Monocolonal Antibody COVID-19 Treatment FAQs

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Monocolonal Antibiody General Information

What are monoclonal antibodies/mAbs?
Monoclonal antibodies are laboratory-produced molecules engineered to bind to SARS-CoV-2, the virus that causes COVID-19. 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 monoclonal antibodies are available?
Bamlanivimab plus etesevimab and casiriviamb plus imdevimab are two examples of monoclonal antibody combinations (mAb) that were granted emergency use authorization for the treatment of COVID-19 in high risk patients. Please refer to the **NM Antimicrobial Stewardship Program** webpage at www.asp.nm.org for the most up-to-date information on available mAb treatments for COVID-19.

Emergency Use Autorization

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. EUA medications have not undergone the same review as an FDA-approved medication.

What are the authorized uses of monoclonal antibodies under the EUA?
At NM facilities, EUA for the use of the unapproved mAb products are 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:

- Older age (for example age ≥65 years of age)
- Obesity or being overweight (for example, adults with BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)

- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

What are the patient eligibility requirements for emergency use of monocolonal antibodies?

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)
- Within 10 days from symptom onset as noted in Epic (ordering physician will enter date of symptom onset in Epic)

What are the limitations of authorized use?

Benefit of treatment with monocolonal antibodies has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies 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

Who can order monoclonal antibody treatment?

All medical staff who currently can order SARS-CoV-2 testing and treatments may refer patients for consideration of monoclonal antibody treatment for emergency use. Initially, providers will place a referral to request the treatment. If the patient is scheduled for infusion, the referring provider will be entered as the ordering/authorizing provider. **NOTE:** Monocolonal antibodies are 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 available, 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 infusion site. 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 monoclonal antibodies was prioritized and fulfilled?

If your referral order for monocolonal antibodies was prioritized and fulfilled, you will receive an 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. This can occur if the patient cannot be contacted, the patient refused the therapy or the patient did not meet eligibility criteria.

Patient Information

How will patients know if their referral for monoclonal antibodies 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 number of 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.

Links to EUA information sheets are available on the **NM Antimicrobial Stewardship Program** webpage at www.asp.nm.org

Why can't all patients receive monocolonal antibody treatment?
NM has a 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 are monoclonal antibody treatments administered?
Monocolonal antibodies are administered through IV infusion. Patients will receive a single dose, which takes 20 minutes to one hour to administer, followed by an observation period of up to one hour.

Side Effects

What are the important possible side effects of monoclonal antibodies?
Allergic reactions can happen during and after infusion, such as:

- Fever
- Chills
- Nausea
- Headache
- Shortness of breath/bronchospasm
- 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 monoclonal antibody treatments. EUA approved monoclonal antibody treatments have not been used in many patients, and serious and unexpected side effects may occur. Monoclonal antibody treatments are still being studied, and it is possible that all of the risks are not known at this time.

It is possible that monoclonal antibodies could interfere with the body's own ability to fight off a future infection of SARS-CoV-2. Similarly, monocolonal antibodies may reduce the body's immune response to a vaccine for SARS-CoV-2. It is currently recommended not to give the SARS-CoV-2 vaccine within 90 days of a dose of monoclonal antibodies. 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-hopsital locations will call 911 as part of their standard processes.

Additional information

For additional information about monoclonal antibody treatment for emergency use, please refer to the **NM Antimicrobial Stewardship Program** webpage at www.asp.nm.org