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 and after a positive COVID-19 test; 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.

Quick Links

- APhA's Pharmacy Models for Expanding Access to COVID-19 Monoclonal Antibody Treatment Open Forum Webinar
- APhA's "Medications Being Studied for COVID-19" in the COVID-19 Resources: Know the Facts library
- NIH's COVID-19 Treatment Guidelines for Anti-SARS-CoV-2 Monoclonal Antibodies
- HHS's Special Projects for Equitable and Efficient Distribution (SPEED) of COVID-19 Outpatient Therapeutics
- ASCP's Monoclonal Antibody Treatments in Long Term Care Settings

Which monoclonal antibody treatments are authorized by the FDA?

Treatment	Dosage	Infusion Time	Emergency Use Authorization
Casirivimab/ Imdevimab	600mg/600mg	60mins	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers
Sotrovimab	500mg	30mins	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers
Bamlanivimab/ Etesevimab (Pause in distribution)	700mg/1,400mg	~20-60mins	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers

What is the benefit of monoclonal antibody therapy?

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. As variants of the virus emerge, some variants may make the virus less susceptible to certain monoclonal antibody therapies. It is important to routinely reference monoclonal antibody therapies authorized by the FDA.

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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. Pharmacists working in appropriate practices, such as long-term care settings or pharmacies accredited in home infusion, may procure monoclonal antibody therapies and work with staff trained to administer IV therapies.

How can patients access monoclonal antibodies?

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

What are the potential side effects and monitoring requirements?

Patients should be monitored during the infusion and for at least 1 hour after the infusion is completed.

- **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?

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

Pharmacists' Referrals for Monoclonal Antibody Treatment (continued)

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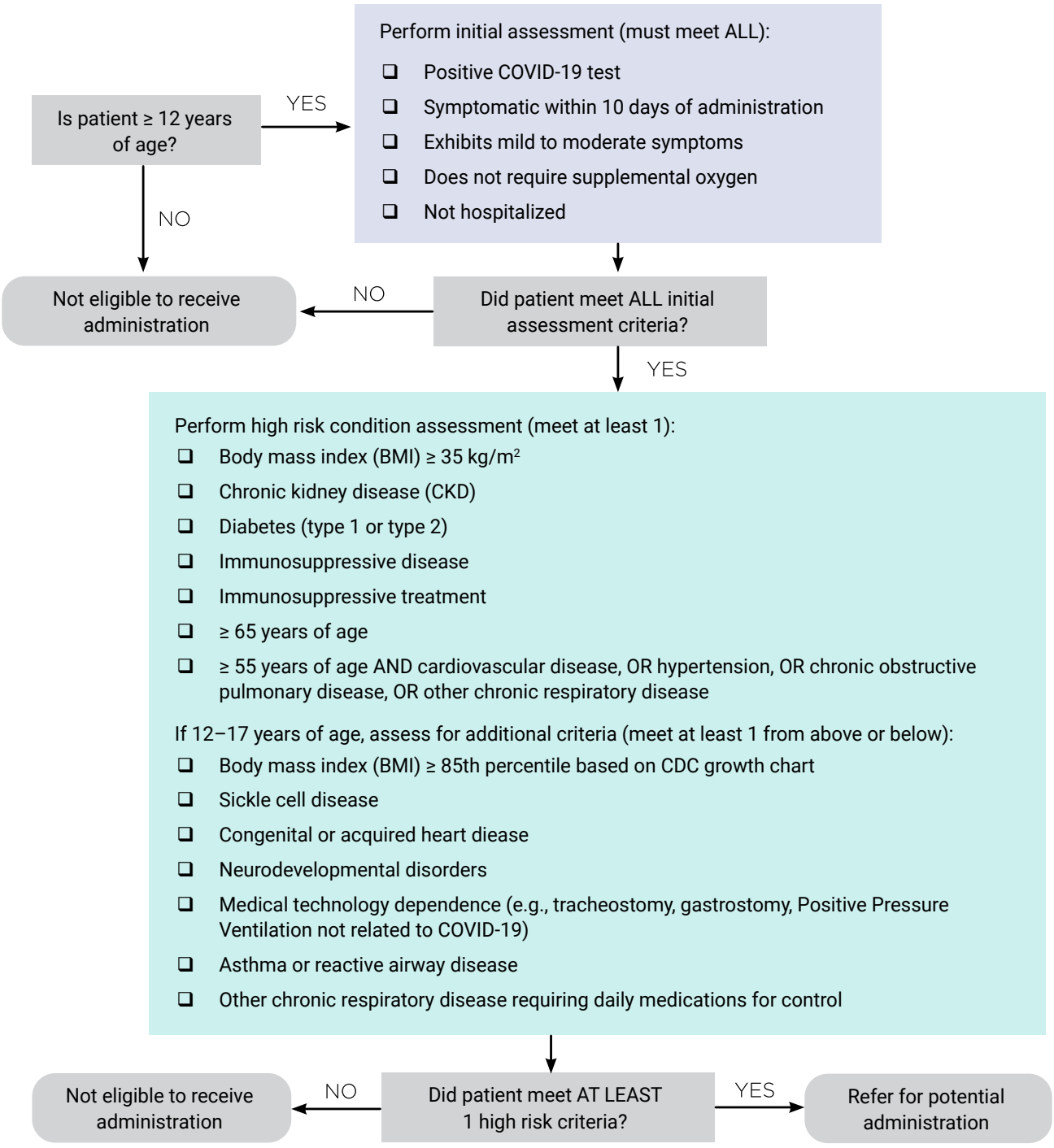
Which patients are eligible for monoclonal antibody therapy?



Pharmacists' Referrals for Monoclonal Antibody Treatment (continued)

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Are these treatments safe for pregnant or breastfeeding patients?

There is limited experience treating pregnant women or breastfeeding mothers with monoclonal antibody therapies. For a mother and unborn baby, particularly a pregnant woman at high risk of progression to severe COVID-19, 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 monoclonal antibody therapies 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.

After receiving monoclonal antibody therapy, **patients should be advised to wait 90 days or more before getting the COVID-19 vaccine.** This is a precautionary measure to ensure the patient has an appropriate vaccine-induced immune response.

What reimbursement is available for monoclonal antibody therapies?

Monoclonal antibody treatments are authorized as vaccines and therefore can be billed as such. The product is currently provided by the federal government free of charge. Reimbursement for administration is available under Medicare Part B, as detailed below. For more information, reference CMS's "Coverage of Monoclonal Antibody Products to Treat COVID-19."

CPT Code	Product	CMS Rate
M0245	Bamlanivir/Etesevimab	$450 – Institution/clinic
M0246	Bamlanivir/Etesevimab	$750 – Home
M0243	Casirivimab/Imdevimab	$450 – Institution/clinic
M0244	Casirivimab/Imdevimab	$750 – Home
M0247	Sotrovimab	$450 – Institution/clinic
M0248	Sotrovimab	$750 – Home

For more information about how to enroll and bill for monoclonal antibody therapies, refer to our practice resources in APhA's COVID-19 Resources: Know the Facts library.