HHS/ASPR Halts Distribution of Bamlanivimab, Etesevimab, and REGEN-COV due to Omicron Variant

Background

On 12/23/21, the Department of HHS issued a halt order for the distribution of bamlanivimab + etesevimab, etesevimab alone, and REGEN-COV due to preliminary resistance data regarding the Omicron (B.1.1.529/BA.1) variant.

As announced by the CDC late Monday, Omicron accounts for more than 73% of new COVID-19 cases nationally, driving the decision to halt distribution of these products. Cell-culture data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant, but further data from the CDC is pending.

In the interim, the Emergency Use Authorizations have **not** been revoked and the situation varies across geographic regions and different health care facilities. There may be circumstances, such as lower frequency of **Omicron (B.1.1.529/BA.1)** in a region and limited supply of alternative treatment options, in which the use of existing site supply of these therapeutics is clinically appropriate.

Sotrovimab appears to retain activity against Omicron (B.1.1.529/BA.1) and will continue to be distributed through the State allocation process, though supply is limited. Sotrovimab is authorized for treatment of COVID-19 only.

What Healthcare Providers Should Do

Health care providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody therapy still available under an EUA for details regarding specific variants and resistance. Providers should also refer to the CDC's Data Tracker for variant frequency data in their area: CDC Data Tracker: Variant Proportions

- Casirivimab & Imdevimab (REGEN-COV)
  - Health Care Provider Fact Sheet for EUA of Casirivimab and Imdevimab
- Bamlanivimab & Etesevimab
  - Health Care Provider Fact Sheet for EUA of Bamlanivimab and Etesevimab
- Sotrovimab
  - Health Care Provider Fact Sheet for EUA of Sotrovimab

PharMerica Continues to Provide Support

Please reference PharMerica's updated Coronavirus Monoclonal Antibodies Policy & Procedures for details on ordering, preparing, administering, monitoring and other essential details for the provision of these EUA-authorized therapies. If needed, please contact your Account Manager for a copy of this Policy and Procedures.