Criteria for Remdesivir Use when in Scarce Supply

Recommendation of Utah Crisis Standard of Care Allocation of Scarce Resources Subcommittee
Aug 20, 2020

These criteria have been approved by a state level committee that represents all four major healthcare systems and unaffiliated hospitals in Utah. It 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 that the State receives will be distributed to the four systems and eligible unaffiliated hospitals based on total inpatient COVID census.

Distribution within each Healthcare System:
Patients meeting the criteria listed below will be evaluated for initiating Remdesivir on an individual basis according to the institution-specific workflows.

1) Meets ALL Inclusion criteria:

a) Early in the course of illness
   - Symptomatic respiratory illness attributable to COVID-19 of $\leq$ 2 weeks duration
   - Laboratory-confirmed SARS-CoV-2 test. Initiating drug in PUIs with high pre-test likelihood of COVID-19 may be considered on a case-by-case basis.

b) Severe COVID-19
   - Radiology imaging consistent with COVID-19.
   - New AND increasing oxygen requirement of $\geq$ 2L nasal cannula*, high-flow oxygen, or NIPPV OR placed on mechanical ventilation within previous 12 hours.

c) Elects not to consent into remdesivir studies, if available.

2) Does not meet any Exclusion criteria:

a) ALT $\geq$ 5x upper limit of normal (300 U/L)
b) GFR < 30 mL/min
c) Mechanical ventilation > 12 hours
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

***Adjusting Clinical Criteria Based on Supply**
If institutional inventory drops below a projected 4-week supply, based on rolling usage rates, institutions should revert to more conservative clinical criteria:

a) $\geq$ 4L nasal cannula*, high-flow oxygen, or NIPPV OR placed on mechanical ventilation within previous 12 hours.

Dosing recommendations (Total duration 5 days, including for patients who are intubated):

- For patients $\geq$ 40kg: 200 mg IV on day 1 followed by 100 mg IV once daily x 4 days.
- For patients 3.5kg to 40kg: 5 mg/kg IV on day 1 followed by 2.5 mg/kg IV once daily x 4 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 $\geq$ 5x upper limit of normal (300 U/L) during treatment
    - Any ALT elevation accompanied by symptoms of hepatitis, increasing direct bilirubin, alkaline phosphatase, or INR