

# Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of Bebtelovimab for Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you or your child with bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate. This Fact Sheet contains information to help you understand the potential risks and potential benefits of receiving bebtelovimab, which you or your child have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make bebtelovimab available during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). Bebtelovimab is not an FDA-approved medicine in the United States. Read this Fact Sheet for information about bebtelovimab. Talk to your healthcare provider about your options or if you have any questions. It is your choice for you or your child to receive bebtelovimab or stop it at any time.

## What is COVID-19?

COVID-19 is caused by a virus called a coronavirus (SARS-CoV-2). You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your or your child's other medical conditions to become worse. Older people and people of all ages with severe, or long lasting (chronic) medical conditions like heart disease, lung disease, diabetes, and obesity, for example, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

## What is bebtelovimab?

Bebtelovimab is an investigational medicine used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]):

- with positive results of direct SARS-CoV-2 viral testing, **and**

- who are at high risk<sup>1</sup> for progression to severe COVID-19, including hospitalization or death, **and**
- for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate.

There is limited information known about the safety and effectiveness of using bebtelovimab for the treatment of mild-to-moderate COVID-19.

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

Bebtelovimab is not authorized for use in people who:

- are likely to be infected with a SARS-CoV-2 variant that is not able to be treated by bebtelovimab based on the circulating variants in your area (ask your health care provider about FDA and CDC’s latest information on circulating variants by geographic area), **or**
- are hospitalized due to COVID-19, **or**
- require oxygen therapy and/or respiratory support due to COVID-19, **or**
- require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity.

**What should I tell my healthcare provider before I or my child receive bebtelovimab? Tell your healthcare provider about all your or your child’s medical conditions including if you or your child:**

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

**How will I or my child receive bebtelovimab?**

Bebtelovimab will be given as an injection through a vein (intravenously or IV) over at least 30 seconds. You will be observed by your healthcare provider for at least 1 hour after you receive bebtelovimab.

**What are the important possible side effects of bebtelovimab?**

- **Allergic reactions.** Allergic reactions can happen during and after injection with bebtelovimab. Tell your healthcare provider right away if you or your child develop any of the following signs and symptoms of allergic reaction: fever, difficulty breathing, low oxygen level in your blood, chills, tiredness, fast or slow heart rate, chest discomfort or

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<sup>1</sup> For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Healthcare providers should consider the benefit-risk for an individual patient.

pain, weakness, confusion, nausea, headache, shortness of breath, low or high blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness, feeling faint, and sweating. These reactions may be severe or life threatening.

The side effects of receiving any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of bebtelovimab. Not many people have received bebtelovimab. Serious and unexpected side effects may happen. All of the risks are not known at this time.

It is possible that bebtelovimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bebtelovimab may reduce the body's immune response to a vaccine for SARS-CoV-2. Talk to your healthcare provider if you have any questions.

### **What other treatment choices are there?**

Veklury (remdesivir) is FDA-approved for the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients. Talk with your doctor to see if Veklury is appropriate for you.

Like bebtelovimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> for information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice for you or your child to be treated or not to be treated with bebtelovimab. Should you decide not to receive it or for your child to not receive it, it will not change your or your child's standard medical care.

### **What if I am pregnant or breastfeeding?**

There is limited experience treating pregnant women or breastfeeding mothers with bebtelovimab. Severe allergic reactions have been observed with administration of bebtelovimab, including in pregnant patients.

For a mother and unborn baby, the benefit of receiving bebtelovimab may be greater than the risk from the treatment. If pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

### **How do I report side effects with bebtelovimab?**

Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088 or to Eli Lilly and Company, Inc. as shown below.

Fax Number	Telephone Number
1-317-277-0853	1-855-LillyC19 (1-855-545-5921)

### How can I learn more about COVID-19?

- Ask your healthcare provider
- Visit <https://www.cdc.gov/COVID19>
- Contact your local or state public health department

### What is an Emergency Use Authorization?

The United States FDA has made bebtelovimab available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bebtelovimab for the treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) **and** who are at high risk of developing severe COVID-19, including hospitalization or death, **and** for whom other COVID-19 treatment options approved or authorized by FDA are not available or clinically appropriate has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for bebtelovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of bebtelovimab, unless terminated or revoked (after which bebtelovimab may no longer be used under the EUA).

### Additional Information

For general questions, visit the website or call the telephone number provided below.

Website	Telephone Number
<a href="http://www.LillyAntibody.com/bebtelovimab">www.LillyAntibody.com/bebtelovimab</a>	1-855-LillyC19 (1-855-545-5921)

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