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
Casirivimab/ imdevimab (REGEN-COV)	Regeneron	• Treatment of mild to moderate COVID-19 infection • Post-exposure prophylaxis	I.V. or Sub-Q	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers
Sotrovimab	GSK	• Treatment of mild to moderate COVID-19 infection	I.V.	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers
Bamlanivimab/ etesevimab	Lilly	• Treatment of mild to moderate COVID-19 infection • Post-exposure prophylaxis	I.V.	• Fact Sheet for Health Care Providers • Fact Sheet for Patients, Parents, and Caregivers

Monoclonal Antibody Therapies (continued)

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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
- 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?

Is the patient ≥12 years old and do they weigh ≥40 kg?

YES

Perform Initial Assessment
Must meet all the following criteria:

- ❑ Positive COVID-19 test
- ❑ ≤10 days since symptoms began
- ❑ Exhibits mild to moderate symptoms
- ❑ Does not require supplemental oxygen
- ❑ Not hospitalized

Did the patient meet all the initial assessment criteria?

NO

Not eligible to receive treatment with COVID-19 monoclonal antibodies

YES

Perform Risk Assessment
Determine if the individual meets at least one of the following conditions with a high risk for progression to severe COVID-19 disease:

- ❑ Age (≥ 65 years)
- ❑ Overweight/Obese
  - Ages 17 years and older: BMI >25 kg/m^2
  - Ages 12–17 years: BMI ≥85th percentile for their age and gender based on CDC growth charts: https://www.cdc.gov/growthcharts/clinical_charts.htm
- ❑ Pregnancy
- ❑ Chronic kidney disease
- ❑ Diabetes
- ❑ Immunosuppressive disease or immunosuppressive treatment
- ❑ Cardiovascular disease or hypertension
- ❑ Chronic lung diseases (e.g., COPD, moderate or severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- ❑ Sickle cell disease
- ❑ Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- ❑ Having a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation)

Did the patient meet at least one high risk condition?

NO

YES

Order and administer REGEN-COV Sub-Q or refer for I.V. COVID-19 monoclonal antibody therapy

Monoclonal Antibody Therapies (continued)

Considerations for Therapy and the Pharmacists' Role

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

Is the patient ≥12 years old and do they weigh ≥40 kg?

YES

Perform Initial Assessment: Must meet <u>at least one</u> of the following criteria:

- ❑ Close contact with an individual infected with COVID-19, as defined as:
  - ≥ 15 minutes of exposure within 6 ft
  - Providing home care
  - Direct physical contact
  - Sharing eating or drinking utensils
  - Exposure to respiratory droplets
- ❑ Resides in an institutional setting (e.g., nursing home, prison) where an occurrence of COVID-19 infection put the individual at high risk of exposure

Did the patients meet at least one initial assessment criteria?

NO

Not eligible to receive COVID-19 monoclonal antibodies for post-exposure prophylaxis

YES

Perform Vaccination Assessment: Must meet <u>at least one</u> of the following criteria:

- ❑ Not fully vaccinated for COVID-19 (Individuals are considered fully vaccinated 2 weeks after vaccine series is completed)
- ❑ Not expected to mount an adequate immune response to full COVID-19 vaccination (e.g., immunocompromised individuals)

Did the patient meet at least one vaccination criteria?

NO

YES

Perform Risk Assessment: Determine if the individual meets <u>at least one</u> of the following conditions with a high risk for progression to severe COVID-19 disease:

- ❑ Age (≥ 65 years)
- ❑ Overweight/Obese
  - Ages 17 years and older: BMI >25 kg/m^2
  - Ages 12–17 years: BMI ≥85th percentile for their age and gender based on CDC growth charts: https://www.cdc.gov/growthcharts/clinical_charts.htm
- ❑ Pregnancy
- ❑ Chronic kidney disease
- ❑ Diabetes
- ❑ Immunosuppressive disease or immunosuppressive treatment
- ❑ Cardiovascular disease or hypertension
- ❑ Chronic lung diseases (e.g., COPD, moderate or severe asthma, interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- ❑ Sickle cell disease
- ❑ Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- ❑ Having a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation)

Did the patient meet at least one high risk condition?

NO

YES

Order and administer REGEN-COV Sub-Q or refer for I.V. COVID-19 monoclonal antibody therapy

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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.