Anti-SARS-CoV-2 Monoclonal Antibodies

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Monoclonal antibodies (mAbs) that target the SARS-CoV-2 spike protein have been shown to have clinical benefits in treating SARS-CoV-2 infection. However, laboratory studies have found that the activity of anti-SARS-CoV-2 mAbs against specific variants and subvariants can vary dramatically. Because of this, these products are not expected to be effective treatments or preventives for COVID-19 in areas where the circulating variants and subvariants are resistant to mAbs.

Recommendation

- The COVID-19 Treatment Guidelines Panel (the Panel) recommends against the use of anti-SARS-CoV-2 mAbs for the treatment or prevention of COVID-19 (AIII) because the dominant Omicron subvariants in the United States are not expected to be susceptible to these products.

- For the Panel’s recommendations on treating nonhospitalized patients with COVID-19, see Therapeutic Management of Nonhospitalized Adults With COVID-19 and Therapeutic Management of Nonhospitalized Children With COVID-19.

Anti-SARS-CoV-2 Monoclonal Antibodies That Have Received Emergency Use Authorizations

Four anti-SARS-CoV-2 mAb products (bamlanivimab plus etesevimab, casirivimab plus imdevimab, sotrovimab, and bebtelovimab) have received Emergency Use Authorizations (EUA) from the Food and Drug Administration (FDA) for the treatment of outpatients with mild to moderate COVID-19. However, they are not currently authorized for use in the United States because the dominant Omicron subvariants are not expected to be susceptible to these products. See the Centers for Disease Control and Prevention COVID Data Tracker for regular updates on the regional proportions of SARS-CoV-2 variants in the United States.

On December 8, 2021, tixagevimab plus cilgavimab (Evusheld) received an EUA from the FDA that allowed this combination to be used as COVID-19 pre-exposure prophylaxis (PrEP). These 2 recombinant human mAbs bind to nonoverlapping epitopes of the spike protein receptor-binding domain of SARS-CoV-2. However, because many Omicron subvariants, including the dominant Omicron subvariants in the United States, are not expected to be susceptible to tixagevimab plus cilgavimab, this product is not authorized for use as COVID-19 PrEP as of January 26, 2023. See Prevention of SARS-CoV-2 Infection for more information.