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SPECIAL EDITION

Tuesday, April 20, 2021

COVID-19 Update: FDA Revoked the EUA for Bamlanivimab When Administered Alone

On April 16, the FDA revoked the Emergency Use Authorization (EUA) for bamlanivimab, when administered alone, due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to this antibody therapy. The FDA determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks.

Medicare will cover and pay for bamlanivimab, when administered alone, for dates of service from November 10, 2020 – April 16, 2021.

The FDA indicates that alternative monoclonal antibody therapies remain appropriate to treat COVID-19 patients, and health care providers may continue using these authorized therapies when administered together:

- Casirivimab & imdevimab
- Bamlanivimab & etesevimab

More Information:

- Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab Section 15, Antiviral Resistance
- Fact Sheet for Health Care Providers EUA of Bamlanivimab and Etesevimab Section 15, Antiviral Resistance
- Monoclonal Antibody COVID-19 Infusion webpage

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