

MONOCLONAL ANTIBODY CONSENT

I understand that I am being offered the opportunity to receive monoclonal antibody treatment for COVID-19 or for post-exposure prophylaxis to an individual infected with COVID-19. Monoclonal antibody therapies such as bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab, and bebtelovimab are investigational drugs that have been authorized for use on an emergency basis by the U.S. Food and Drug Administration (FDA) for **a)** the treatment of mild to moderate COVID-19, or **b)** for post-exposure prophylaxis for those unvaccinated and at high risk of severe COVID, or **c)** vaccinated individuals with an immunocompromising disease state or on an immunosuppressive drug. I understand that an investigational drug is a drug that is not yet approved by the FDA. Instead, the FDA issued an emergency authorization because it found that, based on the information that is currently available, it was reasonable to believe that the known and potential benefits of the monoclonal antibodies outweigh the known and potential risks of the drug for the treatment of patients with COVID-19.

I understand the following statements:

- Because the monoclonal antibodies are investigational, the clinical information currently available about them is limited.
- Serious and unexpected adverse events may occur as a result of treatment with the monoclonal antibodies that have not been previously reported.
- **I may refuse** to receive monoclonal antibody treatment. Even if I am scheduled for treatment, I may cancel or stop it any time.
- My application is not a guarantee of treatment. Grand View Hospital will have to review my case, among others. If there are more applicants than treatment doses available, a first-come, first-served methodology may be used to select patients.
- If my application is approved and I am scheduled to receive treatment, it will be administered intravenously (IV) or subcutaneously (SubQ), followed by a 1-hour period of monitoring at the hospital.

I was given copies of "Fact Sheet for Patients, Parents and Caregivers" for bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab, and bebtelovimab attached to this document that describe the currently known possible risks and side effects of, benefits of, and alternatives to monoclonal antibody treatment, and that document has been explained to me.

I have had the opportunity to discuss with my physician, who has explained the risks and benefits of the treatment and alternatives of treatment. All of my questions have been answered.

Date	Time	Signature of Patient
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If this consent is signed by the patient's authorized representative, the reason for this shall be inserted and the authorized person's signature shall then be witnessed.

Reason:

Date	Time	Signature of Authorized Representative	Relationship
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Date	Time	Witness Signature
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ATTENTION STAFF: if obtaining patient consent via telephone or tele-health, your signature below certifies that you have read this document clearly in its entirety to the patient. You and your witness must be staff members over 18 years of age.

Full Name of Staff Member Obtaining Consent	Date	Time	Full Name of Witness Staff Member
Signature of Staff Member Obtaining Consent			Signature of Witness Staff Member



DETACH HERE AND GIVE FACT SHEET TO PATIENT, PARENT OR CAREGIVER.

FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS
Emergency Use Authorization (EUA) of Sotrovimab for
the Treatment of 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 **sotrovimab** 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. This Fact Sheet contains information to help you understand the potential risks and potential benefits of receiving sotrovimab, 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 sotrovimab 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). Sotrovimab is not an FDA-approved medicine in the United States.

Read this Fact Sheet for information about sotrovimab. Talk to your healthcare provider if you have any questions. It is your choice for you or your child to receive sotrovimab or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. People 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, 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.

What is sotrovimab?

Sotrovimab is an investigational medicine used for the treatment of mild-to-moderate symptoms of 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 of progression to severe COVID-19, including hospitalization or death. Sotrovimab is investigational because it is still being studied. There is limited information about the safety and effectiveness of using sotrovimab to treat people with mild-to-moderate COVID-19.

The FDA has authorized the emergency use of sotrovimab for the treatment of mild-to-moderate symptoms of 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 of progression to severe COVID-19, including hospitalization or death under an EUA. For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this fact sheet.

What should I tell my healthcare provider before I or my child receive sotrovimab?

Tell your healthcare provider about all of 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, over-the-counter, vitamins, or herbal products).

How will I or my child receive sotrovimab?

- You or your child will receive 1 dose of sotrovimab.
- Sotrovimab will be given through a vein (intravenous or IV infusion) over 15 or 30 minutes.
- You or your child will be monitored by your healthcare provider for at least 1 hour after receiving sotrovimab.

Who should generally not receive sotrovimab?

Do not receive sotrovimab if you or your child have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab. See the end of the Fact Sheet for a complete list of ingredients in sotrovimab.

What are the important possible side effects of sotrovimab?

Possible side effects of sotrovimab are:

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

Side effects of receiving sotrovimab intravenously may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of sotrovimab. Not many people have received sotrovimab. Serious and unexpected side effects may happen. Sotrovimab is still being studied, so it is possible that all of the risks are not known at this time.

What other treatment choices are there?

Like sotrovimab, 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 sotrovimab. Should you decide not to receive it or your child not to receive it, it will not change you or your child's standard medical care.

What if I am pregnant or breastfeeding?

There is no experience treating pregnant women or breastfeeding mothers with sotrovimab. For a mother and unborn baby, the benefit of receiving sotrovimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

Pregnancy Registry

There is a pregnancy registry for individuals who receive sotrovimab during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how to take part in this registry. For more information visit <https://covid-pr.pregistry.com> or call 1-800-616-3791.

How do I report side effects with sotrovimab?

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 or call 1-800-FDA-1088, or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684).

How can I learn more?

- Ask your healthcare provider
- Visit <https://www.cdc.gov/COVID19>
- Call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684)

What is an Emergency Use Authorization (EUA)?

The United States FDA has made sotrovimab 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.

Sotrovimab for the treatment of mild-to-moderate symptoms of COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of SARS-CoV-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death, 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, 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 medicine to be used in the treatment of patients during the COVID-19 pandemic. The EUA for sotrovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of sotrovimab, unless terminated or revoked (after which sotrovimab may no longer be used under the EUA).

What are the ingredients in sotrovimab?

Active ingredient: sotrovimab

Inactive ingredients: L-histidine, L-histidine monohydrochloride, L-methionine, polysorbate 80, and sucrose



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**FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People 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 other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, 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 ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab and imdevimab)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
 - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
 - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising

conditions, including someone who is taking immunosuppressive medications),
and

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>, **or**
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **“What is an Emergency Use Authorization (EUA)?”** section at the end of this Fact Sheet.

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the

tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
 - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
 - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

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

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Like REGEN-COV (casirivimab and imdevimab), 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 not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?

Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?

- Ask your health care provider.
- Visit www.REGENCOV.com
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made REGEN-COV (casirivimab and imdevimab) available under an emergency access mechanism called an 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.

REGEN-COV 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 must determine, among other things, that based on the totality of scientific evidence available, 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 medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

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

You or your child are being given two medicines together called **bamlanivimab and etesevimab** for the treatment or post-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab and etesevimab.

Receiving bamlanivimab and etesevimab may help to treat COVID-19 in certain people, or help to prevent COVID-19 in certain people who have been exposed to someone infected with SARS-CoV-2 or who are at high risk of an exposure because of being in the same setting, such as nursing homes or prisons.

Read this Fact Sheet for information about bamlanivimab and etesevimab. Talk to your or your child's healthcare provider if you have questions. It is your choice if you or your child receive bamlanivimab and etesevimab or you may stop them at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People 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. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, 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 are the symptoms of COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause other medical conditions to become worse.

What are bamlanivimab and etesevimab?

Bamlanivimab and etesevimab are investigational medicines used together in adults and children who are at high risk for developing severe COVID-19, including hospitalization or death for:

- **treatment** of mild to moderate symptoms of COVID-19, OR
- **post-exposure prophylaxis for prevention** of COVID-19 in persons who are:
 - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**
 - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising conditions, including someone who is taking immunosuppressive medications), **and**
 - have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>, **or**

- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Bamlanivimab and etesevimab are investigational because they are still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab and etesevimab to treatment or prevention of COVID-19. Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of bamlanivimab and etesevimab together for the treatment of COVID-19 and the post-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section “**What is an Emergency Use Authorization (EUA)?**” at the end of this Fact Sheet.

What should I tell the healthcare provider before I or my child receive bamlanivimab and etesevimab?

Tell the healthcare provider about all of your or your child’s medical conditions, including:

- Having any allergies
- Having received a COVID-19 vaccine
- Having any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How are bamlanivimab and etesevimab given?

- Bamlanivimab and etesevimab are given at the same time through a vein (intravenous or IV).
- One dose of bamlanivimab and etesevimab will be given by IV infusion. The infusion will take 16 – 60 minutes or longer. Your or your child’s healthcare provider will determine the duration of the infusion.

What are the important possible side effects of bamlanivimab and etesevimab?

Possible side effects of bamlanivimab and etesevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab and etesevimab. Tell your or your child’s healthcare provider right away if any of the following signs and symptoms of allergic reactions occur: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of the lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness, and sweating. These reactions may be severe or life threatening.
- Worsening of COVID-19 symptoms after bamlanivimab and etesevimab therapy for active infection: You or your child may experience new or worsening symptoms after infusion for mild to moderate COVID-19, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your or your child’s healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

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

These are not all the possible side effects of bamlanivimab and etesevimab. Not a lot of people have been given bamlanivimab and etesevimab. Serious and unexpected side effects may happen. Bamlanivimab and etesevimab are still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab and etesevimab could interfere with your or your child’s body’s own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab and etesevimab may reduce the body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your or your child’s healthcare provider if you have any questions.

What other treatment choices are there?

Like bamlanivimab and etesevimab, 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 not approved by FDA to treat people with COVID-19. Your or your child's healthcare provider may talk with you about clinical trials you or your child may be eligible for.

It is your choice whether you or your child should be treated or not to be treated with bamlanivimab and etesevimab. Should you decide that you or your child should not receive bamlanivimab and etesevimab or stop it at any time, it will not change your or your child's standard medical care.

What other prevention choices are there?

Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of bamlanivimab and etesevimab does not replace vaccination against COVID-19.

Like bamlanivimab and etesevimab, FDA may allow for the emergency use of other medicines for post-exposure prophylaxis for prevention of 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 not approved by FDA for post-exposure prophylaxis for prevention of COVID-19. The healthcare provider may talk with you about clinical trials you or your child may be eligible for.

Bamlanivimab and etesevimab are not authorized for pre-exposure prophylaxis for prevention of COVID-19.

What if I am pregnant or breastfeeding?

There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab and etesevimab. For a mother and unborn baby, the benefit of receiving bamlanivimab and etesevimab 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 bamlanivimab and etesevimab?

Tell the healthcare provider right away if you or your child have any side effect that bothers you or your child, or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

- Ask your or your child's healthcare provider
- Visit www.LillyAntibody.com
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

The United States FDA has made bamlanivimab and etesevimab available under an emergency access mechanism called an 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.

Bamlanivimab and etesevimab have 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 must determine, among other things, that based on the totality of scientific evidence available, 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 medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for bamlanivimab and etesevimab together is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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Eli Lilly and Company, Indianapolis, IN 46285, USA

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ETE-0005-EUA PAT-20211203

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 risk¹ 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

¹ 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?

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. 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, or call 1-800-FDA-1088 or to Eli Lilly and Company, Inc. as shown below.

Email	Fax Number	Telephone Number
mailindata_gsmtindy@lilly.com	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
www.LillyAntibody.com/bebtelovimab	1-855-LillyC19 (1-855-545-5921)

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