



Date: January 27, 2022
To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

**FDA LIMITS USE OF CERTAIN
MONOCLONAL ANTIBODIES**

Summary:

- This document supersedes the January 21, 2022 guidance titled “Update on COVID-19 Monoclonal Antibody Treatment Recommendations.”
- Lilly’s bamlanivimab plus etesevimab (BAM/ETE) and Regeneron’s casirivimab plus imdevimab (REGEN-COV) are no longer authorized for use anywhere in the U.S., due to the prevalence of Omicron.

On January 24, 2022, the Food and Drug Administration ([FDA updated the Emergency Use Authorization](#) (EUA) fact sheets for two COVID-19 monoclonal antibody (mAb) treatments: Lilly’s bamlanivimab plus etesevimab (BAM/ETE) and Regeneron’s casirivimab plus imdevimab (REGEN-COV). As a result, these two treatments are not currently authorized for use anywhere in the U.S., due to the prevalence of Omicron.

Providers that have BAM/ETE and REGEN-COV on-hand should cease their use but maintain remaining supplies of these mAbs under proper storage conditions so that they may be used if authorization is given for these products again in the future. Providers are encouraged to review the updated FDA Health Care Provider Fact Sheets for [BAM/ETE](#) and [REGEN-COV](#) for specific information.

There are other therapies that are expected to retain activity against the Omicron variant and that are authorized or approved to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease. These include sotrovimab, Paxlovid, molnupiravir, and Veklury (remdesivir). The [HHS COVID-19 Therapeutic Locator Tool](#) can be used to see the amount of available courses of Paxlovid and molnupiravir at your local pharmacies.

COVID-19 therapeutics are most effective when given early after symptom onset (within 5 days for oral antivirals). Providers should continue to advise patients at increased risk for severe COVID-19 about the benefits of prompt treatment with antivirals or monoclonal antibodies to reduce risk of hospitalization and death.

For information on monoclonal antibodies please refer to NYSDOH’s [COVID-19 Monoclonal Antibody \(mAb\) Therapeutics Information for Providers](#).