Monoclonal Antibody Treatment FAQ

Contents

Monoclonal Antibody General Information ................................................................. 2
  What are monoclonal antibodies/mAbs? ................................................................. 2
  What is bamlanivimab? ......................................................................................... 2
Emergency Use Authorization ................................................................................... 2
  What is Emergency Use Authorization? ............................................................... 2
  What are the authorized uses of bamlanivimab under the EUA? ......................... 2
  What are the patient eligibility requirements for emergency use of bamlanivimab? 3
  What are the limitations of authorized use? ........................................................ 3
Ordering Information ................................................................................................. 3
  The order is live as of 11/20/2020 ....................................................................... 3
  Who can order bamlanivimab monoclonal antibody treatment? ......................... 3
  Who is responsible for placing the infusion order? ................................................. 3
  How will I know if my referral order for bamlanivimab was prioritized and fulfilled? 3
Patient Information .................................................................................................. 4
  How will patients know if their referral for bamlanivimab can be accommodated? 4
  Why can’t all patients receive bamlanivimab treatment? ..................................... 4
Administration ........................................................................................................ 4
  How is bamlanivimab administered? ................................................................. 4
Side Effects ............................................................................................................. 4
  What are the important possible side effects of bamlanivimab? ......................... 4
  For rare, but potentially life-threatening side effects that occur while at the infusion center, who will respond? ...................................................... 5
Additional information ........................................................................................... 5
Monoclonal Antibody General Information

What are monoclonal antibodies/mAbs?
Monoclonal antibodies are laboratory-produced molecules engineered to serve as substitute antibodies that can restore, enhance or mimic the immune system's attack on diseases. They are designed to limit viral replication, and may be effective for the treatment of COVID-19 in patients who are at high risk for progressing to severe COVID-19 and/or hospitalization.

What is bamlanivimab?
Bamlanivimab is a monoclonal antibody medication that is being investigated for use in the treatment of COVID-19. Since bamlanivimab is still being studied, there is limited information known about the safety and effectiveness of using bamlanivimab to treat COVID-19. The Food and Drug Administration (FDA) has made bamlanivimab available under an emergency access mechanism called an Emergency Use Authorization (EUA).

Emergency Use Authorization

What is Emergency Use Authorization?
EUA enables the FDA commissioner to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions when there are not approved or available alternatives. Bamlanivimab has not undergone the same type of review as an FDA-approved medication.

What are the authorized uses of bamlanivimab under the EUA?
At NM facilities, EUA for the use of the unapproved product bamlanivimab is intended for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are age 18 or older, weigh at least 40 kg, and are at high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age or older
- Are ≥ 55 years of age and have at least one of the following conditions:
  - Cardiovascular disease
  - Hypertension
  - Chronic obstructive pulmonary disease/other chronic respiratory disease
What are the patient eligibility requirements for emergency use of bamlanivimab?

Patients must meet the following criteria:

- Outpatient with mild to moderate COVID-19 (not currently hospitalized)
- No acute need for oxygen therapy or no acute need to increase oxygen flow in patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity
- ≥ 18 years of age (current age will auto-populate in Epic)
- Weight ≥ 40 kg (last entered weight will auto-populate in Epic)
- Positive results of direct SARS-CoV-2 viral testing (date of last test and result will auto-populate in Epic)
- Less than 10 days from symptom onset (ordering physician will enter date of symptom onset in Epic)

What are the limitations of authorized use?

Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to patients hospitalized with COVID-19 who require high-flow oxygen or mechanical ventilation.

Ordering Information

The order is live as of November 20, 2020

Who can order bamlanivimab monoclonal antibody treatment?

All medical staff who currently can order SARS-CoV-2 testing and treatments may refer patients for consideration of bamlanivimab monoclonal antibody treatment for emergency use. Initially, providers will place a referral to request the treatment. If the patient is prioritized to receive it, the referring provider will be entered as the ordering/authorizing provider. NOTE: Bamlanivimab is not for in-patient use, please refer to the criteria for ordering under the EUA FAQ section or the additional documents provided on Treatment Resources page.

Dot phrases for chart documentation and ED discharge instructions are underdevelopment, please refer to ordering tip sheet for more information.

Who is responsible for placing the infusion order?

The infusion RN will place the actual infusion order upon patient arrival to the clinic. The referral ordering physician will then be routed the infusion order for co-sign per protocol.

How will I know if my referral order for bamlanivimab was prioritized and fulfilled?

If your referral order for bamlanivimab was prioritized and fulfilled, you will receive a Bamlanivimab Infusion order to co-sign within 72 hours. If you don’t receive an infusion order for co-signature, then the request was not able to be fulfilled.
Patient Information

How will patients know if their referral for bamlanivimab can be accommodated?
As part of the discussion with patients, and prior to placing the referral order, please stress the following:

- We have a limited supply of medication and available treatment appointments; not every patient will be offered an appointment to receive the medication.
- If NM is able to accommodate your referral for monoclonal antibody treatment:
  - You will receive a call from Northwestern Medicine within 72 hours.
  - Please answer the call. It is unlikely that you will receive a second call, and there will not be an option for you to call back.
  - During the call, you will be offered available appointment times. Please note that infusion appointments can be as long as four hours.
  - If the NM hospital closest to you doesn’t have any remaining appointments, you will be offered an appointment at another NM hospital.
  - If called in the morning, you may be offered an appointment for later that same day in the afternoon. Please plan ahead and arrange for transportation if needed.
- If NM is not able to accommodate your referral for monoclonal antibody treatment, you will not receive a phone call.

See the Patient Speaking Points document for more information.

EUA information sheets are currently available in English and Spanish to order physicians and at the infusion center. Please utilize your local translator services for any other needs.

Why can’t all patients receive bamlanivimab treatment?
NM has a limited supply of bamlanivimab and limited capacity to deliver the treatment. We are working diligently to add additional capacity across the health system and will keep you informed as we expand availability.

Administration

How is bamlanivimab administered?
Bamlanivimab is administered through IV infusion. Patients will receive a single dose, which takes at least one hour to administer, followed by an observation period of at least one hour.

Side Effects

What are the important possible side effects of bamlanivimab?
Allergic reactions can happen during and after infusion with bamlanivimab, such as:
- Fever
- Chills
- Nausea
- Headache
- Shortness of breath
- Low blood pressure
- Wheezing
- Swelling of lips, face or throat
- Rash, including hives
- Itching
- Muscle aches
- Dizziness

As with any medication given by infusion, side effects may also include:

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

These are not all the possible side effects of bamlanivimab. Bamlanivimab has not been used in many patients, and serious and unexpected side effects may occur. Bamlanivimab is still being studied, and it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with the body’s own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab 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.

For rare, but potentially life-threatening side effects that occur while at the infusion center, who will respond?
MERT/RTTs will be called for infusion centers attached to hospitals. Non-hospital locations will call 911 as part of their standard processes.

Additional information
For additional information about bamlanivimab monoclonal antibody treatment for emergency use, please review the documents below:

- Emergency Use Authorization Letter
- Healthcare Provider Fact Sheet
- Patient and Caregiver Fact Sheet
- NEJM paper
- NIH Panel reviewing Bamlanivimab
- ACEP COVID-19 Treatment resources (Bamlanivimab is at the end)