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: http://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 (February 2021):
    - English: bam-and-ete-eua-factsheet-patient.pdf (lilly.com)
    - Spanish: bam-and-ete-eua-factsheet-patient-span.pdf (lilly.com)
  - The Regeneron REGEN-COV™ Patient Fact Sheet (March 2021) is available at:
    - English: treatment-covid19-eua-fact-sheet-for-patient.pdf (regeneron.com)
    - Spanish: treatment-covid19-eua-fact-sheet-for-patient-spanish.pdf (regeneron.com)
- ☐ **Prepare for the administration process.**
  - Refer to the playbooks and operation guide at the end of this document 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/COVID-Therapeutics-playbook_16April2021.pdf
- **The Lilly Bamlanivimab and Etesevimab Together Antibody Playbook (March 2021):** https://www.covid19.lilly.com/assets/pdf/bam-ete/lilly-antibodies-playbook.pdf
- **The Regeneron REGEN-COV™ (Casirivimab with Imdevimab) EUA Guidebook (February 2021), 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/srys4ukjcermpByaaT80tPFmOP5sv9FNs/8dfaf37933ba8e08d35501f31b5a6bec/Infusion_Units_for_COVID-19_Antibody_Treatment_Operations_Guide.pdf

Additional Resources

Emergency Use Authorization (EUA) Letters of Authorization OF BAMLANIVIMAB AND ETESEVIMAB (reissued February 25, 2021) and CASIRIVIMAB AND IMDEVIMAB (reissued February 3, 2021 and February 25, 2021)
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) (revised March 18, 2021) OF BAMLANIVIMAB AND ETESEVIMAB, and CASIRIVIMAB AND IMDEVIMAB
https://www.fda.gov/media/145802/download
https://www.fda.gov/media/143892/download

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