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Monoclonal Antibody Sites Statewide Will Be Closed After FDA Removes Treatment Authorization

Please see the below message from the Florida Department of Health --

Tallahassee, Fla. — This evening, without any advanced notice, the U.S. Food and Drug Administration (FDA) [revised the Emergency Use Authorizations](#) (EUA) for [bamlanivimab/etesevimab](#) and [REGEN-COV](#). The revised EUAs do not allow providers to administer these treatments within the United States.

Unfortunately, as a result of this abrupt decision made by the federal government, all monoclonal antibody state sites will be closed until further notice.

Individuals with appointments have been directly contacted regarding cancellations. If you have tested positive for COVID-19, please contact your health care provider for more information and resources on treatment options. Resources for emerging treatments can be found at www.HealthierYouFL.org. Pharmacies that have received allocations of anti-viral treatments can be found at www.FloridaHealthCOVID19.gov.

Florida disagrees with the decision that blocks access to any available treatments in the absence of clinical evidence. To date, such clinical evidence has not been provided by the United States Food and Drug Administration (FDA).

As stated in one of the [pre-print studies](#) cited on the [NIH website](#), "despite observing differences in neutralizing activity with certain mAbs, it remains to be determined how this finding translates into effects on clinical protection against B.1.1.529."

For more information on why this decision was made, please contact the FDA at 1-888-463-6332.

The Agency for Health Care Administration is committed to better health care for all Floridians. The Agency administers Florida's Medicaid program, licenses and regulates more than 44,000 health care facilities and 53 health plans, and publishes health care data and statistics at www.FloridaHealthFinder.gov.

Additional information about Agency initiatives is available via:



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