Health Advisory: Pause on Monoclonal Antibody Treatment Bamlanivimab/Etesevimab

Minnesota Department of Health, Mon, June 28 10:00 CDT 2021

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, urgent care centers, emergency departments, pharmacies, and convenience clinics in your jurisdiction.
Hospitals, clinics and other facilities: Please forward to occupational health and employee health leadership, infection preventionists, infectious disease physicians, emergency department staff, hospitalists, primary care clinicians, pharmacists, and all other health care providers who who might see patients with COVID-19.
Health care providers:

- Immediately pause use of the combination monoclonal antibody (mAb) therapy **bamlanivimab/etesevimab**.
- Continue use of alternative monoclonal antibody (mAb) therapies, including REGEN-COV and sotrovimab.
- Contact your regional healthcare coalition for assistance if you do not have alternative mAb therapies on hand to treat eligible patients.

Background

On June 25th, 2021, the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services sent a notification to all states of an immediate pause to all distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supplies of bamlanivimab) on a national basis until further notice. In addition, the Food and Drug Administration (FDA) recommends that health care providers nationwide use alternative authorized monoclonal antibody therapies, as described below, and not use bamlanivimab and etesevimab administered together at this time.

The Centers for Disease Control and Prevention (CDC) has identified that the combined frequencies of the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil) and the B.1.351/Beta variant (first identified in South Africa) throughout the United States now exceed 11% and are trending upward (CDC COVID Data Tracker: Variant Proportions - https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html). Results from in vitro assays that are used to assess the susceptibility of viral variants to particular monoclonal antibodies suggest that bamlanivimab and etesevimab administered together are not active against either the P.1 or B.1.351 variants. In Minnesota, the combined prevalence of the P.1 and B.1.351 variants has reached at least 8.8%. In addition, two other variants which may have reduced susceptibility to bamlanivimab/etesevimab (B.1.526 and B.1.621) have reached a combined prevalence of 7.4%. Based on this data, MDH is recommending that all providers in MN use alternatives to bamlanivimab/etesevimab when administering monoclonal antibody therapy.

REGEN-COV and sotrovimab are alternative monoclonal antibody therapies that are currently authorized for the same use as bamlanivimab and etesevimab administered together. Based on similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1 or B.1.351 variants. Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Provider Fact Sheets for each mAb available under EUA for details regarding specific variants and resistance (available here: FDA: Provider Fact Sheets - https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-fact-sheets-address-sars-cov-2-variants-monoclonal-antibody-products-under).'

All treatment delivery sites can continue ordering REGEN-COV from the authorized distributer by following the existing ordering and reporting procedures. Details on the direct ordering procedure for obtaining REGEN-COV from HHS/ASPR can be found at PHE: Overview of Direct Order Process for COVID-19 Therapeutics - https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/direct-order-process-covid19-mAb.aspx. All treatment sites may also find information on the availability and ordering of sotrovimab by visiting GlaxoSmithKline's website at GSK Sotrovimab Information - https://www.sotrovimabinfo.com/.

Getting mAb therapy to eligible patients is time-sensitive because mAb must be given as soon as possible after a positive COVID-19 test result and within 10 days of a person showing symptoms. The MNRAP system (MDH MRAP - https://www.health.state.mn.us/diseases/coronavirus/mnrap.html) can be used by clinicians and patients to determine if they are eligible to receive therapy and where an infusion facility can be found.

For More Information

- MDH Therapeutic Options for COVID-19 Patients (https://www.health.state.mn.us/diseases/coronavirus/hcp/therapeutic.html)
- Call the MDH Provider Hotline at 651-201-5414, option 3.
- FDA: Revisions to Provider Fact Sheets on Monoclonal Antibody Therapies to address SARS-CoV-2 Variants (https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-fact-sheets-address-sars-cov-2-variants-monoclonal-antibody-products-under)

A copy of this HAN is available at: MDH Health Alert Network (http://www.health.state.mn.us/han)
The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.