

## FAQs on mAbs

1. How do you order mAbs? Is there limited supply?
  - a. Monoclonal antibodies are ordered directly from US HHS. AmerisourceBergen serves as the contract distributor. Orders can be placed using this order form: <https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>. If you don't have an existing AmerisourceBergen account, one will be created for you as part of the ordering process.
  - b. At this time the Federal Government has indicated ample supply.
  - c. Minimum order quantity is 10 vials.
  - d. Orders greater than 100 vials per week are automatically reviews by US HHS to ensure ordering is consistent with reported administrations.
2. How is the product Shipped?
  - a. Product is shipped in 10mL single dose vials at refrigerated temperatures (2-8°C).
  - b. There is only one formulation and it can be used for IV or SubQ administration.
3. How is it paid for? What do providers bill?
  - a. The federal government has pre-purchased REGEN-COV and provides the therapeutic at no cost to the provider.
  - b. Providers can charge an administration fee to insurance. Medicare covers the fee at \$450 for IV or SubQ administration. The reimbursement rate is increased to \$750 for administrations that occur in the home or residence. Most insurers cover as well. The patient can be billed if the insurance does not cover.
  - c. For the uninsured, providers can seek claims reimbursement for monoclonal antibody therapy through [HRSA](#).
4. When should it be administered?
  - a. For Treatment:
    - i. Administered to patients 12 and up, who are considered high-risk for severe COVID-19 who have a positive COVID-19 test result and are within 10 days of symptom onset.
    - ii. EUA allows for provider discretion at determining if a patient is considered "high-risk"
    - iii. IV route is preferred for treatment. However, SubQ route is allowed if IV route is not feasible or would delay treatment to patients.
  - b. For Post-exposure prophylaxis
    - i. Administered to patients who are 12 and up, who are considered high-risk for severe COVID-19, who are not fully vaccinated -OR- are not expected to mount a full vaccination response (i.e., immunocompromised) and have been exposed to COVID and meet CDC's close contact criteria
    - ii. Can also be administered to individuals who are considered at high-risk of exposure to COVID-19 due to an ongoing outbreak in the same institutional setting (nursing home, prison, etc.). These individuals still need to meet the age, High-risk and not fully vaccinated or immunocompromised requirements.
    - iii. For PEP there is no preference between IV or SubQ administration
5. Which application works best in an outpatient urgent care or primary care provider.
  - a. The SubQ injection works well in this setting.

- b. The product must be stored at refrigerated temperatures and product currently shipping does not expire until Feb 2023.
  - c. Patients must be observed for 60 min after injection to monitor for signs of severe infusion or hypersensitivity reactions. Patients can be monitored in a group setting such as a waiting room.
  - d. Providers must have immediate access to medications to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. This is similar to what providers have on hand for COVID-19 vaccine administration.
6. Who can administer?
- a. Physician, Mid-Level provider, Nurse, and Paramedic can administer IV or SubQ.
  - b. Pharmacists are NOT authorized to administer mAbs
  - c. EMTs cannot administer mAbs, but they can perform the post administration monitoring function.
7. What reporting is required? Do administrations need to be entered into a system like CVMS?
- a. NC DHHS collects weekly administration and inventory data from all mAb providers every Wednesday using this link: <https://surveymax.dhhs.state.nc.us/TakeSurvey.aspx?SurveyID=therapeutics#>. A reminder to report is sent via email every week.
  - b. The Federal Government also collects weekly administration and inventory data via their Teletracking system. NC DHHS reports to the federal government on behalf of the hospitals ONLY. All other providers will receive an email from [protect-noreply@hhs.gov](mailto:protect-noreply@hhs.gov) following their first order to sign up for federal reporting.
8. Is there a statewide standing order for mAbs?
- a. No. A physician's order is required for mAb therapy. Patient evaluation and physician order can be done via telemedicine.
9. Is a pharmacy or any special equipment required to prepare mAbs?
- a. No. mAbs can be prepared "at the bed-side" for both IV and SubQ administrations practicing aseptic technique
10. Are IV pumps required for IV administration?
- a. No. mAbs can be administered via gravity infusion.

More info: <https://covid19.ncdhhs.gov/media/1135/download?attachment>