



# Administering Monoclonal Antibody Treatments for COVID-19 in Your Facility

The following summary can help you prepare your site to administer monoclonal antibody treatment.

## Plan\*

- **Prepare your facility to participate** in monoclonal antibody administration for COVID-19.
  - Healthcare providers can only administer monoclonal antibodies for COVID-19 in settings where providers have immediate access to medications to treat a potential severe infusion reaction (such as anaphylaxis) and the ability to activate the emergency medical system (EMS), as necessary.
- Determine how to **allocate dedicated clinical space**.
- Plan to effectively **manage patient flow**.
- Develop your **process for patient screening**.
  - Under the EUA, healthcare providers are authorized to administer monoclonal antibodies to patients if they have experienced the onset of mild to moderate symptoms of COVID-19 in the last 10 days, have tested positive for COVID-19, and have one or more of the following [high-risk](#) factors.<sup>1</sup>
- Develop a process to gain **patient consent** for treatment as indicated by local and state requirements.
- Develop **appropriate isolation and infection control procedures**.
- Ensure a dedicated source of **supplies, including product**.
  - The U.S. Government developed a process for sites to directly order monoclonal antibodies from the distributor, AmerisourceBergen (ABC). An Overview of Direct Order Process for COVID-19 Therapeutics is available at: <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/Overview%20of%20direct%20order%20process%20Fact%20Sheet-508.pdf>
- Establish a process for **reimbursement for administrative costs**.
- Develop a **referral pathway** for providers.

\*Infusion locations should consider all local and state requirements.

## Implement

- **Assign sufficient personnel and resources** to manage expected patient demand.
- **Give patients official fact sheets** with information about the specific treatment given.
  - The Eli Lilly Bamlanivimab and Etesevimab Patient Fact Sheet is available at:
    - English: <https://www.fda.gov/media/145803/download>
    - Spanish: <https://www.fda.gov/media/148713/download>
  - The Regeneron REGEN-COV™ Patient Fact Sheet is available at:
    - English: <https://www.fda.gov/media/145612/download>
    - Spanish: <https://www.fda.gov/media/145713/download>
  - The GSK Sotrovimab Patient Fact Sheet is available at:
    - English: <https://www.fda.gov/media/149533/download>
    - Spanish: <http://infusioncenter.org/wp-content/uploads/2021/06/sotrovimab-eua-fact-sheet-for-patients-in-spanish.pdf>
  - The Genentech Actemra (Tocilizumab) Patient Fact Sheet is available at:
    - English: <https://www.fda.gov/media/150321/download>
- **Prepare for the administration process**.
  - Refer to the playbooks, operation guide, and healthcare provider fact sheets at the beginning of this document and under Resources for details.
- **Monitor patients** for one hour post-administration for potential side effects.





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## Report

- Report adverse events** to FDA MedWatch.
  - MedWatch, the FDA safety information and adverse event reporting program, can be found here: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>
- Report monoclonal antibody therapeutic data** according to your facility type.
  - **For Hospitals**, monoclonal antibody therapeutic data reporting is included in the COVID-19 hospital data reporting as described in the U.S. Department of Health and Human Services FAQ/Guidance: <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>
  - **All Additional Facilities, such as Dialysis Centers, Home Health Services, Oncology, and Infusion Centers** are required to provide the requested data through the following portal: <https://teletracking.protect.hhs.gov>

## Resources

The following primary resources provide an overview of the administration process, procedures, and requirements:

- **The U.S. Government's Monoclonal Antibody Therapeutics Playbook (June 2021):** <https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Documents/USG-COVID19-Tx-Playbook.pdf>
- **The Lilly Bamlanivimab and Etesevimab Together Antibody Playbook (May 2021):** <https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf>
- **The Regeneron REGEN-COV™ (Casirivimab with Imdevimab) EUA Guidebook, developed with the National Infusion Center Association (March 2021):** <http://regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf>
- **The Eli Lilly Infusion Units for COVID-19 Antibody Treatment Operations Guide (Version 1.0):** [https://assets.ctfassets.net/srys4ukjcerm/pByaaT80tPFmOP5sv9FNs/8dfaf37933ba8e08d35501f31b5a6bec/Infusion\\_Units\\_for\\_COVID-19\\_Antibody\\_Treatment\\_Operations\\_Guide.pdf](https://assets.ctfassets.net/srys4ukjcerm/pByaaT80tPFmOP5sv9FNs/8dfaf37933ba8e08d35501f31b5a6bec/Infusion_Units_for_COVID-19_Antibody_Treatment_Operations_Guide.pdf)
- **The Sotrovimab Detailed Guide (June 2021):** [http://infusioncenter.org/wp-content/uploads/2021/06/EUA\\_A-Detailed-Guide-for-The-Use-Of-Sotrovimab.pdf](http://infusioncenter.org/wp-content/uploads/2021/06/EUA_A-Detailed-Guide-for-The-Use-Of-Sotrovimab.pdf)

## Additional Resources

Emergency Use Authorization (EUA) Letters of Authorization OF BAMLANIVIMAB AND ETESSEVIMAB, CASIRIVIMAB AND IMDEVIMAB, SOTROVIMAB, and TOCILIZUMAB

- <https://www.fda.gov/media/145801/download>
- <https://www.fda.gov/media/145610/download>
- <https://www.fda.gov/media/149532/download>
- <https://www.fda.gov/media/150319/download>

## References

1. FACT SHEETS FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESSEVIMAB, CASIRIVIMAB AND IMDEVIMAB, SOTROVIMAB, and TOCILIZUMAB
  - <https://www.fda.gov/media/145802/download>
  - <https://www.fda.gov/media/145612/download>
  - <https://www.fda.gov/media/149534/download>
  - <https://www.fda.gov/media/150321/download>

For more information, visit  
**CombatCOVID.hhs.gov**

English: 1-877-332-6585 • Spanish: 1-877-366-0310



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