13 December 2024

IMPORTANT PRESCRIBING INFORMATION

Subject: Revocation of Emergency Use Authorization 111, Bebtelovimab for the Treatment of Mild to Moderate Coronavirus Disease 2019 (COVID-19).

Dear Healthcare Provider:

In response to a request from the U.S. Food and Drug Administration (FDA), the Emergency Use Authorization (EUA) of bebtelovimab for the treatment of mild to moderate COVID-19 (EUA 111) has been revoked, effective 13 December 2024.

Bebtelovimab has not been authorized for the treatment of mild to moderate COVID-19 in any US region since November 30, 2022, due to the high prevalence of bebtelovimab resistant variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in circulation. Importantly, the revocation of bebtelovimab (EUA 111) is not due to any new safety concerns.

Lilly has removed information on the use of bebtelovimab from all U.S. commercial websites. This DHCP letter will be posted to the website that is printed on the carton, container labels, and package insert (www.bebtelovimabHCPinfo.com) as well as to Lilly's commercial website (www.covid19.lilly.com/bebtelovimab) for a period of 6 months. Should healthcare providers have questions about the revocation of bebtelovimab (EUA 111), they should contact The Lilly COVID-19 Hotline at 1-855-LillyC19 (1-855-545-5921).

How to Handle the Product:
All lots of bebtelovimab are expired and should not be prescribed or dispensed to patients. Sites should destroy product according to their facility's procedures. If a site is unable to destroy product, product can be returned to Lilly for destruction only. For information about Return Authorization, please see the Lilly Return Goods Procedure at www.trade.lilly.com.

Reporting Adverse Events:
Per requirements, healthcare providers are responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bebtelovimab therapy. Healthcare providers should report an adverse event or product complaint to The Lilly COVID-19 Hotline at 1-855-LillyC19 (1-855-545-5921). Alternatively, adverse event information may be reported to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Sincerely,

ELI LILLY AND COMPANY

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