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FDA RESTRICTS THE USE OF SOTROVIMAB

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Tallahassee, Fla. — On April 5, 2022, the U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorization (EUA) for sotrovimab. The revised EUA does not allow providers to administer this treatment within the United States.

This decision leaves the State of Florida with only a single monoclonal antibody treatment, bebtelovimab.

The FDA based its decision on the Centers for Disease Control and Prevention's (CDC's) Nowcast estimates. Unlike previous revisions on EUAs that stopped treatments at an estimate of 80%, the authorization for sotrovimab removed its use at 50%. According to CDC's current estimate, 40% of COVID-19 cases in Florida would still benefit from this life-saving treatment.

As is tradition at the FDA, this change comes after a single live virus pre-print study with no clinical data. Florida disagrees with decisions on preventions and treatments without being provided any supporting clinical data.

For more information, please contact the FDA at 1-(888)-463-6332.

To find locations with prevention and treatment options, visit the Florida Department of Health treatment locator.

About the Florida Department of Health
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Corrections & Clarifications
Original Published 7:43 PM ET, Wed April 06, 2022 | C&C on 11:46 AM ET, Mon April 11, 2022
Original: This decision leaves the State of Florida with only a single post-exposure monoclonal antibody treatment, bebtelovimab.
C&C: This decision leaves the State of Florida with only a single monoclonal antibody treatment, bebtelovimab.
RFC: Re-word this content to be consistent with the EUA.