04 January 2024

IMPORTANT PRESCRIBING INFORMATION

Subject: Revocation of Emergency Use Authorization 94, Bamlanivimab and Etesevimab Administered Together for the Treatment of Mild to Moderate Coronavirus Disease 2019 (COVID-19) and for Post-Exposure Prophylaxis of COVID-19.

Dear Healthcare Provider:

In response to a request from Eli Lilly and Company, the U.S. Food and Drug Administration (FDA) has revoked the Emergency Use Authorization (EUA) of bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis of COVID-19 (EUA 94).

Lilly made this request because all lots of bamlanivimab and etesevimab are expired. In addition, bamlanivimab and etesevimab administered together have not been authorized for treatment of mild to moderate COVID-19 or for post-exposure prophylaxis of COVID-19 since January 24, 2022. This Limitation of Authorized Use has been in effect because the preceding and current prevalence of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) variants in the U.S. are not neutralized by the combination therapy. Importantly, the revocation of bamlanivimab and etesevimab administered together (EUA 94) is not due to any new safety concerns.

Lilly has removed information on the use of bamlanivimab and etesevimab administered together 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.bamlanivimabHCPinfo.com, www.etesevimabHCPinfo.com) and Lilly's commercial website (www.covid19.lilly.com/bam-ete) for a period of 6 months. Should healthcare providers have questions about the revocation of bamlanivimab and etesevimab administered together (EUA 94), they should contact The Lilly COVID-19 Hotline at 1-855-LillyC19 (1-855-545-5921).

How to Handle the Product:

All lots of bamlanivimab and etesevimab 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 bamlanivimab and etesevimab 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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