



Arkansas Department of Health

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FDA Revokes Emergency Use Authorization for Bamlanivimab for treatment of mild to moderate COVID 19

On Friday, April 16, 2021 the U.S. Food and Drug Administration (FDA) [revoked the Emergency Use Authorization](#) (EUA) that allowed for the investigational monoclonal antibody bamlanivimab, ***administered alone***, to be used for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients. Ongoing analysis of emerging scientific data has shown a sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone, resulting in an increased risk of treatment failure. Therefore, the FDA has determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use. Subsequently, the agency determined that the criteria for issuance of an authorization are no longer met and has revoked the EUA. Please see the full FDA statement [here](#).

REGEN-COV (casirivimab and imdevimab administered together) as well as bamlanivimab and etesevimab (**administered together**) continue to be available under EUA. There is no shortage of monoclonal antibody product. Sites that are administering monoclonal antibodies can order bamlanivimab and etesevimab together; etesevimab can also be ordered alone to be paired with the current supply of bamlanivimab that the site has available. Alternatively, REGEN-COV can be ordered from the authorized distributor using the [direct ordering](#) process.