

FDA-AUTHORIZED MONOCLONAL ANTIBODY THERAPIES FOR TREATMENT OR PREVENTION OF COVID-19 INFECTION

COVID-19 vaccines and booster shots are the best preventive measure available against severe disease, hospitalization and death due to COVID-19. However, some blood cancer patients will not get optimal protection from vaccines. Monoclonal antibodies can provide another layer of protection for blood cancer patients and others who are at high-risk of serious illness if they become infected with COVID-19. However, monoclonal antibodies treatments are currently in short supply.

Evusheld¹ (tixagevimab and cilgavimab)	
Authorized for	Prevention of infection <i>before</i> known exposure to COVID-19
For use in adults, and children 12 and older who weigh at least 88 pounds	Who are not currently infected with COVID-19 and have not had known recent exposure to an infected person and <ul style="list-style-type: none"> • Are moderately to severely immunocompromised due to a medical condition (such as blood cancer patients and some survivors) or immune-suppressing treatment (e.g., BTK inhibitors, CD20 antibodies, CD-19 CAR T-therapy) and may not mount an adequate immune response to COVID-19 vaccination or • Cannot be vaccinated with any COVID-19 vaccine according to the approved schedule or has had a severe allergic reaction to any vaccine component
Activity against Omicron	In the laboratory, Evusheld is active against the Omicron variant, but its potency is reduced compared to earlier COVID-19 strains. ²⁻⁶ Activity is retained against the Delta variant. As with vaccines, breakthrough infection is possible after antibody treatment
Dosing/Timing	Two consecutive injections into the muscle, one for tixagevimab and one for cilgavimab Treatment can be repeated every six months

Xevudy⁷ (sotrovimab)	
Authorized for	Treatment of mild-to-moderate COVID-19
For use in adults, and children 12 and older who weigh at least 88 pounds	Who have mild-to-moderate COVID-19 symptoms and have tested positive for the infection, and <ul style="list-style-type: none"> • Are not hospitalized or requiring supplemental oxygen, and • Are at increased risk of progressing to severe COVID-19 (such as blood cancer patients and some survivors)
Activity against Omicron	Expected to protect against serious outcomes of infection with Omicron and Delta variants. ²⁻⁶
Dosing/Timing	Given as a single IV infusion over 30 minutes Should be given as soon as possible after positive results of a COVID-19 test and within 10 days of symptom onset

Regen-COV⁸ (casirivimab and imdevimab)	
Authorized for	Treatment of mild-to-moderate COVID-19 Prevention of infection <i>after</i> recent known exposure to COVID-19
For use in adults, and children 12 and older who weigh at least 88 pounds	Who are at increased risk of progressing to severe COVID-19 (such as blood cancer patients and some survivors) As treatment <ul style="list-style-type: none"> • Patients with mild-to-moderate COVID-19 symptoms who have tested positive for the infection, and • Who are not currently hospitalized or requiring supplemental oxygen As prevention <ul style="list-style-type: none"> • For people who are not expected to mount an adequate immune response to vaccination or who are not yet fully vaccinated, and <ul style="list-style-type: none"> • Who have been exposed to an individual infected with COVID-19, consistent with close contact criteria per Centers for Disease Control and Prevention or • Who are at ongoing high risk of exposure to individuals infected with COVID-19 because of setting (e.g., nursing homes, prisons)
Activity against Omicron	REGEN-COV is not active at blocking an Omicron infection in the laboratory. ²⁻⁶
Dosing/Timing	As treatment <ul style="list-style-type: none"> • One-time IV infusion of casirivimab and imdevimab administered together. IV infusion is strongly recommended, but injection under the skin is an option when intravenous infusion is not feasible and would lead to delay in treatment. • Give as soon as possible after positive results of a COVID-19 test and within 10 days of symptom onset As prevention <ul style="list-style-type: none"> • IV infusion or injection under the skin that can be given every four weeks for the duration of the ongoing exposure to COVID-19 • Give as soon as possible after exposure to COVID-19

Bamlanivimab and etesevimab⁹	
Authorized for	Treatment of mild-to-moderate COVID-19 Prevention of infection <i>after</i> recent known exposure to COVID-19
For use in adults and children including neonates	Who are at high risk for progression to severe COVID-19 (such as blood cancer patients and some survivors) As treatment <ul style="list-style-type: none"> • Patients with mild-to-moderate COVID-19 symptoms who have tested positive for the infection, and <ul style="list-style-type: none"> • Who do not require supplemental oxygen (all ages), and • Who are not hospitalized (ages 2+ only) As prevention <ul style="list-style-type: none"> • For people who are not expected to mount an adequate immune response to vaccination or who are not yet fully vaccinated, and <ul style="list-style-type: none"> • Who have had close contact with a person infected with COVID-19, or • Who are at ongoing high-risk of exposure to individuals infected with COVID-19 because of setting (e.g., nursing homes, prisons)
Activity against Omicron	The bamlanivimab and etesevimab antibody combination is not active against the Omicron variant.
Dosing/Timing	As treatment <ul style="list-style-type: none"> • One-time IV infusion • Give as soon as possible after positive results of a COVID-19 test and within 10 days of symptom onset As prevention <ul style="list-style-type: none"> • Bamlanivimab and etesevimab administered together as a single IV infusion • Give as soon as possible after exposure to COVID-19 Note: Dosages are adjusted in children based on age and weight

1. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Evusheld™; 2. VanBlargan LA et al. An infectious SARS-CoV-2 B.1.1.529 Omicron virus escapes neutralization by several therapeutic monoclonal antibodies; 3. Dejnirattissai W et al. Omicron-B.1.1.529 leads to widespread escape from neutralizing antibody responses; 4. Aggarwal A et al. SARS-CoV-2 Omicron: evasion of potent humoral responses and resistance to clinical immunotherapeutics relative to viral variants of concern; 5. Xie et al. B.1.1.529 escapes the majority of SARS-CoV-2 neutralizing antibodies of diverse epitopes; 6. Coronavirus antiviral & resistance database. 7. Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab; 8. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV® (casirivimab and imdevimab). 9. Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab.