

**Subject:** UPDATE - COVID-19 variants/impact on mAb distribution

**Date:** Thursday, March 18, 2021 at 7:16:16 PM Eastern Daylight Time

**From:** ASPRStakeHolderNoReply (OS/ASPR)

**To:** ASPR Stake Holder (OS/ASPR)

**Priority:** High

March 18, 2021

Dear Stakeholders,

We are committed to ensuring you receive timely and transparent communication regarding the allocation and distribution of COVID-19 monoclonal antibody treatments currently being provided by the U.S. Government (USG).

As a follow-up to our message on March 10, 2021, alerting you of an ongoing evaluation with our federal partners on SARS-CoV-2 viral variants, we are providing additional information that became available today:

- The U.S. Food and Drug Administration (FDA) has updated the Fact Sheets for all three authorized products ([bamlanivimab](#), [bamlanivimab with etesevimab](#), and [casirivimab with imdevimab](#)) with information on antiviral resistance
- The FDA has released a [Centers for Drug Evaluation and Research statement](#) highlighting the changes in the Fact Sheets
- The Centers for Disease Control and Prevention (CDC) has updated their website with available [proportions of SARS-CoV2 variants of concern by state](#)

As noted in the FDA Fact Sheets for each of the authorized monoclonal antibody products, circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies. Health care providers should review the Antiviral Resistance information in Section 15 of the Fact Sheets for details regarding specific variants and resistance, and refer to the CDC website (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html>) as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

ASPR will continue to work with the CDC, NIH, and FDA on surveillance of variants that may impact the use of the monoclonal antibodies authorized under emergency use. We will update our stakeholders with any new information.

Please contact [COVID19Therapeutics@hhs.gov](mailto:COVID19Therapeutics@hhs.gov) with any questions. We thank you for your continued support and efforts in the fight against COVID-19.

Regards,

Meredith Chuk, MD

Lead, COVID-19 Monoclonal Antibody Therapeutics Team

Office of the Assistant Secretary for Preparedness and Response