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 outpatient 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.[1]
- ☐ 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
- ☐ **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 outpatient administration process, procedures, and requirements:

- **The U.S. Government's Monoclonal Antibody Therapeutics Playbook:** 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:** 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

Additional Resources

Emergency Use Authorization (EUA) Letters of Authorization OF BAMLANIVIMAB AND ETESEVIMAB and CASIRIVIMAB AND IMDEVIMAB

https://www.fda.gov/media/145801/download
https://www.fda.gov/media/145610/download

References

1. FACT SHEETS FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB AND ETESEVIMAB, and CASIRIVIMAB AND IMDEVIMAB

https://www.fda.gov/media/145802/download
https://www.fda.gov/media/145611/download

For more information, visit

CombatCOVID.hhs.gov

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

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