



September 13, 2021

Resumption in Use and Distribution of Bamlanivimab/Etesevimab in all U.S. States, Territories, and Jurisdictions

Update:^{1,2}

On September 2, 2021, the Assistant Secretary for Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services **authorized a resumption of use and distribution of bamlanivimab and etesevimab, administered together, in all U.S. states, territories, and jurisdictions** under the conditions of use for [Emergency Use Authorization \(EUA\) 094](#).

Background:^{2,3}

On August 27, 2021, the FDA announced that bamlanivimab and etesevimab, administered together, are not authorized for use in states, territories, and U.S. jurisdictions in which the most recently published combined frequency of variants resistant to bamlanivimab and etesevimab exceeds 5%. FDA determines the list of authorized states, territories and U.S. jurisdictions considering current variant frequency data, trends in variant frequency over time, the precision of the estimates and information regarding emerging variants of concern. The FDA will update the list of states, territories, and U.S. jurisdictions in which bamlanivimab and etesevimab administered together are authorized as new data and information becomes available. Health care providers should refer to the [FDA webpage](#) regularly for updates.

Guidance:^{1,3}

Based on the most currently available data, bamlanivimab and etesevimab are now authorized in all U.S. states, territories, and jurisdictions.

Health care providers should review a patient's travel and contact history within two weeks prior to infection. People who have traveled to, resided in, or had close contact with an infected individual from an area where the frequency of resistant variants to bamlanivimab and etesevimab exceeds 5% should not receive bamlanivimab and etesevimab.

Since June 2021, there has been a sustained increase in the circulation of the Delta variant (B.1.617.2). Based on in vitro assays that are used to assess the susceptibility of viral variants to monoclonal antibodies, bamlanivimab and etesevimab, administered together, are expected to retain activity against the Delta variant (B.1.617.2), which is now the dominant variant in the United States. The increase in prevalence of the Delta variant has been associated with a decrease at the same time in the frequency of identified variants that are expected to be resistant to bamlanivimab and etesevimab.

ASPR and FDA will continue to work with the CDC and the National Institutes of Health on surveillance of variants that may impact the use of the monoclonal antibody therapies authorized for emergency use. We will provide further updates and consider additional action as new information becomes available.

Criteria & Scope of Emergency Use Authorization:^{2, 4, 5}

SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that bamlanivimab and etesevimab administered together may be effective in treating mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and that, when administered as described in the Scope of Authorization (Section II) and used under the conditions described in this authorization, the known and potential benefits of bamlanivimab and etesevimab outweigh the known and potential risks of such product.

1. The bamlanivimab and etesevimab covered by the authorization will be administered together only by healthcare providers to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
2. Etesevimab may only be administered together with bamlanivimab.
3. Bamlanivimab and etesevimab are authorized for use **only** in states, territories, and U.S. jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%, as determined by FDA.
4. Bamlanivimab and etesevimab are not authorized for use in the following patient populations;
 - Adults or pediatric patients who are hospitalized due to COVID-19, or
 - Adults or pediatric patients who require oxygen therapy due to COVID-19, or
 - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.
5. Bamlanivimab and etesevimab may only be administered together in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.
6. The use of bamlanivimab and etesevimab covered by this authorization must be in accordance with the authorized Fact Sheets.

Availability:²

Distribution of bamlanivimab and etesevimab will be controlled by the United States Government for use consistent with the terms and conditions of the EUA. **I/T/U sites can resume ordering bamlanivimab/etesevimab and etesevimab (for co-administration with existing stock of bamlanivimab) through the IHS National Supply Service Center by following the existing ordering procedures (i.e., Form 413).**

References:

1. Department of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. Public Health Emergency. [Resumption in the Use and Distribution of Bamlanivimab/Etesevimab in all U.S. States, Territories, and Jurisdictions](#). Published September 2, 2021.
2. U.S. Food and Drug Administration. [Emergency Use Authorization \(EUA\) 094](#). Published August 27, 2021.
3. U.S. Food and Drug Administration. [Bamlanivimab and Etesevimab Authorized States, Territories, and U.S. Jurisdictions](#). Published September 8, 2021.
4. U.S. Food and Drug Administration. [Fact Sheet for Healthcare Providers](#). Bamlanivimab/etesevimab. Published August 27, 2021.
5. U.S. Food and Drug Administration. [Fact Sheet for Patients, Parents, and Caregivers](#). Published August 27, 2021.