LEUKEMIA & LYMPHOMA SOCIETY®

# 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.*

| **Evusheld**[1] (tixagevimab and cilgavimab) | |
|---|---|
| **Authorized for** | **Prevention** of infection *before* 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**<br>• 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**<br>• 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.<br>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.**<br>**The dosing regimen was revised to increase protection against two emerging Omicron subvariants BA.1 and BA.1.1.**<br>Evusheld should be deferred for at least two weeks after COVID-19 vaccination<br>Vaccination does not need to be deferred for any period after Evusheld administration<br>Given as two consecutive injections into the muscle, one for tixagevimab and one for cilgavimab<br>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<br>Click here to read the manufacturer's Fact Sheet for Patients, Parents and Caregivers. |

*Continued*

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# FDA-Authorized Monoclonal Antibody Therapies for Treatment or Prevention of COVID-19 Infection

## Bebtelovimab[7]

| | |
|---|---|
| **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**<br>• Are not hospitalized or requiring supplemental oxygen, **and**<br>• 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.[8] |
| **Dosing/Timing** | There is no waiting period between bebtelovimab and COVID-19 vaccination, or between COVID-19 vaccination and bebtelovimab<br>Given as a single IV injection over at least 30 seconds<br>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<br>Click here to read the manufacturer's Fact Sheet for Patients, Parents and Caregivers. |

## **Xevudy** (sotrovimab)

As of April 5, 2022, the FDA advised that "the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time."

Click here to read more.

## **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 for Bebtelovimab; 8. Iketani S et al. Antibody evasion properties of SARS-CoV-2 Omicron sublineages.

As of April 6, 2022