

# Is a COVID-19 monoclonal antibody therapy right for my child?

## Who is bamlanivimab and etesevimab together for?

Bamlanivimab and etesevimab are investigational monoclonal antibody therapies authorized for use together as an infusion for children of any age who are at high risk to get very sick from COVID-19:

1. For the treatment of mild to moderate symptoms in children recently diagnosed with COVID-19;
2. For post-exposure prevention in children who are not fully vaccinated OR have a condition, including taking medication, that weakens the immune system, AND
  - a. were recently exposed to someone with COVID-19, OR
  - b. are in certain settings that put them at high risk of being exposed to someone who has COVID-19.

## How do COVID-19 antibody treatments work?

When someone has a virus, like the virus that causes COVID-19, it takes time for their body to learn to make antibodies to fight it. In the meantime, they could get very sick or even die. Antibody therapies give your child antibodies that may start working more quickly to help your child's body fight the virus.

Antibody therapy is not the same as a vaccine and does not replace vaccination against COVID-19. Vaccines are for people who do not have the disease. They help your child's body learn to make their own antibodies over time.

## Which children are at high risk to get very sick from COVID-19?

There is no way to know for sure if your child will get very sick from COVID-19. Therefore, it is important to talk with your child's healthcare provider. There are certain health conditions that may put a child at higher risk for getting very sick, including<sup>1</sup>:

- <1 year old
- Overweight or obesity
- Heart disease, high blood pressure, or chronic kidney disease
- Diabetes
- Weakened immune system because of a medicine they take or a condition they have, including sickle cell disease
- Long-term lung diseases like asthma or chronic obstructive pulmonary disease (COPD)
- Developmental or genetic conditions like cerebral palsy or Down syndrome

These are not all the conditions that may put children at high risk to get very sick from COVID-19. If you're not sure whether an antibody therapy is an option for your child, talk with their healthcare provider.

Healthcare providers along with parents and caregivers can consider the benefit-risk for an individual pediatric patient using the [Fact Sheet for Healthcare Providers](#), [Fact Sheet for Patients, Parents and Caregivers](#) and the [CDC website](#) as guidance.

## Reference

<sup>1</sup> U.S. Department of Health and Human Services: [People with Certain Medical Conditions](#)

## What are the side effects?

Side effects from bamlanivimab and etesevimab together may include allergic reactions or worsening of COVID-19 symptoms.

If these occur, contact your child's healthcare provider right away or seek immediate medical attention as these reactions may be severe or life-threatening.

These are not all the possible side effects. Please see the next page for full Authorized Use and Safety Summary.

## AUTHORIZED USE AND SAFETY SUMMARY

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 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 not authorized for pre-exposure prophylaxis for prevention of COVID-19.

Bamlanivimab and etesevimab have not been approved, but have been authorized for emergency use by the FDA. Bamlanivimab and etesevimab are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of bamlanivimab and etesevimab under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

### Warnings

Important possible side effects of bamlanivimab and etesevimab:

### 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, 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 not all of the risks are 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 COVID-19. Similarly, bamlanivimab and etesevimab may reduce the body's immune response to a vaccine for COVID-19. 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.

### Tell your or your child's 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/or herbal products)

### 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.

Read the [Fact Sheet for Patients, Parents and Caregivers](#) for more information about bamlanivimab and etesevimab.

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