

COVID-19 Monoclonal Antibody Therapies Implementation Guide

COVID-19 monoclonal antibody therapies can be administered to patients at risk of progressing to severe COVID-19 disease. To learn more about monoclonal antibodies authorized for treatment and/or post-exposure prophylaxis, reference “Monoclonal Antibody Therapies: Considerations for Therapy and the Pharmacists’ Role” in [APhA’s COVID-19 Resources: Know the Facts](#) library. It is important to note that these therapies may be administered via intravenous infusion or subcutaneous injection.

This resource will outline the key steps to implementing administration services for COVID-19 monoclonal antibody therapies given by subcutaneous injection in an outpatient setting.

Quick Links

- ASPR’s [COVID-19 Monoclonal Antibody Therapeutics](#) resource center
- CMS’s [Monoclonal Antibody COVID-19 Infusion](#) reimbursement resource center
- APhA’s [Pharmacy Models for Expanding Access to COVID-19 Monoclonal Antibody Treatment](#) open forum webinar

Authority

1. Understand your federal authority to order and/or administer COVID-19 therapeutics.

- Licensed pharmacists are [authorized](#) by the Department of Health and Human Services (HHS) to order and administer COVID-19 therapeutics that the Food and Drug Administration (FDA) has approved, authorized, cleared, or licensed.
- The therapeutic must be administered by subcutaneous, intramuscular, or oral route.
- Pharmacy interns and pharmacy technicians are authorized to assist with administration only.
- At this time, there is only one COVID-19 therapeutic that can be given subcutaneously. [REGEN-COV \(casirivimab/imdevimab\)](#) is a monoclonal antibody therapy with an emergency use authorization (EUA) for the treatment of COVID-19 infection and for post-exposure prophylaxis in certain individuals. For treatment, intravenous infusion is strongly recommended, and subcutaneous injection should be considered when intravenous infusion is not feasible and would lead to delay in treatment.

In some states (such as Arkansas, Mississippi, and Oregon), pharmacists have the authority to order and administer COVID-19 monoclonal antibody therapies administered by intravenous infusion.

When ordering a COVID-19 therapeutic, verify health care personnel (e.g., nurses) have the authority to administer a pharmacist-ordered therapeutic.

COVID-19 Monoclonal Antibody Therapies Implementation Guide (continued)

2. Verify that you meet the requirements to be considered authorized to order and/or administer COVID-19 therapeutics.

- Reference “Authority to Provide COVID-19 Therapeutics” in [APhA’s COVID-19 Resources: Know the Facts](#) library to learn the requirements.
- APhA designed a training program, [Monoclonal Antibodies: Assessment and Administration of COVID-19 Therapy](#), to help pharmacists, pharmacy technicians, and pharmacy interns fully satisfy the requirements by supplementing the Pharmacy-based Immunization Delivery certificate training program.

Resources

3. Determine whether your pharmacy practice has the resources to implement a COVID-19 monoclonal antibody program.

- **Gather information:** Reference the federal [Monoclonal Antibody Clinical Implementation Guide](#) for a comprehensive overview of the infrastructure and supplies needed for success.
- **Identify staffing and PPE needs:** Be aware of the staffing and PPE demands that must be met to safely treat patients with an active COVID-19 infection. Patients should be given a N95 mask upon arrival. Pharmacies may be able to order PPE through their local and state public health departments.
- **Establish a designated administration space:** A designated area should be established to keep infected patients away from others. It is estimated that the patient will spend about 1.5 hours in the designated area (administration, plus an hour of monitoring). Therefore, it is important to provide patient chairs that are comfortable and easy to disinfect. Consider how you will make restrooms and drinking water available to the patient in the designated area.
- **Obtain monitoring equipment:** Adequate staffing is needed to ensure patients are actively monitored after therapy is administered. The pharmacy must be prepared to respond to potential serious allergic reactions or patient decompensation. Basic monitoring equipment must include a blood pressure cuff, pulse oximeter, and a thermometer.
- **Consider COVID-19 testing services:** To receive REGEN-COV for COVID-19 infection, the patient must present proof of a positive test result during intake. Pharmacies offering COVID-19 testing services can establish a test-and-treat care model that ensures eligible patients who test positive are quickly able to access treatment with REGEN-COV. [Learn more about COVID-19 testing.](#)
- **Consider home visits:** Depending on pharmacy resources, home visits can also be considered.

COVID-19 Monoclonal Antibody Therapies Implementation Guide (continued)

Distribution

4. Reach out to your state pharmacy association or local public health officials to assess the supply of REGEN-COV available to you.

- The federal government manages supplies of COVID-19 monoclonal antibodies and has implemented a state-coordinated distribution system.
- State public health officials will determine which sites in their jurisdiction receive product and how much.
- State pharmacy associations and local health departments can assist with the process and advocate for your pharmacy as an access point for patients.
- REGEN-COV is indicated for post-exposure prophylaxis and treatment of COVID-19; however, due to limited supplies, many states prioritize use for treatment only.
- Sites should report inventory and usage to their state public health officials weekly, even if they do not need more product. This helps ensure accurate federal allocations.

Screening and Referrals

5. Establish a process for screening and referrals.

- Patients must have proof of a positive COVID-19 test and present within 10 days since symptom onset or have a high-risk prophylaxis exposure.
- COVID-positive patients must be 12 years of age and present with mild to moderate symptoms of COVID-19 disease and be at risk of progressing to severe COVID-19 disease.
- Consult APhA's resource, "Monoclonal Antibody Therapies: Considerations for Therapy and the Pharmacists' Role" in the [COVID-19 Resources: Know the Facts](#) library to learn eligibility criteria and get an overview of COVID-19 monoclonal antibody therapies.
- Be aware of the limitations of authorized use found in the [REGEN-COV Fact Sheet](#).
- Assess the patient's presenting oxygen level, blood pressure, and overall clinical status to determine symptom severity.
- Refer patients to the hospital when they are too sick to receive therapy (<92–94 pulse ox). It is very common for patients to seek COVID-19 monoclonal antibody therapy as a last resort before going to the hospital. If patients are too sick, their condition may worsen after monoclonal antibody therapy. Don't hesitate to call 911 if needed.

COVID-19 Monoclonal Antibody Therapies Implementation Guide (continued)

Administration

6. Review how to administer REGEN-COV subcutaneously.

- Reference [Treatment and Post-Exposure Prophylaxis of REGEN-COV \(casirivimab and imdevimab\)](#) for a comprehensive overview of the steps to administer REGEN-COV.
- You may receive casirivimab/imdevimab as the REGEN-COV co-formulated product or as Dose Packs (two vials) or Co-Packs (two vials per carton). The REGEN-COV Dose Packs is labeled to contain one treatment dose—this is incorrect. Each dose pack contains 1,200 mg of casirivimab and 1,200 mg of imdevimab that can be used to prepare multiple doses. The co-packs carry the Roche logo and do not show the REGEN-COV brand name. Always check the [REGEN-COV Fact Sheet](#) for the most up-to-date information.
- Reference [REGEN-COV: Subcutaneous Injection Instructions for Healthcare Providers](#) to guide injection technique.
- REGEN-COV sub-Q is given as four 2.5 mL injections. The product is very viscous after refrigeration, so permitting the product to warm to room temperature can help ease administration.
- If administering monoclonal antibodies off site, remember that REGEN-COV must be stored in the pharmacy when not in use (dependent on board of pharmacy regulations).

7. Establish a workflow.

- It is critical to design the workflow around an administration and monitoring location that keeps COVID-positive patients separated from others.
- Pharmacy technicians and pharmacy interns may administer REGEN-COV sub-Q, subject to certain requirements. Refer to steps 1 and 2 to determine how you can incorporate technicians and interns into your workflow.
- Patients must be monitored closely during administration and for an hour after injection for allergic reactions. Reactions can include fever, chills, nausea, and other anaphylactic-type reactions and may be severe or life threatening.
- Reach out to your state pharmacy association and work with your state and local health departments for help developing a workflow.

Note: The patient should not receive a COVID-19 vaccine for at least 90 days following administration of monoclonal antibody therapy.

COVID-19 Monoclonal Antibody Therapies Implementation Guide (continued)

Reimbursement

8. Understand reimbursement for monoclonal antibody therapies.

- The cost of the monoclonal antibody product is covered by the federal government.
- Reimbursement is available for administration services through Medicare, Medicaid, and private payers. Medicare will cover and pay for these injections the same way it covers and pays for COVID-19 vaccines—under Part B in the medical benefit. Private health plans are required to cover administration through either the medical or prescription benefit. To submit medical claims to health plans, pharmacies may need to enroll with the plan and should work with a medical intermediary (medical claims clearinghouse).
- Reimbursement is also available through the [HRSA Uninsured Program](#), so pharmacies are encouraged to enroll in this program if they haven't done so already to bill for COVID-19 vaccines.
- For more information about how to enroll and bill for monoclonal antibody therapies, refer to our "Billing & Reimbursement" resources in APhA's [COVID-19 Resources: Know the Facts](#) library.
- Medicare reimbursement rates are \$450 for administration in a clinic (pharmacy) setting and \$750 for administration in a home setting. The amount reimbursed may vary for Medicaid and commercial health plans.
- The indication (treatment versus post-exposure prophylaxis) and administration route (I.V. versus S.C.) do not affect reimbursement rates. It is important to use the correct codes to indicate the dose administered.

9. Understand how to submit a claim for administration services.

- Pharmacy software systems are built on National Council for Prescription Drug Program (NCPDP) standards. All COVID-19 vaccine claims originating from a pharmacy will use standardized data elements outlined in NCPDP [emergency guidance](#). Table 1 lists required data elements for claim submission.
- The NCPDP claim format can be used to submit reimbursement to a pharmacy benefit manager (PBM) as a pharmacy benefit claim. The format can also be used to submit claims to medical intermediaries who will convert pharmacy claims into medical benefit claims.
- Often, COVID-19 monoclonal antibody administration is covered under the medical benefit, and the claim will either be transmitted to the pharmacy's medical intermediary to be processed or the pharmacy will need to submit a medical bill to the health plan. Before billing, medical intermediary and pharmacy representatives should discuss the data that must be included in COVID-19 monoclonal antibody medical claims to various payers, including data required for out-of-network billing.
- When a pharmacy submits a medical claim to the medical intermediary, an appropriate current procedural terminology (CPT) code is assigned to the claim by the intermediary. Pharmacists should be familiar with these codes. See Table 2.
- For more information, reference CMS's quick reference guide, [Coverage of Monoclonal Antibody Products to Treat COVID-19](#), and their online toolkit, [Monoclonal Antibody Products to Treat COVID-19](#).

COVID-19 Monoclonal Antibody Therapies Implementation Guide (continued)

Table 1: NCPDP Claim Format for Administration of COVID-19 Monoclonal Antibodies

Data Elements
<ul style="list-style-type: none"> Product NDC Days' supply: 1 Quantity dispensed: Use actual liquid volume (e.g., 10mL) Professional service code: "MA" for medication administration Ingredient cost: \$0.00 (some payers may require \$0.01 to be entered) Incentive amount submitted: Submitted to indicate that the pharmacy is seeking reimbursement for administration of the product (e.g., \$450) <ul style="list-style-type: none"> In situations where a different incentive fee is offered based on the service location, the place of service field may be required Gross amount due: Submitted to include "incentive amount submitted: for the vaccine administration fee and zero cost of the vaccine" (e.g., \$450) Basis of cost: 15 (no cost)

Table 2: CPT Codes for Administration of COVID-19 Monoclonal Antibodies

Administration CPT Code	Product	CMS Rate
M0240	Casirivimab/imdevimab (600 mg)	\$450—Institution/clinic
M0241	Casirivimab/imdevimab (600 mg)	\$750—Home
M0243	Casirivimab/imdevimab (2,400 mg)	\$450—Institution/clinic
M0244	Casirivimab/imdevimab (2,400 mg)	\$750—Home
M0245	Bamlanivimab/estivimab* (2,100 mg)	\$450—Institution/clinic
M0246	Bamlanivimab/estivimab* (2,100 mg)	\$750—Home
M0247	Sotrovimab* (500 mg)	\$450—Institution/clinic
M0248	Sotrovimab* (500 mg)	\$750—Home

**Administered by intravenous infusion only*

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.