

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.

This table is for informational purposes only. Treatments require a prescription and should be guided by a patient's healthcare team.

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
	 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	IMPORTANT NOTE: On February 24, 2022, the FDA increased the recommended dose of Evusheld Patients who received Evusheld before this date should check with their healthcare provider about receiving an additional dose as soon as possible.
	The dosing regimen was revised to increase protection against two emerging Omicron subvariants BA.1 and BA.1.1.
	Evusheld should be deferred for at least two weeks after COVID-19 vaccination
	Vaccination does not need to be deferred for any period after Evusheld administration
	Given as two consecutive injections into the muscle, one for tixagevimab and one for cilgavimab
	If Evusheld retains activity against future COVID virus variants, FDA is likely to recommend repeat dosing for at-risk individuals. Patients can check for the latest information here .
Manufacturer	AstraZeneca
	<u>Click here</u> to read the manufacturer's Fact Sheet for Patients, Parents and Caregivers.

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Xevudy ⁷ (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 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	NOTE: On February 23, the FDA said Xevudy should not be used in geographic areas of the country where COVID infection is likely to be caused by a variant that Xevudy is not active against.
Dosing/Timing	There is no waiting period between Xevudy and COVID-19 vaccination, or between COVID-19 vaccination and Xevudy 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
Manufacturer	GSK <u>Click here</u> to read the manufacturer's Fact Sheet for Patients, Parents and Caregivers.

Bebtelovimab ⁸	
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, <u>and</u>
	 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, including with the omicron variant and the recently identified omicron subvariant. ⁹
Dosing/Timing	There is no waiting period between bebtelovimab and COVID-19 vaccination, or between COVID-19 vaccination and bebtelovimab
	Given as a single IV injection over at least 30 seconds
	Should be given as soon as possible after positive results of a COVID-19 test and within 7 days of symptom onset
Manufacturer	Eli Lilly
	Click here to read the manufacturer's Fact Sheet for Patients, Parents and Caregivers.



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Regen-COV (casirivimab and imdevimab)

As of January 24, 2022, the FDA advised that "this treatment is not authorized for use in any U.S. states, territories or jurisdictions because it is highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States."

Click here to read more.

Bamlanivimab and etesevimab

As of January 24, 2022, the FDA advised that "this treatment is not authorized for use in any U.S. states, territories or jurisdictions because it is highly unlikely to be active against the omicron variant, which is circulating at a very high frequency throughout the United States."

Click here to read more.

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 Healthcare Providers: Emergency Use Authorization for Bebtelovimab; 9. Iketani S et al. Antibody evasion properties of SARS-CoV-2 Omicron sublineages.

As of March 1, 2022