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. The anti-SARS-CoV-2 mAb products that have received Emergency Use Authorizations (EUAs) from the Food and Drug Administration (FDA) are not expected to be effective against the currently circulating SARS-CoV-2 variants and subvariants. As a result, these products are not currently recommended by the COVID-19 Treatment Guidelines Panel (the Panel) for the treatment or prevention of COVID-19.

See Table 4b for information on the clinical trials that have evaluated the safety and efficacy of using anti-SARS-CoV-2 mAbs in patients with COVID-19.

Recommendation

- The Panel **recommends against** the use of anti-SARS-CoV-2 mAbs for the treatment or prevention of COVID-19 **(AIII)**.

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

Several anti-SARS-CoV-2 mAb products (bamlanivimab plus etesevimab, casirivimab plus imdevimab, sotrovimab, and bebtelovimab) have received EUAs from the FDA for the treatment of outpatients with mild to moderate COVID-19.[1-4] However, these products are not currently authorized for use in the United States because the dominant Omicron subvariants are not expected to be susceptible to these products. The Centers for Disease Control and Prevention COVID Data Tracker provides regular updates on the regional proportions of SARS-CoV-2 variants in the United States.

Tixagevimab plus cilgavimab (Evusheld) received an EUA from the FDA for pre-exposure prophylaxis (PrEP) of COVID-19,[5] and bamlanivimab plus etesevimab and casirivimab plus imdevimab received EUAs for SARS-CoV-2 post-exposure prophylaxis (PEP).[1,2] However, because many Omicron subvariants, including the dominant Omicron subvariants in the United States, are not expected to be susceptible to these anti-SARS-CoV-2 mAb products, these products are not currently authorized for use as PrEP of COVID-19 or SARS-CoV-2 PEP. See Prevention of SARS-CoV-2 Infection for more information.

References

1. Food and Drug Administration. Fact sheet for health care providers: Emergency Use Authorization (EUA) of bamlanivimab and etesevimab. 2022. Available at: https://www.fda.gov/media/145802/download.
2. Food and Drug Administration. Fact sheet for health care providers: Emergency Use Authorization (EUA) of REGEN-COV (casirivimab and imdevimab). 2021. Available at: https://www.fda.gov/media/145611/download.
3. Food and Drug Administration. Fact sheet for healthcare providers: Emergency Use Authorization (EUA) of sotrovimab. 2023. Available at: https://www.fda.gov/media/149534/download.
4. Food and Drug Administration. Fact sheet for healthcare providers: Emergency Use Authorization for bebtelovimab. 2022. Available at: https://www.fda.gov/media/156152/download.

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5. Food and Drug Administration. Fact sheet for healthcare providers: Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab). 2023. Available at: https://www.fda.gov/media/154701/download.

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