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GAVIN NEWSOM
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California Department of Public Health 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-dependent RNA polymerase. The global supply of remdesivir is currently extremely limited. Clinical trial data have shown equivalent outcomes with 5 days of treatment compared with 10 days of treatmentⁱ and better outcomes if treatment is started early (within 10 days of symptom onset)ⁱⁱ. Treating for 5 days and treating people with severe illness early could maximize the public health benefit of this medication.

Additional clinical trial data:

- NIH's Adaptive COVID-19 Treatment Trial (1,068 participants) reported a 31% faster time to recovery (11 days vs. 15 days) for participants who received remdesivir compared with those who received placebo ($p < 0.001$)ⁱⁱⁱ. Results also suggested a survival benefit, with a mortality rate of 8.0% for the group receiving remdesivir versus 11.6% for the placebo group ($p = 0.059$).

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.
- A 5-day treatment course (6 doses) 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 (11 doses) 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 ≥ 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. A limited supply of medication is anticipated to be sent to the state of California this week, with additional allotments to be sent on a regular cadence going forward.

All California acute care hospitals submit daily data to the California Department of Public Health (CDPH) on the number of patients with COVID-19 who are hospitalized, including those who are in the ICU.

For each allotment received from the federal government, CDPH will use the most recent hospital census data to proportionately distribute remdesivir to the counties’ Medical and Health Operational Area Coordinator (MHOAC) per the established Multi-Agency Coordination Group (MAC Group) process. Since the minimum treatment course requires 6 doses of remdesivir, any county whose allocation is fewer than 6 doses will have its allocation redistributed.

Until the number of patients who are eligible for remdesivir treatment under the EUA no longer significantly outstrips the available supply, CDPH recommends a random allocation among all acute care hospitals in the county that are treating COVID-19 patients. Counties should track the cumulative distribution of medication to each hospital.

Hospitals should consider an ethical framework for the distribution of remdesivir to patients, and refer to the California SARS-CoV-2 Crisis Care Guidelines and California Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19. Specific recommendations for remdesivir 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 with severe illness within 10 days of symptom onset.

- Children and pregnant mothers are currently eligible to receive remdesivir through compassionate use from Gilead directly and should not utilize the donated remdesivir allocation.
- Patients who have already received remdesivir should not be eligible to receive additional doses from this donated allocation.

ⁱ <https://www.gilead.com/news-and-press/press-room/press-releases/2020/4/gilead-announces-results-from-phase-3-trial-of-investigational-antiviral-remdesivir-in-patients-with-severe-covid-19>

ⁱⁱ 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)

ⁱⁱⁱ NIH press release. Accessed May 8, 2020. <https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>

^{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>