

# Monoclonal Antibody Therapies

## Considerations for Therapy and the Pharmacists' Role

### Quick Links

- HHS's [Monoclonal Antibody Resources for Clinicians](#)
- NIH's [COVID-19 Treatment Guidelines for Anti-SARS-CoV-2 Monoclonal Antibodies](#)

### What is the benefit of monoclonal antibody therapy?

Monoclonal antibody therapies use exogenously generated antibodies that neutralize the SARS-CoV-2 virus's ability to infect cells. This can reduce the severity of COVID-19 symptoms in patients at high risk for developing COVID-19 disease.

Food and Drug Administration (FDA) has [authorized](#) monoclonal antibody therapies to treat individuals with mild to moderate COVID-19 disease who are at risk of developing severe disease. Casirivimab/imdevimab (REGEN-COV) is also authorized for prophylaxis in high-risk individuals who have been exposed to COVID-19.

These therapies should not be considered a substitute for vaccination or be used for pre-exposure prophylaxis, i.e., to prevent COVID-19 infection.

### Which monoclonal antibody therapies have received FDA authorization?

Therapy	Manufacturer	Authorized Use	Dosage Form	Emergency Use Authorization Fact Sheets
<b>Casirivimab/ imdevimab (REGEN-COV)</b>	Regeneron	<ul style="list-style-type: none"> <li>• Treatment of mild to moderate COVID-19 infection</li> <li>• Post-exposure prophylaxis</li> </ul>	I.V. or Sub-Q	<ul style="list-style-type: none"> <li>• <a href="#">Fact Sheet for Health Care Providers</a></li> <li>• <a href="#">Fact Sheet for Patients, Parents, and Caregivers</a></li> </ul>
<b>Sotrovimab</b>	GSK	<ul style="list-style-type: none"> <li>• Treatment of mild to moderate COVID-19 infection</li> </ul>	I.V.	<ul style="list-style-type: none"> <li>• <a href="#">Fact Sheet for Health Care Providers</a></li> <li>• <a href="#">Fact Sheet for Patients, Parents, and Caregivers</a></li> </ul>
<b>Bamlanivimab/ etesevimab</b>	Lilly	<ul style="list-style-type: none"> <li>• Treatment of mild to moderate COVID-19 infection</li> <li>• Post-exposure prophylaxis</li> </ul>	I.V.	<ul style="list-style-type: none"> <li>• <a href="#">Fact Sheet for Health Care Providers</a></li> <li>• <a href="#">Fact Sheet for Patients, Parents, and Caregivers</a></li> </ul>

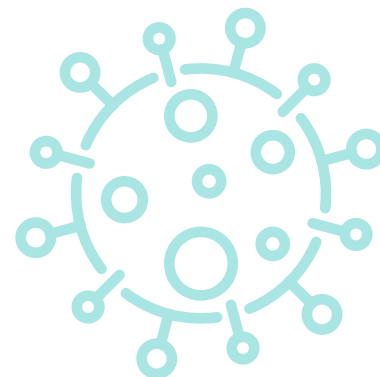
# Monoclonal Antibody Therapies (continued)

## Considerations for Therapy and the Pharmacists' Role

### When should monoclonal antibody therapies be administered?

For the **treatment** of mild to moderate COVID-19 infection, individuals who have tested positive for COVID-19 should receive monoclonal antibody therapies **within 10 days of symptom onset**. Monoclonal antibodies for **post-exposure prophylaxis** should be administered **as soon as possible**.

Patients should not receive monoclonal antibody therapy if they exhibit severe symptoms of COVID-19 infection or if they require supplemental oxygen. Monoclonal antibody therapies can worsen disease in patients who exhibit signs of severe disease; therefore, it is critical that patients receive these treatments as soon as possible and are assessed before the therapy is administered.



### How should REGEN-COV be administered?

The intent of therapy informs whether REGEN-COV should be administered by intravenous infusion (I.V.) or subcutaneous injection (Sub-Q). For treatment, I.V. is strongly recommended, but Sub-Q alternatively be used when I.V. is not feasible and would delay treatment. For post-exposure prophylaxis, either Sub-Q or I.V. can be used.

### What are the potential side effects and how should they be monitored?

Patients may experience hypersensitivity reactions, including anaphylaxis and serious infusion-related reactions. These reactions can take place during administration or up to 24 hours after. It is important to be prepared to manage adverse reactions and required that patients be monitored during administration and for at least 1 hour after.

Clinical worsening can occur in patients who exhibit severe symptoms indicative of disease progression. Pharmacists should encourage patients who experience clinical worsening to seek immediate medical attention—the patient may need to be hospitalized.

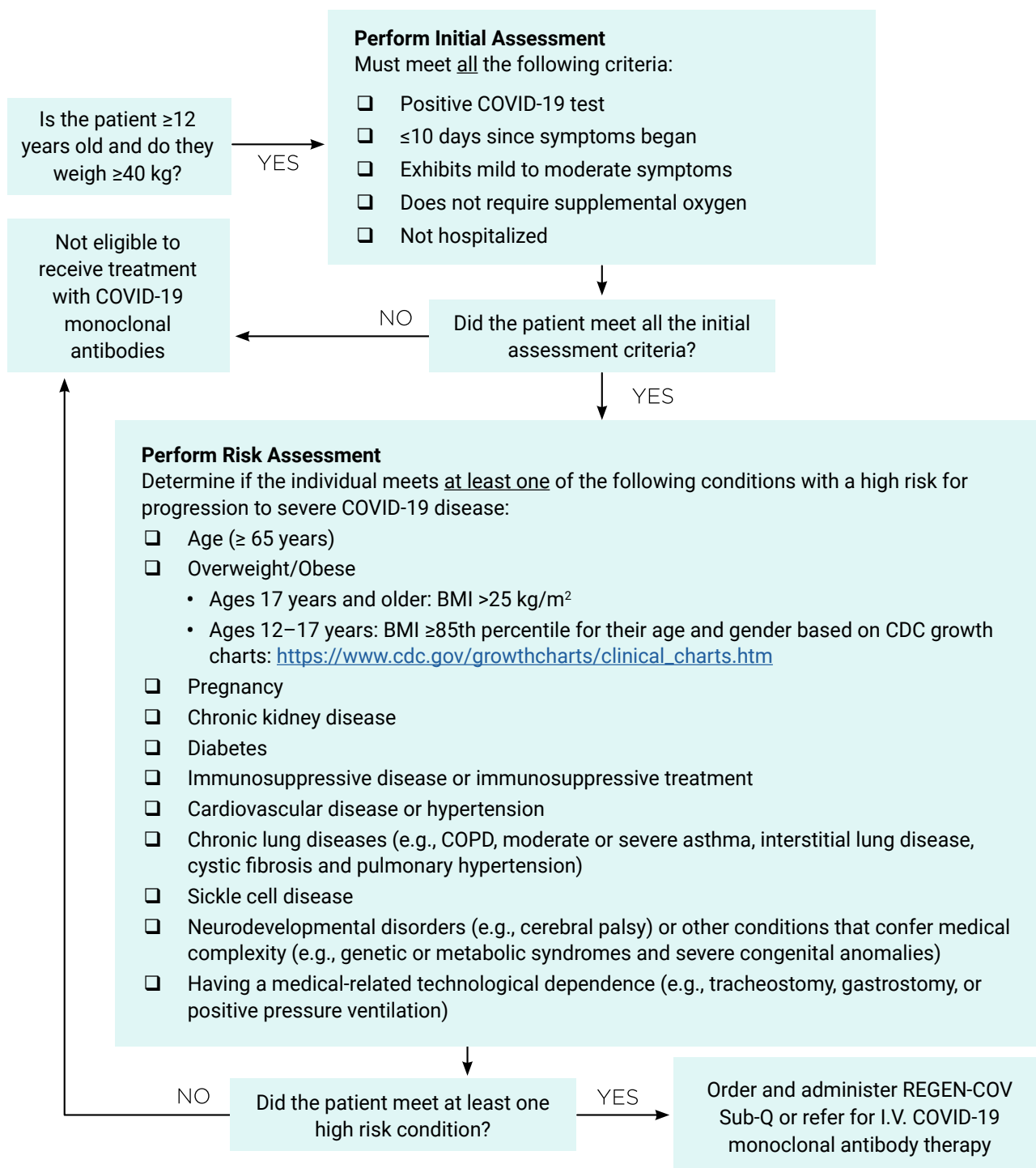
Report side effects to FDA MedWatch via one of the following:

- [www.fda.gov/medwatch](https://www.fda.gov/medwatch)
- 1-800-FDA-1088
- 1-844-734-6643

# Monoclonal Antibody Therapies (continued)

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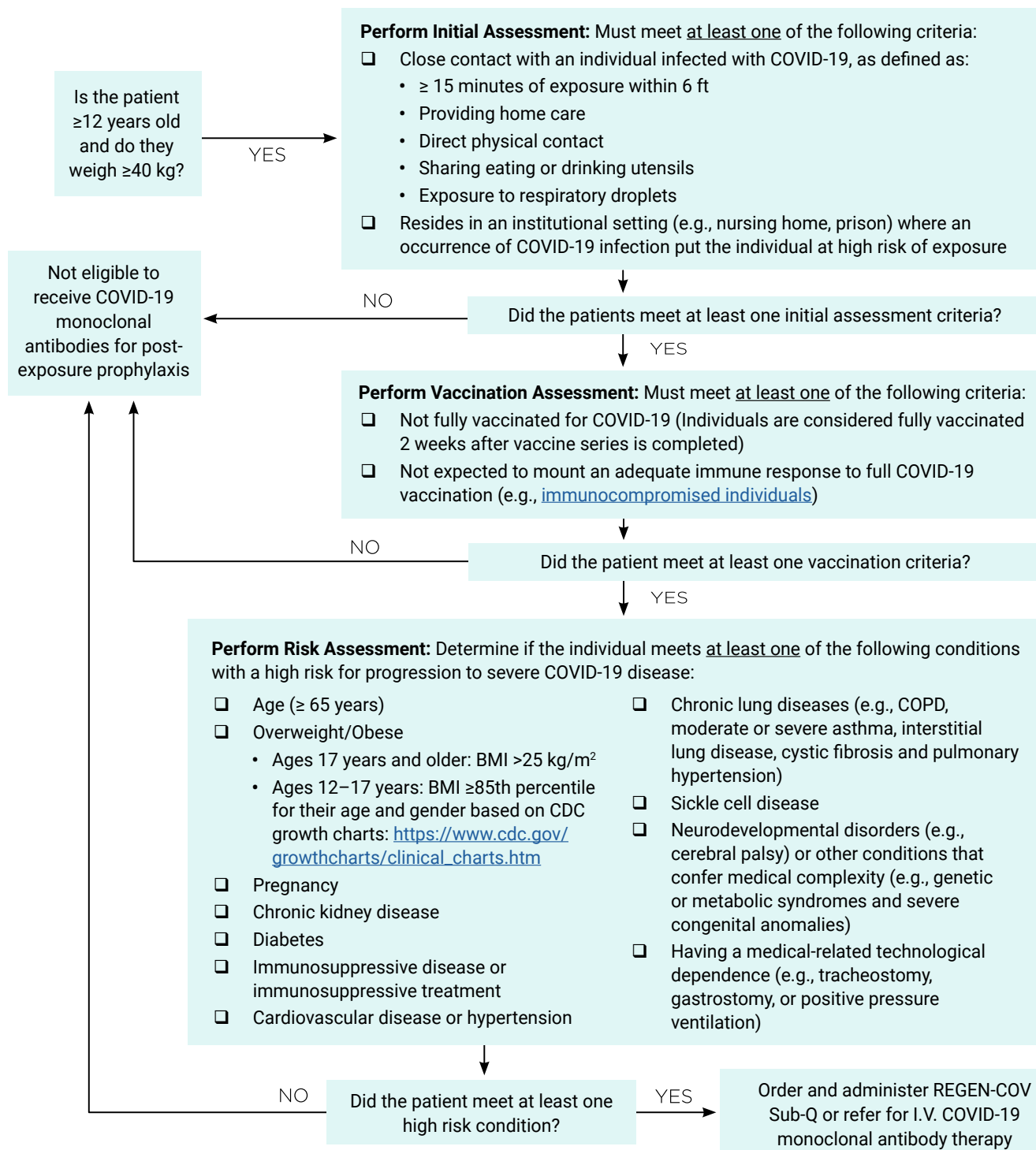
### Who can receive monoclonal antibody therapy for mild to moderate COVID-19 infection?



# Monoclonal Antibody Therapies (continued)

## Considerations for Therapy and the Pharmacists' Role

### Who can receive monoclonal antibody therapy for post-exposure prophylaxis?



# Monoclonal Antibody Therapies (continued)

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### What else should patients know?

**Monoclonal antibody therapies are not cures.** Patients who receive these therapies should continue to 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, adhere to CDC guidelines unless or until cleared by a provider.

**Patients should wait 90 or more days** after receiving monoclonal antibody therapy **before getting the COVID-19 vaccine.** This is a precautionary measure to ensure the patient has an appropriate vaccine-induced immune response. Vaccination status should not affect treatment decisions (e.g., when a patient develops COVID-19 after they receive the vaccine).

### How can pharmacists increase access to monoclonal antibody therapies?

Pharmacists are uniquely positioned to increase awareness of and access to these therapies.

- **Increase awareness** by encouraging and answering patient questions about monoclonal antibody therapies. Pharmacies can
  - Serve as an access point for answering patient questions
  - Display a [poster](#) that summarizes the most vital information
  - Distribute a [flyer](#) to patients who have tested positive for COVID-19
  - Share a [resource](#) with answers to patients' most common questions
- **Incorporate patient assessments and counseling into point-of-care [COVID-19 testing](#) services** to identify eligible individuals who test positive for COVID-19.
- **Order and administer** monoclonal antibody therapies. The Public Readiness and Emergency Preparedness (PREP) Act [authorizes](#) pharmacists to order and administer FDA-authorized, approved, licensed, or cleared COVID-19 therapeutics. Pharmacists are authorized to order the monoclonal antibody therapies for subcutaneous, intramuscular, or oral administration. The PREP Act also authorizes pharmacy interns and pharmacy technicians to administer these therapeutics under supervision.
- **Connect patients** to nearby infusion clinics to initiate therapy. Locate nearby infusion centers: <https://protect-public.hhs.gov/pages/therapeutics-distribution>
- **Refer patients for hospitalization** if assessment indicates they require advanced care and monitoring.

*Disclaimer: The information in this document is provided only for general informational purposes and does not constitute business or legal advice. Information related to the COVID-19 pandemic is changing rapidly and continuously. The material and information contained in this publication is believed to be current as of the date included on this document. The American Pharmacists Association assumes no responsibility for the accuracy, timeliness, errors, or omission contained herein. Links to any sources do not constitute any endorsement of, validity, or warranty of the information contained on any site. The user of these materials should not under any circumstances solely rely on, or act based on this publication. Pharmacy professionals retain the responsibility for using their own professional judgment and practicing in accordance with all rules, regulations, and laws governing the pharmacy practice within their jurisdiction.*