

Criteria for Remdesivir Use when in Scarce Supply

Recommendation of Utah Crisis Standard of Care Allocation of Scarce Resources Subcommittee
May 28, 2020

This document is intended to guide the allocation of remdesivir outside of clinical trials, within the state of Utah, ONLY when remdesivir supply is significantly less than demand. These criteria have been developed by expert consensus and based on best available evidence, to meet the goal of “greatest good for the greatest number.” These criteria will be adjusted and amended as additional evidence becomes available and as supplies change. This protocol does not discriminate based on race, color, national origin, disability, sex, or exercise of conscience and religion. It meets the CSC ethical goals of fairness, duty to care, transparency, consistency, proportionality, and accountability.

Distribution from the State to the Healthcare Systems

Allocations of remdesivir that the State receives from HHS will be distributed to hospitals and systems based on total inpatient COVID census. This allocation will be triggered based on ongoing monitoring by the UCSC ASM Subcommittee, and communication to Unified Command.

Distribution within each Healthcare System

- a) If there are remdesivir courses available, all patients meeting the criteria listed below will be evaluated for initiating remdesivir once a day.
- b) If the number of eligible patients outnumber the available remdesivir courses, a randomization or lottery process should be utilized.

1) Meets ALL Inclusion criteria:

- a) Early in the course of illness
 - Symptomatic respiratory illness attributable to COVID-19 of ≤ 2 weeks duration
 - PCR confirmed SARS-CoV-2 test within last 2 weeks (no positive test prior to 2 weeks)
- b) Severe COVID-19
 - Radiology imaging consistent with COVID-19
 - New AND increasing oxygen requirement of ≥ 4 L nasal cannula or high-flow oxygen or NIPPV, but NOT on mechanical ventilation PRIOR to consideration by the healthcare system’s therapeutics committee.
- c) Elects not to consent into remdesivir studies, if available.

2) Does not meet any Exclusion criteria:

- a) ALT ≥ 5 x upper limit of normal (300 U/L)
- b) GFR < 30 mL/min
- c) Requiring ECMO
- d) Poor prognosis defined as unlikely to survive this hospitalization, a $> 50\%$ 30-day predicted mortality, or an irreversible terminal condition with a life expectancy of six months or less

Suggested dosing recommendations for adults weighing ≥ 40 kg

- For all patients: 200mg IV on day 1 followed 100mg IV qday x 4 days (total duration 5 days)

Monitoring

- a) Liver function tests should be performed in all patients prior to starting Remdesivir and daily while receiving remdesivir.
- b) Remdesivir should be discontinued in patients who develop:
 - ALT ≥ 5 x upper limit of normal (300 U/L) during treatment
 - Any ALT elevation accompanied by symptoms of hepatitis, increasing direct bilirubin, alkaline phosphatase, or INR