Pharmacists’ Referrals for Monoclonal Antibody Treatment

Assessing patients for potential COVID-19 treatment with monoclonal antibodies

The Food and Drug Administration (FDA) has issued emergency use authorizations (EUA) for monoclonal antibodies for the treatment of mild to moderate COVID-19 disease. These treatments must be administered at an infusion center within 10 days of symptom onset; pharmacists can play an important role in bringing awareness to these important treatment options. The purpose of this resource is to provide pharmacists with information about monoclonal antibody treatments and patient eligibility so that pharmacists are prepared to make these potentially life-saving referrals.

Which monoclonal antibody treatments are authorized by the FDA?

Three monoclonal antibodies (mAb)—bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab—recently received EUAs. Monoclonal antibody treatments use exogenously generated antibodies to neutralize the SARS-CoV-2 virus’s ability to infect cells, which can reduce the severity of COVID-19 symptoms in patients who have confirmed COVID-19 infections. Bamlanivimab has reportedly reduced hospitalizations by up to 70%; however, because these medications must be administered by infusion, they are often overlooked and underutilized.

What is the pharmacist’s role in patient access to monoclonal antibody treatments?

Pharmacists in community-based settings can help increase patient awareness of these treatment options, assess for patient eligibility, and refer patients to their provider for treatment. Pharmacists are uniquely positioned to identify patients who may benefit from these underutilized and time-sensitive treatments through point-of-care COVID-19 testing, counseling, and/or clinical assessment. Pharmacists can help route patients to an appropriate provider and provide the location of an infusion clinic to initiate therapy.

How can patients access monoclonal antibodies?

Locate nearby infusion centers at: https://protect-public.hhs.gov/pages/therapeutics-distribution

- Bamlanivimab: Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers (Spanish Version).
- Bamlanivimab/Etesevimab: Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.
- Casirivimab/Imdevimab: Access the FDA Fact Sheet for Health Care Providers and the Fact Sheet for Patients, Parents, and Caregivers.

• Positive COVID-19 test
• Symptom onset within 10 days
• High risk

Referral to a medical provider

Find a nearby location for infusion services
Assessing patients for potential COVID-19 treatment with monoclonal antibodies

Which patients are eligible for therapy with bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab?

1. **Is patient ≥ 12 years of age?**
   - **YES**: Perform initial assessment (must meet ALL):
     - Positive COVID-19 test
     - Symptomatic within 10 days of administration
     - Exhibits mild to moderate symptoms
     - Does not require supplemental oxygen
     - Not hospitalized
   - **NO**: Not eligible to receive administration
   - **Did patient meet ALL initial assessment criteria?**
     - **YES**: Perform high risk condition assessment (meet at least 1):
       - Body mass index (BMI) ≥ 35 kg/m²
       - Chronic kidney disease (CKD)
       - Diabetes (type 1 or type 2)
       - Immunosuppressive disease
       - Immunosuppressive treatment
       - ≥ 65 years of age
       - ≥ 55 years of age AND cardiovascular disease, OR hypertension, OR chronic obstructive pulmonary disease, OR other chronic respiratory disease
       - If 12-17 years of age, assess for additional criteria (meet at least 1 from above or below):
         - Body mass index (BMI) ≥ 85th percentile based on CDC growth chart
         - Sickle cell disease
         - Congenital or acquired heart disease
         - Neurodevelopmental disorders
         - Medical technology dependence (e.g., tracheostomy, gastrostomy, Positive Pressure Ventilation not related to COVID-19)
         - Asthma or reactive airway disease
         - Other chronic respiratory disease requiring daily medications for control
     - **NO**: Not eligible to receive administration
     - **Did patient meet AT LEAST 1 high risk criteria?**
       - **YES**: Refer for potential administration
       - **NO**: Not eligible to receive administration
What are the potential side effects?

- Allergic reactions, although rare, can happen during and after infusion and should be handled in accordance with the facility’s emergency action plans. Some examples of known reactions are: 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 lips, face, or throat; rash including hives; itching; muscle aches; dizziness; and sweating. These reactions may be severe.

- Worsening symptoms after treatment can include: fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness, or confusion. If these occur, seek immediate medical attention, as some of these events require hospitalization.

- Signs and symptoms of infusion-related reactions include: fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, and dizziness.

How should side effects be reported with bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab?

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

Are these treatments safe for pregnant or breastfeeding patients?

There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab and casirivimab/imdevimab. For a mother and unborn baby, the benefit of receiving these monoclonal antibodies may be greater than the risk from the treatment; discuss options with the patient.

What are some additional patient counseling points?

It is important to note that bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab are not cures. Patients should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and wash hands frequently) and, in general, continue to adhere to CDC guidelines unless or until cleared by a provider.