



Coronavirus Disease 2019

Information for Clinicians on Investigational Therapeutics for Patients with COVID-19

Updated April 13, 2020

There are no drugs or other therapeutics approved by the US Food and Drug Administration to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. Interim guidelines for the medical management of COVID-19 will be provided soon by the Department of Health and Human Services COVID-19 Treatment Guidelines Panel.

Remdesivir

Remdesivir is an investigational intravenous drug with broad antiviral activity that inhibits viral replication through premature termination of RNA transcription, and has in-vitro activity against SARS-CoV-2 and in-vitro and in-vivo activity against related beta coronaviruses. Information about clinical trials of remdesivir is available at ClinicalTrials.gov[®]. For patients unable to enroll in a clinical trial, Gilead Sciences is coordinating access to remdesivir [through an expanded access program](#)[®]. Pregnant women and children less than 18 years of age with confirmed COVID-19 and severe manifestations of disease can still access the drug through the manufacturer's [compassionate use program](#)[®].

Hydroxychloroquine and Chloroquine

Hydroxychloroquine and chloroquine are oral prescription drugs that have been used for treatment of malaria and certain inflammatory conditions. Hydroxychloroquine and chloroquine are under investigation in clinical trials for pre-exposure or post-exposure prophylaxis of SARS-CoV-2 infection, and treatment of patients with mild, moderate, and severe COVID-19. More information on clinical trials can be found at ClinicalTrials.gov[®]. FDA issued an [Emergency Use Authorization \(EUA\)](#)[®] to authorize use of [chloroquine](#)[®] and [hydroxychloroquine](#)[®] from the Strategic National Stockpile for treatment of hospitalized adults and adolescents (weight ≥ 50 kg) with COVID-19 for whom a clinical trial is not available or participation is not feasible. The prescribing health care provider is responsible for submitting patient outcomes reports as described in the Emergency Use Authorization, and all serious adverse events and medication errors should be reported to FDA's medical product safety reporting program [MedWatch](#)[®].

MedWatch is FDA's medical product safety reporting program for health professionals, patients and consumers.

Other Drugs

Several other drugs (e.g., investigational antivirals, immunotherapeutic, host-directed therapies) are under investigation in clinical trials or are being considered for clinical trials of pre-exposure prophylaxis, post-exposure prophylaxis, or treatment of COVID-19 in the United States and worldwide. Information on registered clinical trials for COVID-19 in the United States is available at ClinicalTrials.gov[®]. FDA has issued guidance for administering or studying use of [convalescent plasma for treatment](#)[®] of patients with COVID-19.

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