Information about the COVID-19 Bamlanivimab and Etesevimab Monoclonal Antibodies Treatment

Disclaimer: as of January 24, 2022, the U.S. Food and Drug Administration has revoked approval of the COVID-19 monoclonal antibody (mAb) treatment called bamlanivimab and etesevimab in all U.S. states and territories. This is due to an increase in COVID-19 cases caused by the Omicron variant and data showing that REGEN-COV is unlikely to be as effective against it.[1]

Like many other viruses, COVID-19 is evolving and changing over time. This means that what made the virus susceptible to certain treatments or vaccines may change. As COVID-19 becomes an endemic disease, meaning that it is still present but not causing significant disruption in our daily lives, the virus will continue to change and new variants will arise.

In the future, new variants may arise that may once again be treatable with bamlanivimab and etesevimab.

On February 9, 2021, the US Food and Drug Administration approved the COVID-19 monoclonal antibodies (mAbs) treatment, bamlanivimab (bam-la-niv-i-mab) and etesevimab (e-te-sev-i-mab), that is administered together as a single treatment to prevent severe illness in those infected with COVID-19.[2]

This treatment is made by Eli Lilly and Company and approved for emergency use during the current pandemic. On September 16th, 2021, this authorization was updated to include post-exposure prophylaxis for those who have been exposed to the COVID-19 virus and are at high risk of developing serious complications.[3]

This fact sheet contains information about the bamlanivimab and etesevimab treatment to help you make informed decisions about COVID-19 treatments that may help reduce your risk of severe illness.

How does the treatment work?

The bamlanivimab and etesevimab treatment provides your immune system with antibodies to protect you from COVID-19. The antibodies recognize and attack the virus that causes COVID-19 to stop it from entering the cells in your body.

Monoclonal antibody treatments are most effective in the 10 days from when you first started showing COVID-19 symptoms. It is important that you are tested and contact your health care provider as soon as possible if you are experiencing COVID-19 symptoms.[4]

Who is the treatment for?

The bamlanivimab and etesevimab treatment has been authorized to treat mild to moderate cases of COVID-19.[5] Those that receive treatment must be 12 years of age and older, weigh at least 40kg/88lbs, and be at high risk for progressing to severe COVID-19 symptoms and/or hospitalization.[5]

You are considered high risk if you meet at least one of the following criteria[6]:

- Have a body mass index (BMI) equal to or over 35
- Have chronic kidney disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are 65 years of age or older
- Are 55 years of age or older AND have
  - Cardiovascular disease, or
  - Hypertension, or
  - Chronic obstructive pulmonary disease, or
  - Other chronic respiratory diseases.
- Are 12–17 years of age AND have
  - BMI in the 85th percentile or over for their age and gender-based on CDC growth charts, or
  - Sickle cell disease, or
  - Congenital or acquired heart disease, or
  - Neurodevelopmental disorders (e.g., cerebral palsy), or
  - A medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation unrelated to COVID-19), or
  - Asthma, reactive airway, or other chronic respiratory diseases that require daily medication for control

Bamlanivimab and etesevimab's revised authorization for post-exposure prophylaxis is for those that are high-risk of progressing to severe COVID-19 as previously defined AND[3]

- Are not fully vaccinated or expected to mount an adequate immune response (are immunocompromised or immunosuppressed),
- Have been exposed to an individual with COVID-19 through close contact, or
- Are at high risk of close contact exposure to an individual infected with COVID-19 in the same institutional setting (such as a nursing home or prison)

Before receiving the bamlanivimab and etesevimab treatment, you should talk with your provider to discuss potential risks and benefits if you.[5]

- 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)

Bamlanivimab and etesevimab treatment is not authorized for use in people who[6]

- Are already hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- Require an increase in baseline oxygen flow rate due to COVID-19 for those on chronic oxygen therapy

How is the treatment given?

The bamlanivimab and etesevimab treatment is administered as a single dose through intravenous (IV) infusion or a subcutaneous (under the skin) injection by a medical provider.[5] Delivering the treatment often lasts between 20-60 minutes but can take longer. Patients are monitored during the infusion and for at least one hour afterwards.[5]

What are the possible benefits?

Possible benefits of receiving bamlanivimab and etesevimab treatment include[5]:

- Reduced risk of severe COVID-19 symptoms
- Reduced risk of hospitalization
- Reduced risk of death from COVID-19

What are the possible side effects?

Possible temporary side effects of receiving the treatment include[5]

- Nausea
- Diarrhea
- Worsening of existing symptoms of covid-19
- Vomiting
- Dizziness
- Headache
- Itching
- Allergic reaction

Possible temporary side effects of getting any medicine by infusion may include[5]

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

It is also possible that bamlanivimab and etesevimab could interfere with your body's ability to fight off future COVID-19 infection. Similarly, bamlanivimab and etesevimab may reduce your body's immune response to a COVID-19 vaccine.[5]

Can I be vaccinated for COVID-19 if I am treated with bamlanivimab and etesevimab for COVID-19?

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

The Advisory Committee on Immunization Practice recommends that you wait 90 days after receiving a COVID-19 mAbs 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.[7]

Should I continue to follow CDC guidelines?

You should continue to practice all safety measures because receiving a treatment does not protect against future COVID-19 infections.

To protect yourself and your community we recommend that you

- Continue to wear a mask
- Continue to social distance
- Continue to wash your hands
- Follow public health recommendations

References

1. Coronavirus (COVID-19) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant. U.S. Food and Drug Administration. Updated January 24, 2022. Accessed April 15, 2022. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron
2. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19. FDA. Published February 9, 2021. Accessed November 30, 2021. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0
3. U.S. Food and Drug Administration. FDA authorizes bamlanivimab and etesevimab monoclonal antibody therapy for post-exposure prophylaxis (prevention) for COVID-19. Published online September 16, 2021. Accessed November 30, 2021. www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-bamlanivimab-and-etesevimab-monoclonal-antibody-therapy-post-exposure-prophylaxis
4. Anti-SARS-CoV-2 Monoclonal Antibodies. COVID-19 Treatment Guidelines. Accessed November 30, 2021. www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/
5. Eli Lilly and Company. Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of Baricitinib. Eli Lilly and Company. Published July 2021. Accessed September 15, 2021. http://pi.lilly.com/eua/baricitinib-eua-factsheet-patient.pdf
6. U.S. Food and Drug Administration. Fact Sheet For Health Care Providers Emergency Use Authorization (EUA) Of Bamlanivimab And Etesevimab. www.fda.gov/media/145802/download. Updated March 2021. Accessed May 3, 2021
7. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC. CDC. Published September 17, 2021. Accessed September 20, 2021. www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html