



FDA COMBATING COVID-19 WITH THERAPEUTICS

Since the beginning of the COVID-19 pandemic, the FDA has been working to facilitate the development and availability of therapeutics as expeditiously and safely as possible for use by patients, physicians and health systems. In order to facilitate the development of potential COVID-19 treatments, the FDA created the [Coronavirus Treatment Acceleration Program](#) (CTAP), a new program designed to expedite the development of potential COVID-19 therapeutics by using every tool at the agency’s disposal to determine if the therapeutics are safe and effective for their intended uses.

Numerous therapeutics are currently being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19. The CTAP webpage includes a dashboard with a snapshot of the development of potential COVID-19 therapeutics. [As of August 31, 2020, there are more than 310 active trials of therapeutic agents and more than 590 development programs for therapeutic agents in the planning stages.](#)

The FDA continues to provide advice, guidance, and technical assistance to help expedite the development of these products and intends to use regulatory flexibility in making these products and other critical medical countermeasures available to prevent and treat COVID-19. Sponsors wishing to develop therapeutics for proposed COVID-19 use are encouraged to submit information and request for drug development to the CTAP email: COVID19-productdevelopment@fda.hhs.gov.

The FDA and other government partners are working with industry to make treatment options available to patients and providers who are not able to participate in clinical trials, including through expanded access under investigational new drug (IND) applications.

Additionally, if certain statutory criteria are met, the FDA may issue an emergency use authorization (EUA) to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear threat agents when, among other factors, there are no adequate, approved, and available alternatives.

As of September 16, 2020, the FDA has authorized six EUAs, and revoked one of the initial six, to treat COVID and serious conditions caused by COVID-19:

EMERGENCY USE AUTHORIZATION	SPONSOR	DESCRIPTION
Convalescent Plasma Emergency Use Authorization	Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human	This EUA authorizes the distribution of COVID-19 Convalescent Plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with the disease.

	Services	<ul style="list-style-type: none"> • Updated Evidence to Support Emergency Use of COVID-19 Convalescent Plasma • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Parents/ Caregivers <p>Fact sheets for patients/caregivers and health care providers are also available in multiple languages.</p>
REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit Emergency Use Authorization	Baxter Healthcare Corporation	<p>This EUA authorizes REGIOCIT to be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting.</p> <ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Caregivers • REGIOCIT package insert for EUA
Veklury (Remdesivir) Emergency Use Authorization	Gilead Sciences, Inc.	<p>This EUA authorizes remdesivir to be distributed in the U.S. and administered intravenously by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized adult and pediatric patients.</p> <ul style="list-style-type: none"> • Fact Sheet for Health Care Providers • Fact Sheet for Patients and Parent/Caregivers (Spanish) • Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients
Fresenius Propoven 2% Emulsion Emergency Use Authorization	Fresenius Kabi USA, LLC.	<p>This EUA authorizes the use of Fresenius Propoven 2% Emulsion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an ICU setting.</p> <ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Parent/Caregivers • Propoven 2% Wall Chart
multiFiltrate PRO System and multiBic/multiPlus Solutions Emergency Use Authorization	Fresenius Medical Care	<p>This EUA authorizes this continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.</p> <ul style="list-style-type: none"> • Fact Sheet for Healthcare Providers • Fact Sheet for Patients

Additional Resources for Therapeutic Developers:

- Guidances to support the accelerate development of prevention and treatment options for COVID-19
 - [COVID-19 Public Health Emergency: General Considerations for Pre-IND \(Investigational New Drug application\) Meeting Requests for COVID-19 Related Drugs and Biological Products](#)
 - [COVID-19: Developing Drugs and Biologics for Treatment or Prevention](#)
 - [Guidance on Conduct of Clinical Trials for Medical Products during COVID-19 Pandemic](#). For further questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.
- [FDA Emergency Use Authorization Information and list of all current EUAs](#)
 - Those interested in pre-EUA discussions, or have general questions about EUAs for CDER-regulated products, can email COVID19-ProductDevelopment@fda.hhs.gov. Those interested in pre-EUA discussions, or have general questions about EUAs for CBER-regulated products, can email CBEREUA@fda.hhs.gov. Formal EUA requests can be sent via email to EUA.OCET@fda.hhs.gov.

Additional Resources for Patients and Providers:

- [Coronavirus Disease 2019 \(COVID-19\) Resources for Patients](#)
- People who have fully recovered from COVID-19 for at least two weeks are encouraged to consider donating plasma, which could potentially help save the lives of COVID-19 patients. Those willing to donate are urged to visit the [FDA website](#) for information about donating or contact their local blood donor or plasma collection center.
- Information for healthcare providers about the administration and study of investigational convalescent plasma: [Revised Information for Investigational COVID-19 Convalescent Plasma](#).