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Allocation Guidelines for Remdesivir if Demand Outstrips Supply

University of California Critical Care Bioethics Working Group

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On May 1, 2020, the Federal Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the use of remdesivir in the treatment of patients with COVID-19. Remdesivir, an antiviral drug which targets RNA dependent polymerase in SARS-CoV2, has been shown in a recent NIH sponsored trial to hasten the time to recovery by 31% compared with placebo (11 v 15 days) among patients with COVID-19 infection.

The EUA allows for the treatment of COVID-19 in adults and children who are hospitalized with severe disease as defined by a room air oxygen saturation of ≤94%. Because of the limited distribution, and because pregnant women and children may receive remdesivir from Gilead through the Compassionate Use Program, the California Department of Public Health (CDPH) has determined that the EUA supply be reserved for non-pregnant adults at this time. If there is delay in receiving remdesivir through this program, pregnant people and children should be included in the EUA allocation.

The data on remdesivir remains new and evolving. Therefore, additional therapies through controlled trials should also be considered, as well as opportunities for therapies through compassionate use (e.g. convalescent plasma). Additionally, the administration of remdesivir through existing trials should be supported if available and if patient qualifies and consents. However, there may be a patient who may not have the opportunity for a clinical trial or may not consent, for whom EUA remdesivir may be utilized.

Eligibility Considerations

In an effort to prioritize distribution of EUA remdesivir given the limited supply, we are recommending remdesivir be considered for individuals who meet the following strict criteria:

1. Positive SARS-CoV-2 RT-PCR result
2. ≥18 years of age
3. Negative pregnancy test, if applicable
4. Hypoxia – SpO_2≤94% on room air or requiring supplemental oxygen, mechanical ventilation, or ECMO.
5. AST/ALT < 5x ULN prior to initiation

Triage Teams and Allocation

Allocation decisions regarding offering remdesivir through the EUA should not be made by the patients treating clinicians, but instead by a separate triage team composed of an infectious disease expert, a clinical leader from executive leadership, a pharmacist with expertise in the medication, a member of the ethics team, a representative from Equity, Diversity and Inclusion Divisions, with input about relevant clinical criteria by the treating clinicians and consultants. Each patient meeting eligibility should undergo an assessment by the triage team in conjunction with the treating physician. This strategy provides for the most objective approach to allocation and preserves the critical input of treating providers. In the event that the number of patients exceeds supply, a randomization tool should be used to determine who will receive the available courses of remdesivir.

Specific steps in the allocation process:

1. Eligibility is identified daily at a set time by the Triage Team
2. The Triage Team contacts the eligible patient's treating Physician
    a. The treating Physician may also contact the Triage Team
3. Resource scarcity is evaluated daily
4. If there are more eligible patients than availability of Remdesivir, eligible patients will be given a lottery number
    a. Lottery numbers are assigned only once to a patient, not daily
5. The treating Physician is informed of the lottery results and the patient or next of kin is then notified
6. If the lottery number falls within the range of availability of Remdesivir, the patient will receive the medication
7. The assignment of lottery numbers is to be performed by two members of the triage team and documentation of the process is placed in the medical record

These recommendations may undergo revision based upon the science of the efficacy of Remdesivir and solicitation of public input.