websites including the FDA's Emergency Use Authorization portal and on the"Frequently Asked Questions on the EUA for Bamlanivimab". Since the COVID-19 pandemic is dynamic, we strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO) to assure that your practices are consistent with the most updated information. It is also important to keep up-to-date about the role of pharmacists in the COVID-19 vaccination response.

PharmPix is committed to our member's health and wellness, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

Clinical Department

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