Remdesivir Allocation Guidance and Procedures

Background

- Remdesivir (RDV) is an antiviral that interferes with viral RNA replication. It has recently been released by the FDA for emergency use with guidelines for use to treat COVID19 as in a small study it was found to decrease recovery time from 15 to 11 days.
- RDV is being allocated for use to hospitals by the federal government. Supplies are beginning to arrive at various MedStar Health hospitals. It is currently available, but we are unaware if the supply will be sufficiently replenished.
- Consequently, we must assure that RDV is used judiciously per current guidelines.
- We must quickly modify guidance as more evidence becomes available.

Goals

- To maximize the likelihood and magnitude of clinical benefit to patients from available supplies of RDV.
- Provide a fair, transparent, and consistent process of allocation if supply becomes compromised.

Indications and Precautions

These are based upon the criteria of the ACTT trial sponsored by the NIAID and used by the FDA to reach its emergency release decision.

- Patient must be receiving supplemental oxygen
- Pulmonary function not improving
- Patients must be <10 days of hospitalization with laboratory confirmation of COVID-19
- There must be an eGFR >30, not on renal replacement therapy,
- AST/ALT must be < 5x the upper limit of normal
- Reasonable expectation of survival
- Patient will not have a medical condition that will result in near-term mortality (life expectancy under 6 months) even with aggressive therapy
- Patient will not have an advanced and irreversible neurologic event or a condition such that patient will be unable to later perceive the benefits of having received treatment.

Process of Approval to Distribute

- A patient's treating physician identifies patients for whom RDV is clinically indicated.
- An allocation team including two physicians versed in the care of COVID19 patients, who are preferably an Infectious Disease attending, and a Critical Care attending, and a pharmacy director or designee, not directly involved in the patient's care, reviews those recommended by the treating team each morning at 10am. It will review RDV use based upon guidelines from below and approve it for patients who are suitable candidates.
- If supply exceeds demand at the 10a review, RDV will be distributed to all eligible patients that consent to treatment.

- When remdesivir demand exceeds supply, the available supply will be allocated to patients based on a random selection process (See supply limitations, below).
- If a Maryland site has less than 6 vials remaining (i.e. a full 5-day course of therapy), it should be sent to another MD hospital as designated by the system Pharmacy team.
- The treating physician of patients determined not to be candidates may appeal a decision to the hospital VPMA.

Distribution and Administration

- A patient or surrogate must provide verbal informed consent to receive RDV, documented in the EMR. Consent should include discussion that RDV is not yet approved by the FDA, but that limited quantities are available under an emergency use authorization.
- A course of therapy shall be five days. For patients on a ventilator at the onset of therapy, a second 5-day course of therapy may be requested.
- If additional therapy is requested, a new review is required (and another lottery if demand exceeds supply).

Supply Limitations

If there is not enough RDV for all patients who meet the above requirements, the following factors should be considered:

- If demand exceeds supply at the 10am review, all patients will be prioritized by a random number generator at each site before they are approached to provide consent.
- Patients will be approached for consent by the priority sequence determined by the random generator.
- Remdesivir supplies will be shared among MedStar Maryland hospitals as they are available and required. By regulation, supplies cannot be shared among MSH DC hospitals.
- These guidelines will apply equally to all patients.
- Candidacy for RDV will not be assessed using any other non-clinical factor or sociodemographic characteristic such as race, color, ethnicity, national origin, age, language, physical or mental disability, religion, sex, sexual orientation, gender identity or expression, immigration status, or ability to pay.
- Persons with disabilities will not be denied medical care based on stereotypes, assessments of quality of life, or judgments about a person's relative "worth" based on the presence or absence of disabilities.

Citations

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- Troug R., Mitchell C. and Daley, G. "The Toughest Triage – Allocating Ventilators in a Pandemic." NEJM, March 2020
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