June 17, 2021

Dear Colleagues,

We are writing to inform you of updated recommendations regarding the use of authorized monoclonal antibody therapies in NYC due to changes in local epidemiology.

The NYC Department of Health and Mental Hygiene (NYC Health Department) has identified increasing prevalence of the P.1 (Gamma) variant of COVID-19 (first identified in Brazil) in NYC, which now makes up 17.1% of tested cases in the last week. For NYC variant data, see the NYC Health Department’s Variant Data webpage. 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 (Gamma) or B.1.351 (Beta, first identified in South Africa) variants. These assays use pseudo-virus particles that help determine likely susceptibility of the live virus.

REGEN-COV and sotrovimab are alternative monoclonal antibody therapies that are authorized for the same use as bamlanivimab and etesevimab administered together. Based on available in vitro assay data, REGEN-COV and sotrovimab are likely to retain activity against these variants. All treatment delivery sites can continue ordering REGEN-COV free of charge from the authorized distributor by following the existing ordering and reporting procedures. Sotrovimab is commercially available, and information on availability and ordering is available on GlaxoSmithKline’s website at sotrovimab.com.

The U.S. food and Drug Administration (FDA) has recommended that health care providers in areas with at least 10% of resistant variants use the alternative authorized monoclonal antibody therapies described above.

Providers should review the antiviral resistance information in Section 15 of the FDA Emergency Use Authorization Fact Sheets for each monoclonal antibody therapy for details about specific variants and resistance. Providers and facilities outside of NYC should refer to the Centers for Disease Control and Prevention’s (CDC) website and information from their state and local health authorities regarding reports of viral variants in their region to guide treatment decisions.

Supplies of bamlanivimab and etesevimab can continue to be stored on-site in case local epidemiologic changes allow for use. You can also send unused supplies to facilities outside of NYC if appropriate or back to the manufacturer. For guidance on returning bamlanivimab and bamlanivimab/etesevimab, see The Lilly Return Goods Procedure. Detailed guidance can be found at lillytrade.com.
The NYC Health Department will continue to work with the FDA, CDC, the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response and academic partners on surveillance of variants that may impact the use of authorized monoclonal antibody therapies. We will provide updates as new information becomes available and local epidemiology changes. Contact COVID19Therapeutics@hhs.gov with any questions. We thank you for your continued support and efforts in the fight against COVID-19.

Sincerely,

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