WHAT'S NEW: Gilead's Expanded Access Program (EAP) noted as being discontinued on May 29, 2020

Remdesivir is manufactured by Gilead Lifesciences and is only available through one of the pathways listed below.

1. Through a clinical trial
2. Through an Expanded Access Program (discontinued by Gilead as of May 29, 2020)
3. Through FDA's Emergency Use Agreement (EUA)
4. Through a Single Patient Emergency Investigational New Drug (EIND) use

More information on each of these options is presented below.

1. **Clinical Trials (research)**

There are currently several trials underway with the use of remdesivir. Gilead has initiated two Phase 3 clinical studies to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19. These randomized, open-label, multicenter studies began enrolling patients in March 2020 and will enroll a total of approximately 1,000 patients in the initial phase of the studies in countries with high prevalence of COVID-19.

One study will evaluate the safety and efficacy of both a 5-day and a 10-day dosing duration of remdesivir, in addition to standard of care, for patients with severe manifestations of COVID-19. More information on the Gilead study in patients with moderate disease can be found at [https://clinicaltrials.gov/ct2/show/NCT04292730](https://clinicaltrials.gov/ct2/show/NCT04292730)

The second study will evaluate the safety and efficacy of both a 5-day and a 10-day dosing duration of remdesivir in addition to standard of care for patients with moderate manifestations of COVID-19, compared to standard care alone. More information on the Gilead study in patients with severe disease can be found at [https://clinicaltrials.gov/ct2/show/NCT04292899](https://clinicaltrials.gov/ct2/show/NCT04292899)

The U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has initiated a Phase 2 adaptive, randomized, double-blind, placebo-controlled trial into remdesivir as a potential treatment for hospitalized adult patients diagnosed with COVID-19. More information on the NIAID study can be found at [https://clinicaltrials.gov/ct2/show/NCT04280705](https://clinicaltrials.gov/ct2/show/NCT04280705)

These studies require review and approval by your local Institutional Review Board (IRB) prior to enrolling patients.
Due to the overwhelming interest in these studies it is not known if additional sites are being accepted for clinical trials. To learn more about becoming a site, reach out to the contact listed under the "Contact" section of the web listings.

2. **Expanded Access Program (EAP) (non-research)**

In late March 2020 Gilead introduced an Expanded Access Program for remdesivir. However, with the FDA's Emergency Use Authorization (EUA) announcement for remdesivir effective May 1, 2020, this program has been discontinued by Gilead as of May 29, 2020.

3. **FDA’s Emergency Use Authorization (EUA) (non-research)**

The U.S. FDA announced on May 1, 2020 that remdesivir had been granted Emergency Use Authorization (EUA) for the treatment of COVID-19. The U.S. government is coordinating the distribution of Gilead’s remdesivir supply to hospitals most heavily impacted by COVID-19, working with AmerisourceBergen as the exclusive distributor.

No IRB reporting is required for remdesivir administration under an EUA; however, under the terms of the EUA, a "Fact Sheet" must be made available to patients and healthcare providers. See the COVID-19 "Treatment Guidance" for additional details on the documentation of this process.

Healthcare providers should refer to FDA’s "Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734)" for details on the mandatory requirements for remdesivir administration under and EUA, including required reporting of adverse events.


In late March 2020 Gilead significantly curtailed the criteria for requesting remdesivir for a single patient expanded access EIND. This pathway is only available for pregnant women and children < 18 years of age with significant clinical manifestations. More information on this program, and the patient criteria, can be found at https://rdvcu.gilead.com/

While EUA supply is the primary access pathway for remdesivir, if a facility does not have access to drug under the EUA and a patient meets the criteria for the EIND, a request for the drug can be made directly to Gilead.

See "Remdesivir Work Flow Expanded Access" document on the Trinity Health COVID-19 website for further details on this program, including required IRB reporting for every patient use.