Information about the COVID-19 Bebtelovimab Monoclonal Antibody Treatment

Disclaimer: as of November 30, 2022, the U.S. Food and Drug Administration has revoked approval of the COVID-19 monoclonal antibody (mAb) treatment called bebtelovimab in all U.S. states and territories. This is due to an increase in COVID-19 cases caused by the Omicron BQ.1 and BQ.1.1 sub-variants and data showing that bebtelovimab is unlikely to be as effective against them.[1]

On February 11, 2022, the US Food and Drug Administration approved the COVID-19 monoclonal antibody (mAb) treatment called bebtelovimab made by Eli Lilly and Co., making it available for emergency use.[2] This fact sheet contains information about the bebtelovimab treatment to help you make informed decisions about treatments for COVID-19 that may help reduce your risk of severe illness.

How does bebtelovimab work?

Bebtelovimab provides your immune system with antibodies to protect you from COVID-19. The antibodies recognize and attack the SARS-CoV-2 virus and stop it from entering the cells in your body. The treatment is given to you as soon as possible after testing positive for COVID-19.[2]

Who is bebtelovimab for?

Bebtelovimab treats mild to moderate COVID-19 in adults and pediatric patients ages 12 and over and weighing at least 40 kilograms—or about 88 pounds. Recipients must have a **positive PCR test result** and are at **high risk** of severe COVID-19, hospitalization, and/or death (see Figure 1), and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate.[2,3]

Before receiving bebtelovimab, you should talk with your provider to discuss potential risks and benefits if you…[4]

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over the counter, vitamins, herbal products, and traditional medicines)

Bebtelovimab is not authorized for use in people who…[3]

- Are already hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- Require supplemental oxygen therapy due to COVID-19 for those on chronic oxygen therapy due to a pre-existing medical condition

How is bebtelovimab given?

Bebtelovimab is given within seven days of symptom onset as a single injection over 30 seconds into an intravenous (IV) line. After the dose has been administered, the IV line will be flushed with saline to ensure the entire dose enters the bloodstream. Patients are monitored after receiving bebtelovimab for at least one hour for possible side effects.[3]

What are the possible benefits of receiving bebtelovimab?

The known and potential benefits of receiving Bebtelovimab as a treatment for COVID-19 include reduced risk of severe COVID-19 symptoms, hospitalization, and death.[2,4]

What are the possible side effects of receiving bebtelovimab?

Bebtelovimab is still being studied for its safety and effectiveness. Although not all side effects are currently known, the potential risks continue to be monitored by the FDA.[4]

Possible temporary side effects of bebtelovimab treatment include the following[3]:

- Allergic reactions including anaphylaxis
- Rash
- Dizziness
- Chills
- Worsening of existing COVID-19 symptoms

Possible temporary side effects of getting any medicine by infusion may include[4]:

- Brief pain
- Bleeding
- Bruising of the skin
- Soreness
- Swelling
- Possible infection at the injection site

It is also possible that bebtelovimab may interfere with your body's ability to fight off a future COVID-19 infection.[4] Similarly, bebtelovimab may reduce your body's immune response to a COVID-19 vaccine.[4]

Can I be vaccinated for COVID-19 if I am treated with bebtelovimab?

Currently, there is no data on the safety and effectiveness of COVID-19 vaccines in people who received a COVID-19 mAb treatment like bebtelovimab.

The Advisory Committee on Immunization Practice recommends that you wait 90 days after receiving a COVID-19 mAb treatment to get vaccinated to avoid any possible interactions between the treatment and vaccine. This is the recommended wait time because data suggest that reinfection of COVID-19 is uncommon within 90 days.[6]

Should I continue to follow CDC guidelines?

You should continue to practice all recommended safety measures to stop the spread of COVID-19, even if you have received the bebtelovimab treatment. This is important because receiving this treatment does not protect you against future COVID-19 infections.

To protect yourself and your community we recommend that you continue to…

- Wear a mask
- Social distance
- Wash your hands
- Follow all public health guidelines and recommendations

Figure 1: You are considered high-risk if you meet at least one of the following criteria[5]:

- Are 65 years of age or older
- Have a body mass index (BMI) equal to or over 25
- Are pregnant
- Have cancer
- Have a chronic kidney disease
- Have a chronic liver disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Have a heart condition
- Have hypertension
- Have sickle cell disease
- Have a chronic lung disease such as chronic obstructive pulmonary disease, moderate to severe asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Have a neurodevelopmental disorder such as cerebral palsy
- Have a mental health condition
- Have a medical-related technological dependence such as a tracheostomy or gastrostomy

This list does not include all medical conditions that place a person at higher risk of severe illness from COVID-19. Talk with your healthcare provider about your risk.

Resources

1. FDA announces bebtelovimab is not currently authorized in the US. *U.S. Food and Drug Administration*. Published November 30, 2022. Accessed December 6, 2022. https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-bebtelovimab-not-currently-authorized-any-us-region.
2. Coronavirus (COVID-19) update: FDA authorizes additional monoclonal antibody for treatment of COVID-19. *U.S. Food and Drug Administration.* Published February 11, 2022. Accessed February 11, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-monoclonal-antibody-treatment-covid-19-retains
3. Fact sheet for healthcare providers: emergency use authorization for bebtelovimab. *U.S. Food and Drug Administration*. Accessed June 16, 2022. https://www.fda.gov/media/156152/download
4. Fact sheet for patients, parents and caregivers emergency use authorization (EUA) of bebtelovimab for treatment of Coronavirus Disease 2019 (COVID-19). *U.S. Food and Drug Administration.* Accessed April 14, 2022. https://www.fda.gov/media/156153/download
5. People with certain medical conditions. *U.S. Centers for Disease Control and Prevention*. Accessed April 14, 2022. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
6. Interim clinical considerations for use of COVID-19 vaccines. *U.S. Centers for Disease Control and Prevention*. Published August 6, 2021. Accessed February 11, 2021. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html