

Cecile Erwin Young *Executive Commissioner*

The FDA has granted Emergency Use Authorization (EUA) for two new treatments for COVID-19. These treatments are what is referred to as monoclonal antibodies, and both have been authorized to treat non-hospitalized adults and children 12 years of age and older.

Monoclonal antibodies are laboratory-produced molecules that act as substitute antibodies to restore, enhance, or mimic the immune system's function to attack foreign cells, in this case the COVID-19 virus. These treatments attack a COVID-19 protein making it more difficult for the virus to attach to and enter human cells.

These treatments are designed for non-hospitalized adults and children who have recently tested positive for COVID-19, are within 10 days of symptom onset, and are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes people who are:

- 65 years of age and older
- Have moderate to severe obesity
- Have certain chronic medical conditions

If you would like to request monoclonal antibody infusions, you may call the hotline below. The infusion specialist will walk you through the following questions:

- Facility name and address
- Facility point of contact and alternate
- Current facility census
- Number of patients that may be qualified for monoclonal antibody infusions, including day of onset of symptoms
- Whether consent has or can be obtained from those patients
- Whether a team is needed to administer
- If you are only requesting therapeutics, whether your facility can handle storage, handling, and documentation requirements
- Name of the facility Medical Director or other prescribing physician
- Facility UFID number

To request infusion of monoclonal antibodies and a medical team at your facility, you may call the 24-hour State Infusion Hotline at 1-800-742-5990.

An Infusion Specialist will record your information and process your request. Once complete, a specialized medical team trained in the administration of monoclonal antibodies can dispatch to your facility within 24 hours of your request. These teams are equipped with all the necessary supplies, equipment, and knowledge to administer therapeutics to patients who meet criteria for infusions.

Be advised, there is a specific set of criteria that must be met to be eligible to receive the treatment. Monoclonal antibodies are not authorized for use in patients:

- who are hospitalized due to COVID-19, or
- who require oxygen therapy due to COVID-19, or
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

If you prefer to only receive the medication and your facility is set up to provide infusions, you may also request immediate delivery of monoclonal antibody therapeutics to your facility.

To request delivery of monoclonal antibody therapeutics only to your facility, you may call the 24-hour Infusion Hotline at 1-800-742-5990.

An Infusion Specialist will record your information and process your request. Once complete, a specialized delivery team will dispatch to your facility within 24 hours of your request. Delivery teams are equipped with all the necessary equipment to ensure rapid and efficient delivery of monoclonal antibody therapeutics anywhere in the State of Texas. Additionally, our teams can also provide saline infusion bags, should your facility need those supplied.

Please note that these services are offered by the Texas Department of State Health Services at no cost to your facility.

Monoclonal Antibody Resources

Emergency Use Authorization: Bamlanivimab https://www.fda.gov/media/143603/download

Emergency Use Authorization: Casirivimab/Imdevimab (Regeneron) https://www.fda.gov/media/143892/download

Bamlanivimab Antibody Playbook

https://www.covid19.lilly.com/assets/pdf/bamlanivimab/lilly-antibodies-playbook.pdf

Casirivimab/Imdevimab (Regeneron) Playbook

https://www.regeneroneua.com/Content/pdf/treatment-covid19-eua-guide-book.pdf

Bamlanivimab Fact Sheet for Patients, Parents, and Caregivers https://www.fda.gov/media/143604/download

Casirivimab/Imdevimab (Regeneron) Fact Sheet for Health Care Providers https://www.fda.gov/media/143892/download

Managing COVID Symptoms at Home – English https://www.cdc.gov/coronavirus/2019-ncov/downloads/10Things.pdf

Managing COVID Symptoms at Home – Spanish https://www.cdc.gov/coronavirus/2019-ncov/downloads/10Things-spanish.pdf