

# Monoclonal Antibody Therapies

Considerations for therapy and pharmacists' role



APhA COVID-19 RESOURCES:  
KNOW THE FACTS

## Quick Links

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

Monoclonal antibody therapies can be used for prevention or treatment in patients at high risk for developing severe COVID-19. These therapies work by neutralizing the SARS-CoV-2 virus' ability to infect cells and can therefore reduce the risk of developing COVID-19 and its progression. These therapies can save lives when accessed in a timely manner.

Each COVID-19 monoclonal antibody therapy is different, so it is important to know how each therapy is authorized to be used, and for whom therapy is indicated. It is important to note that COVID-19 variants such as Omicron can reduce the effectiveness of these products. As a result, some products might not be distributed to areas with a high prevalence of these variants. Monitor for [allocation and distribution updates](#).

Table 1 summarizes key information about the monoclonal antibody therapies currently [authorized](#) by FDA for emergency use. Depending on the therapy, it may be authorized for

- Treatment of mild to moderate COVID-19 disease
- Post-exposure prophylaxis
- Pre-exposure prophylaxis

For each indicated use, individuals must meet certain criteria to be eligible for therapy (Table 2).



# Monoclonal Antibody Therapies (continued)

Considerations for therapy and pharmacists' role



APhA COVID-19 RESOURCES:  
KNOW THE FACTS

**Table 1: COVID-19 monoclonal antibodies currently authorized by FDA**

Therapy	Manufacturer	Authorized use	Minimum age/ weight	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 disease</li><li>• Post-exposure prophylaxis</li></ul>	≥12 years old weighing ≥40kg	I.V. or S.C.	<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><li>• <a href="#">Frequently asked questions</a></li></ul>
<b>Bamlanivimab/ Etesevimab</b>	Lilly	<ul style="list-style-type: none"><li>• Treatment of mild to moderate COVID-19 infection in areas where authorized</li><li>• Post-exposure prophylaxis</li></ul>	No minimum age or weight required	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><li>• <a href="#">Frequently asked questions</a></li></ul>
<b>Tixagevimab/ cilgavimab (Evusheld)</b>	AstraZeneca	<ul style="list-style-type: none"><li>• Pre-exposure prophylaxis</li></ul>	≥12 years old weighing ≥40kg	I.M.	<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><li>• <a href="#">Frequently asked questions</a></li></ul>
<b>Sotrovimab</b>	GSK	<ul style="list-style-type: none"><li>• Treatment of mild to moderate COVID-19 disease</li></ul>	≥12 years old weighing ≥40kg	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><li>• <a href="#">Frequently asked questions</a></li></ul>



# Monoclonal Antibody Therapies (continued)

Considerations for therapy and pharmacists' role



APhA COVID-19 RESOURCES:  
KNOW THE FACTS

**Table 2: Considerations for use of authorized COVID-19 monoclonal antibodies**

Indication	Treatment	Post-exposure prophylaxis	Pre-exposure prophylaxis
<b>Timing</b>	Must receive treatment within 10 days of symptom onset	Administer as soon as possible after exposure	Administer to eligible individuals when indicated
<b>Eligibility criteria</b>	<p>A high-risk individual* must meet <u>all</u> the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Positive COVID-19 test</li> <li><input type="checkbox"/> ≤10 days since symptoms began</li> <li><input type="checkbox"/> Exhibits mild to moderate symptoms</li> <li><input type="checkbox"/> Does not require supplemental oxygen</li> <li><input type="checkbox"/> Not hospitalized</li> </ul>	<p>A high-risk individual* must meet <u>at least one</u> of the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Close contact with an individual infected with COVID-19</li> <li><input type="checkbox"/> Resides in an institutional setting (e.g., nursing home, prison) where there is a high risk of exposure to an individual infected with COVID-19</li> </ul> <p>AND must meet <u>at least one</u> of the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Not fully vaccinated for COVID-19 (2 weeks after vaccination with primary series)</li> <li><input type="checkbox"/> Not expected to mount an adequate immune response to full COVID-19 vaccination</li> </ul>	<p>Individual must meet <u>all</u> the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Not infected with COVID-19</li> <li><input type="checkbox"/> No known recent exposure to an individual infected with COVID-19</li> </ul> <p>AND must meet <u>at least one</u> of the following criteria:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Individual who is moderately to severely immunocompromised**</li> <li><input type="checkbox"/> Individual for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction)***</li> </ul>
<b>Vaccination</b>	Defer for 90 days after treatment	Defer for 30 days after treatment	N/A

# Monoclonal Antibody Therapies (continued)

Considerations for therapy and pharmacists' role



APhA COVID-19 RESOURCES:  
KNOW THE FACTS

**\*An individual is considered at high risk for progression to severe COVID-19 disease if they meet at least one of the following criteria:**

- ☐ Age ( $\geq 65$  years)
- ☐ Overweight/Obese
  - ☐ Ages 18 years and older: BMI  $>25$  kg/m<sup>2</sup>
  - ☐ Ages 12-17 years: BMI  $\geq 85$ th percentile for their age and gender based on CDC growth charts: [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](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)

**\*\*An individual is considered moderately to severely immunocompromised if they meet at least one of the following criteria:**

- ☐ Active treatment for solid tumor and hematologic malignancies
- ☐ Receipt of solid-organ transplant and taking immunosuppressive therapy
- ☐ Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- ☐ Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- ☐ Advanced or untreated HIV infection (people with HIV and CD4 cell counts  $<200$ /mm<sup>3</sup>, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- ☐ Active treatment with high-dose corticosteroids (i.e.,  $\geq 20$ mg prednisone or equivalent per day when administered for  $\geq 2$  weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

\*\*\*See contraindications and precautions in CDC's [interim clinical considerations for use of COVID-19 vaccines](#).



# Monoclonal Antibody Therapies (continued)

## Considerations for therapy and pharmacists' role



APhA COVID-19 RESOURCES:  
KNOW THE FACTS

### Pharmacists' role

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

#### Pharmacists can

- **Increase awareness** by encouraging and answering patients' questions about monoclonal antibody therapies. Pharmacies can
  - Serve as an access point for answering patients' 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** some monoclonal antibody therapies. Refer to the COVID-19 monoclonal antibody therapies implementation guide in APhA's [COVID-19 resources: Know the facts](#) library.
- **Connect patients** to nearby infusion clinics to initiate therapy. Locate nearby infusion centers using [HHS' therapeutics location tool](#).
- **Refer patients for hospitalization** if assessment indicates they require supplemental oxygen.



*Disclaimer: 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.*