

August 17, 2021



Dear Colleagues,

The Tennessee Department of Health (TDH) is providing this information to increase awareness and encourage administering of monoclonal antibodies to COVID-19 positive individuals who meet the criteria in hopes of healing more people in Tennessee rapidly and decreasing the current pressures to hospitals.

- Monoclonal antibodies (mAbs) have been available through FDA Emergency Use Authorization (EUA) since November 2020. The one outpatient mAb currently available is casirivimab/imdevimab (REGEN-COV[®]) by Regeneron. It is preferred to be administered via IV infusion. However, it is now also authorized to be administered subcutaneously if arranging for IV infusion would delay treatment. The EUA includes the criteria for use, and appropriate storage and preparation of the mAb. Below are the links to the FDA EUA Fact Sheets for Health Care Providers, and Patients and Parents/Caregivers.

casirivimab/imdevimab (REGEN-COV[®]) by Regeneron

<https://www.fda.gov/media/145611/download>

<https://www.fda.gov/media/141479/download>

- The Federal Government purchased the current stock of mAb authorized for outpatient use. Initially it was provided through State Health Department allocations. Since March 2021, there has been plentiful supply and casirivimab/imdevimab has been requested directly from the Federally-contracted wholesaler. Below is the link that must be used to acquire the mAb.
<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>
- The mAb has been shipped to more than 140 sites within Tennessee. We are hoping you will assist with administering this mAb to any who meet the criteria. However, if you are not able to administer this therapy to a patient and need to refer them for treatment, the link below is a perpetually updated listing of sites available for administering this therapy.
https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/Monoclonal_Antibody_Availability.pdf
- Casirivimab/imdevimab (REGEN-COV[®]) is supplied to the requesting providers and administered to patients free of charge. However, the administration fee may be reimbursed. Below is a link to more reimbursement information from CMS.
<https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-mono-clonal-antibodies>

Additional information and FAQs concerning monoclonal antibody therapeutics can be found through the Federal link below.

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/FAQs-mAB.aspx>

Questions regarding this overall program may be directed to **Dr. Calita Richards** at Calita.Richards@tn.gov.

Thank you for all that you do to keep Tennesseans safe and healthy.

Tennessee Department of Health