Important Updates Regarding the FDA Emergency Use Authorization for Monoclonal Antibody Cocktail - Casirivimab and Imdevimab

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FDA Updates Emergency Use Authorization for Monoclonal Antibody Cocktail - Casirivimab and Imdevimab

The U.S. Food and Drug Administration (FDA) has updated the Emergency Use Authorization (EUA) for REGEN-COV™, adding an alternative route of administration (subcutaneous) and lowering the dose to 1,200 mg (600 mg casirivimab and 600 mg imdevimab), which is half the dose originally authorized. The EUA provides that casirivimab and imdevimab are to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Additional Resources

- Important Prescribing Information Regarding REGEN-COV™ (casirivimab and imdevimab)
- Fact Sheet for Health Care Providers Regarding EUA of REGEN-COV™ (casirivimab and imdevimab)
- Information Regarding Monoclonal Antibodies for High-Risk COVID-19 Positive Patients
- Monoclonal Antibody Resources for Clinicians