



# Health Alert Network Message 22-07: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

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## FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

On Monday, January 24th the U.S. Food and Drug Administration (FDA) revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments. The FDA states that because data show these treatments are highly unlikely to be active against the Omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in these regions.

Currently the Omicron variant is estimated to account for over 99% of all circulating SARS-CoV-2, the virus that causes COVID-19, both nationally and in Louisiana’s region.

Full FDA statement will be pasted below.

Monoclonal antibody providers that have remaining Regen-COV (casirivimab and imdevimab) or bamlanivimab/etesevimab on hand are asked to maintain their stock in appropriate storage, if able, with hopes it may be of use in the future.

### Available therapeutics to treat COVID-19

The FDA recently expanded the approved indication for **Veklury (remdesivir)** to allow for outpatient use of a 3-day course to treat mild-moderate COVID-19 disease in certain non-hospitalized adult and pediatric patients. More information here: <https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19>

The monoclonal antibody **sotrovimab** is available under an Emergency Use Authorization for the treatment of COVID-19 in certain at-risk individuals and retains efficacy against the Omicron variant. At this point in time supply is very limited. A list of facilities receiving allocations of sotrovimab can be found here: <https://ldh.la.gov/page/monoclonal-antibodies>

The oral medicines **Paxlovid (nirmatrelvir/ritonavir)** and **molnupirivir** are also available under an Emergency Use Authorization and retain efficacy against the Omicron variant,

although they are limited in supply as well. Providers should carefully review the respective FDA fact sheets as potentially significant cautions and drug interactions exist. Facilities/pharmacies supplied with these two medications can be found here: <https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/>

Paxlovid fact sheet: <https://www.fda.gov/media/155050/download>

molnupirivir fact sheet: <https://www.fda.gov/media/155054/download>

## FDA STATEMENT

# Coronavirus (COVID-19) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

*The following is attributed to Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research*

### For Immediate Release:

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### Statement From:

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Director - Center for Drug Evaluation and Research

As we have throughout the COVID-19 pandemic, the U.S. Food and Drug Administration has used the best available science as the virus has evolved to make informed decisions with the health and safety of the American public in mind. Ensuring that healthcare providers on the frontlines have the best tools available to treat patients is a top priority for the agency.

In light of the most recent information and data available, today, the FDA revised the authorizations for two monoclonal antibody treatments – bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) – to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.

Because data show these treatments are highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. states, territories, and jurisdictions at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in these regions.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses, like SARS-CoV-2. And like other infectious

organisms, SARS-CoV-2 can mutate over time, resulting in certain treatments not working against certain variants such as omicron. This is the case with these two treatments for which we're making changes today.

Based on Centers for Disease Control and Prevention data, the omicron variant of SARS-CoV-2 is [estimated to account for more than 99% of cases in the United States](#) as of Jan. 15. Therefore, it's highly unlikely that COVID-19 patients seeking care in the U.S. at this time are infected with a variant other than omicron, and these treatments are not authorized to be used at this time. This avoids exposing patients to side effects, such as injection site reactions or allergic reactions, which can be potentially serious, from specific treatment agents that are not expected to provide benefit to patients who have been infected with or exposed to the omicron variant.

The [NIH COVID-19 Treatment Guidelines Panel](#), an independent panel of national experts, recently recommended against the use of bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) because of markedly reduced activity against the omicron variant and because real-time testing to identify rare, non-omicron variants is not routinely available.

Importantly, there are [several other therapies](#) – Paxlovid, sotrovimab, Veklury (remdesivir), and molnupiravir – that are expected to work 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, including hospitalization or death. Healthcare providers should consult the NIH panel's COVID-19 treatment guidelines and assess whether these treatments are right for their patients.

While it's critical that we have ways to treat those who contract COVID-19, the authorized treatments are not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. Data has clearly demonstrated that the [available, safe and effective vaccines](#) can lower your risk of developing COVID-19 and experiencing the potential associated serious disease progression, including hospitalization and death.

The FDA is committed to continuing to review emerging data on all COVID-19 therapies related to the potential impact of variants and revise the authorizations further as appropriate to ensure healthcare providers have an effective arsenal of treatments for patients.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.