

## VDH Information about Investigational Therapeutics, including Remdesivir

Currently, there are no antiviral drugs licensed by the U.S. Food and Drug Administration (FDA) to treat patients with COVID-19. In the United States, the National Institutes of Health (NIH) and collaborators are working on development of candidate vaccines and therapeutics. Some in-vitro or in-vivo studies suggest potential therapeutic activity of compounds against related coronaviruses, but there are no available data from randomized controlled trials in humans to support recommending any investigational therapeutics for patients with confirmed or suspected COVID-19 at this time. Remdesivir is an investigational antiviral drug that was reported to have in-vitro activity against SARS-CoV-2.<sup>i</sup> Remdesivir has not been demonstrated to be safe or effective for any use.

Potential options for U.S. clinicians to obtain investigational therapeutics are listed below.

1. Remdesivir: Enroll in a NIH adapted randomized controlled clinical trial
  - This study is an adaptive, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of novel therapeutic agents in hospitalized adult patients diagnosed with COVID-19. The study is a multicenter trial that will be conducted in up to 50 sites globally. For more information, including criteria for inclusion and exclusion, see [ClinicalTrials.gov Identifier NCT042807050](https://clinicaltrials.gov/ct2/show/study/NCT042807050).
2. Remdesivir: Enroll in other remdesivir clinical trials for COVID-19 patients in the United States (participants with severe and moderate coronavirus disease).
  - Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment. For more information, including criteria for inclusion and exclusion, see [ClinicalTrials.gov Identifier NCT04292730](https://clinicaltrials.gov/ct2/show/study/NCT04292730). Contact: Gilead Clinical Study Information Center at 1-833-445-3230 (GILEAD-0) or email [GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com).
  - Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Severe Coronavirus Disease (COVID-19). For more information, including criteria for inclusion and exclusion, see [ClinicalTrials.gov Identifier NCT04292899](https://clinicaltrials.gov/ct2/show/study/NCT04292899). Contact: Gilead Clinical Study Information Center at 1-833-445-3230 (GILEAD-0) or email [GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com).
3. For other investigational therapeutics, other trials might be available
  - For information on specific clinical trials underway for treatment of patients with COVID-19, see [clinicaltrials.gov](https://clinicaltrials.gov) and [www.chictr.org.cn](http://www.chictr.org.cn)
4. Remdesivir: Submit a compassionate use request to Gilead Sciences
  - For general information, see [www.gilead.com/purpose/advancing-global-health/covid-19](http://www.gilead.com/purpose/advancing-global-health/covid-19). All requests must be made through the portal <https://rdvcu.gilead.com/> to be reviewed. Compassionate use requests must be submitted by a patient's lead treating physician. Gilead is currently assessing requests on an individual basis and requires, at a minimum, that the patient be hospitalized with confirmed COVID-19 infection with significant clinical manifestations. Individual compassionate use requests will only be considered when enrollment in a clinical trial is not a feasible option.

For more information: CDC: COVID-19 Clinical care [www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html](https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html)

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<sup>i</sup> Wang M, Cao R, Zhang L, et al. Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro. Cell Res. 2020 Feb 4. doi: 1038/s41422-020-0282-0. [Epub ahead of print] PubMed PMID: 32020029.