

## Health Alert Network Message for Healthcare Providers

### Update on monoclonal antibodies (mAbs) for treatment of COVID-19

April 6, 2021

Several recent changes have occurred regarding monoclonal antibodies (mAbs) for the treatment of certain high-risk patients with mild to moderate COVID-19. These changes include:

#### 1. Caution against use of bamlanivimab alone

- SARS-CoV-2 viral variants may be resistant to mAbs. The FDA has updated the authorized fact sheets for healthcare providers for all of the mAb products to include a section (Section 15) with information on the susceptibility of SARS-CoV-2 variants to the mAb product. See links, below.
- Currently, there is concern about variants that are resistant to treatment with bamlanivimab alone. The revised Fact Sheet for Healthcare Providers for bamlanivimab advises healthcare providers that the use of alternative authorized mAbs that are expected to retain activity against circulating viral variants may reduce the risk of treatment failure should a patient be infected with a SARS-CoV-2 viral variant that is resistant to bamlanivimab alone.

#### 2. Availability of bamlanivimab/etesevimab combination and recommendation for use

- On February 9, 2021, the FDA issued an [emergency use authorization \(EUA\)](#) for the use of bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in certain patients who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Bamlanivimab/etesevimab is the third mAb treatment to have been granted an EUA from the FDA, in addition to bamlanivimab and casirivimab/imdevimab. Bamlanivimab/etesevimab has the same indications for use as the other mAb treatments. The data supporting its use include more clinical events than the currently reported data for bamlanivimab and casirivimab/imdevimab, and the NIH COVID-19 Treatment Panel *recommends its use* for individuals who meet the EUA criteria.

#### 3. Clinical practice guidelines updates

- [National Institutes of Health \(NIH\) COVID-19 Treatment Guidelines](https://www.covid19treatmentguidelines.nih.gov/anti-sars-cov-2-antibody-products/anti-sars-cov-2-mono-clonal-antibodies/)  
<https://www.covid19treatmentguidelines.nih.gov/anti-sars-cov-2-antibody-products/anti-sars-cov-2-mono-clonal-antibodies/> and  
<https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-plus-etesevimab-eua/>
- [Infectious Disease Society of America](#)

<https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>

#### 4. Access to treatment

- The U.S. Department of Health and Human Services (HHS) continues to maintain the [treatment locator](#) to assist providers and the public in finding treatment locations with these therapeutics.
- Your local hospital's inpatient pharmacy may be able to provide information on whether the treatments are available, even if the hospital is not displayed on the treatment locator site.
- mAbs are now available for direct order through the distributor, AmerisourceBergen; the Idaho Department of Health and Welfare is no longer involved in the allocation. At this time, the mAbs available for order include bamlanivimab/etesevimab, casirivimab/imdevimab, and etesevimab alone to be administered with existing site supply of bamlanivimab. Bamlanivimab alone is no longer available for order given the concern about possible treatment failure with certain viral variants and the availability of alternatives. See [Overview of the Direct Order Process for COVID-19 Therapeutics](#) (link provided below) for more information.
- Additional information about mAb therapeutics and the role of HHS in the distribution of these products can be found on the [HHS Monoclonal Antibody Therapeutics webpage](#) (link provided below).

#### Links

FDA EUA for bamlanivimab/etesevimab: <https://www.fda.gov/media/145801/download>  
Fact Sheets for Healthcare Providers

- Bamlanivimab: <https://www.fda.gov/media/143603/download>
- Bamlanivimab and etesevimab: <https://www.fda.gov/media/145802/download>
- Casirivimab and imdevimab: <https://www.fda.gov/media/145611/download>

HHS Treatment Locator: <https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations>

HHS information about mAb therapeutics:

<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx>

Overview of direct order process: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf>

A list of SARS-CoV-2 variants of concern identified to date in Idaho can be found here:

<https://public.tableau.com/profile/idaho.division.of.public.health#!/vizhome/DPHIdahoCOVID-19Dashboard/Home>

For additional questions, please contact [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov).