



SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

State of California—Health and Human Services Agency
California Department of Public Health



GAVIN NEWSOM
Governor

**California Health and Human Services
Remdesivir Distribution Fact Sheet**

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Remdesivir is the only antiviral effective against COVID-19 in a clinical trial. This intravenous investigational drug inhibits viral RNA polymerase. The supply of remdesivir is limited. Clinical trial data have shown equivalent outcomes with 5 days of treatment compared with 10 days of treatmentⁱ and better outcomes in people who started treatment before requiring mechanical ventilationⁱⁱ. Treating for 5 days and treating people with severe illness early before they require mechanical ventilation could maximize the public health benefit of remdesivir.

Additional clinical trial data:

- NIH's Adaptive COVID-19 Treatment Trial (1,059 participants) reported a 32% faster time to recovery (11 days vs. 15 days) for participants who received remdesivir compared with those who received placebo ($p < 0.001$). Results also suggested a survival benefit, with a mortality rate of 7.1% for the group receiving remdesivir versus 11.9% for the placebo group ($p = 0.059$). In a subgroup analysis, participants with hypoxemia who required oxygen therapy but not mechanical ventilation (or high-flow oxygen or noninvasive ventilation) had the most benefit.
- A Gilead remdesivir clinical trial (397 participants) reported equivalent rates of clinical improvement among participants with severe COVID-19 illness (oxygen saturation $\leq 94\%$ or receiving supplemental oxygen) but not requiring mechanical ventilation who were randomized to a 5-day or 10-day treatment course. Another Gilead remdesivir clinical trial (584 participants) reported improved clinical outcomes in patients with moderate COVID-19 illness (hospitalized but not requiring oxygen) who received a 5-day treatment course compared with standard care.
- Study conducted in China (236 participants) showed no difference in time to recovery except a trend toward faster recovery in participants treated early (within 10 days of symptoms onset) ⁱⁱⁱ.
- The benefit of remdesivir and optimal duration of treatment in people with severe COVID-19 illness who require mechanical ventilation is still being evaluated. In Gilead's trial, among participants who progressed to require mechanical ventilation on day 5, the mortality rate was 40% in the 5-day group compared with 17% in the 10-day group.

FDA issued an emergency use authorization (EUA) on May 1, 2020

The fact sheet for health care providers reviews the full conditions of use^{iv}, and should be reviewed prior to administration of the medication.

The EUA allows treatment of COVID-19 in adults and children hospitalized with severe disease (defined as a low blood oxygen level (oxygen saturation \leq 94%), needing oxygen therapy, or requiring mechanical ventilation or extracorporeal membrane oxygenation (ECMO)).

EUA conditions of use include that:

- Empiric treatment of hospitalized patients with suspected COVID-19 can be considered pending laboratory confirmation of COVID-19 infection.
- Remdesivir is administered by intravenous infusion of 200 mg on Day 1 followed by 100 mg/day.
- A 5 day treatment course is recommended for adults and pediatric patients not requiring invasive mechanical ventilation or ECMO. Treatment may be extended up to 10 days if not showing clinical improvement.
- A 10 day treatment course is recommended for adult and pediatric patients requiring invasive mechanical ventilation or ECMO.
- All patients must have an estimated glomerular filtration rate (eGFR) determined and hepatic laboratory testing performed before dosing.
- Health care providers are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths considered to be potentially attributable to remdesivir.
- Health care providers must communicate information consistent with the "Fact Sheet for Patients and Parents/Caregivers"^v (and provide a copy) prior to the patient receiving remdesivir.
- Hepatic laboratory testing should be performed daily while receiving remdesivir. Remdesivir should be discontinued in patients who develop an ALT \geq 5 times the upper limit of normal or an ALT elevation accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR. Grade 3 or 4 hepatic laboratory abnormalities were reported in approximately 5% of participants receiving remdesivir in Gilead's clinical trial.

Allocation of remdesivir for EUA use

Access to remdesivir is currently being coordinated by the U.S. government and being distributed by AmerisourceBergen. Allotments of donated remdesivir are being sent to the state of California every two weeks until the full inventory of donated remdesivir has been allocated during the week of June 29th. Each allotment is then allocated to hospitals in California via the counties' Medical and Health Operational Area Coordinator (MHOAC) based on the current census of hospitalized patients with confirmed COVID-19.

Beginning in July (after the donated supply of remdesivir has been allocated), hospitals will be charged no more than the Wholesale Acquisition Price (WAC) for remdesivir. Gilead has announced that the Wholesale Acquisition Price (WAC) is \$520 per vial adding up to \$3,120 for a five-day treatment course^{vi}. The federal government with input from state governments will continue to direct the allocation of remdesivir supply from July to September. Hospitals will receive the product shipped directly from AmerisourceBergen instead of from the MHOACs. Details on the distribution process are posted on the California Department of Public Health's [website](#).

As the supply of remdesivir is limited, facilities should consider an ethical framework for distribution and refer to CHHS's Guidance for Hospitals Regarding [Allocation of Scarce Medications for COVID-19](#). Considerations for allocation include:

- A clinical prioritization team to make allocation decisions that is distinct from the clinicians providing direct care is recommended to protect the integrity of the patient-provider relationship and to ensure that decisions are fair and consistent.
- Withholding or reserving remdesivir for future use is not recommended, particularly if there are current patients presenting with severe illness.
- If patients receiving remdesivir are transferred to another hospital, their remaining doses of remdesivir should transfer with them.
- Children and pregnant mothers are still eligible to receive remdesivir through compassionate use from Gilead (instead of the donated supply).
- Patients who have already received remdesivir should not be eligible to receive additional doses from this donated allocation.

ⁱ Goldman JD, Lye DCB, Hui DS, et al. Remdesivir for 5 or 10 days in patients with severe Covid-19. *N Engl J Med*. DOI: 10.1056/NEJMoa2015301.

ⁱⁱ Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the treatment of Covid-19 — preliminary report. *N Engl J Med*. DOI: 10.1056/NEJMoa2007764.

ⁱⁱⁱ Wang Y, Zhang D, Du G, et al. Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial. *Lancet*. Published online April 29, 2020. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31022-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31022-9/fulltext)

^{iv} FDA Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734™). Accessed May 8, 2020. <https://www.fda.gov/media/137566/download>

^v FDA Fact Sheet for Patients and Parents/Caregivers. Accessed May 8, 2020. <https://www.fda.gov/media/137565/download>

^{vi} Open Letter from Gilead, June 29, 2020. Accessed June 29, 2020. <https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29>