

Remdesivir Emergency Use Authorization (EUA) Requirements

May 2020

VA Pharmacy Benefits Management Services

Remdesivir covered by the FDA Emergency Use Authorization (EUA) is only to treat adults and children who meet specific criteria. It is NOT an FDA approved drug. Use of product under the EUA must be consistent with and may not exceed terms of the Authorization (Section II), including scope of the Authorization and the Conditions of the Authorization (Section IV).

Ethical Principles

General ethical principles such as transparency, consistency, and fairness guide ethically strong practices for allocation of remdesivir in a way that will allow VHA to do the most good (i.e., benefit the most patients) with the limited supply that we have.

Assuming that remdesivir is truly a scarce resource, and there can be no further augmentation of the supply, and that there is very limited objective data to inform optimal patient selection based on prognosis with/without the drug or timing of the dosing, allocation should:

- 1) Begin with general exclusion criteria to avoid giving the scarce resource to patients who are unlikely to benefit substantively regardless of COVID outcome; and, for patients without exclusion criteria
- 2) Remdesivir should be allocated on a first-come-first-served basis to patients with clinical indication, and no contraindications to the drug; and
- 3) The inclusion criteria should be continually adjusted if more information about which patients would most likely benefit becomes available.

Remdesivir may only be requested for patients when the following criteria and requirements are met:

EXCLUSION CRITERIA (If the patient meets any of these criteria, they should not receive agent. All answers must be NO in order to go to inclusion criteria)

Labs*: ALT \geq 5X Upper Limit of Normal; eGFR < 30 mL/min; positive pregnancy test	YES	NO
Confirmed presence of any advanced disease (other than COVID-19) with average life expectancy of 6 months or less (e.g., advanced cancer or end-stage organ failure with less than 6 months average survival)	YES	NO
Patient eligible but declines treatment (respect patient self-determination)	YES	NO

*Required labs upon initiation include: Serum creatinine, eGFR, Hepatic panel (AST/ALT, alkaline phosphatase, bilirubin). If patient has hepatic impairment, the provider understands it is not known if dosage adjustment is needed but the provider feels the potential benefit outweighs the potential risk

INCLUSION CRITERIA (The patient must meet all these criteria. All answers must be YES to receive agent)

Patient is hospitalized with laboratory <u>confirmed</u> COVID-19 diagnosis	YES	NO
The patient meets at least one of the following: need for mechanical ventilation, extracorporeal membrane oxygenation (ECMO), supplemental oxygen, or room air O ₂ saturation \leq 94%	YES	NO
Counseling provided and documented in the electronic health record as per EUA **	YES	NO

** The provider has communicated with the patient/caregiver information consistent with the "[Fact Sheet for Patients and Patients/Caregivers](#)" prior to the patient receiving remdesivir, and has documented in the medical record that the patient/caregiver has been given the Fact sheet, informed that remdesivir is an unapproved drug authorized for use under EUA, given information on alternatives and their risks and benefits, and the patient/caregiver has the right to refuse or accept

Suggested Dosing and Administration of Remdesivir per the EUA

- 200 mg by intravenous infusion over 30-120 minutes on day 1, followed by 100mg on subsequent days

- Suggested duration is 10 days total for patients on mechanical ventilation or ECMO, and 5 days for others (which may be extended for UP TO 5 additional days if the patient does not improve, up to a total of 10 days)
- Remdesivir is diluted in up to 250mL 0.9% sodium chloride. Once diluted, it is stable for 4 hours at room temperature or 24 hours refrigerated. For additional information regarding dose preparation, storage, stability and administration – see the [Gilead remdesivir Pharmacy Guide](#)

Monitoring and Reporting of Adverse Events

- The following laboratory tests are recommended to be ordered daily while on remdesivir: serum chemistries, hematology, AST/ALT, bilirubin, alkaline phosphatase, creatinine and eGFR. Remdesivir should be discontinued in patients who have an ALT increase to ≥ 5 times upper limit of normal on therapy OR any elevation with signs or symptoms of liver inflammation
- The prescribing provider is responsible for MANDATORY reporting of all serious medication errors and adverse events that COULD BE potentially related to remdesivir (those resulting in death, a life-threatening event, hospitalization or prolonging or hospitalization, persistent or significant incapacity, or one requiring medical or surgical intervention to prevent death, hospitalization, disability or a life-threatening event)
- **How to report adverse events:** ALL Adverse Drug Events related to Remdesivir must be reported to VA ADERS as a MedWatch report (a separate FDA MedWatch report is not required). The report is to be submitted in VA ADERS for report review and validation of required elements. VA ADERS staff will submit to FDA MedWATCH program per EUA requirements. The words “Remdesivir under Emergency Use Authorization (EUA)” should be in the description section of the report
 - Adverse events based on prior data: infusion reactions, rash, elevation in transaminases, thrombocytopenia

VHA Specific Request Process:

- Fill out ALL information on the Remdesivir Order form electronically submit to VA PBM.
- Once the form is received, if the patient meets the EUA criteria as indicated on the form and remdesivir supply is available,
 - If the number of patients is less than or equal to the number of treatment courses available, then all patients will receive a 10-day course of treatment
 - If the number of patients exceeds the number of courses available, then a random number generator will be used to determine which patients receive courses of treatment.
- CMOP will initiate a shipment in a cooler via next day air.
 - Orders received on Friday or too late to make a Thursday shipment will be shipped on Friday for Saturday delivery. Sites receiving a Saturday delivery will need to make definitive arrangements for someone to be available to receive the drug on Saturday from UPS.
 - CMOP will send tracking information for each shipment to the site POC’s listed on the form.
 - CMOP will ship an entire 10-day treatment course per individual patient request.
- Patient orders must be entered in the VISTA IV package, and local drug file entry should read: INV-REMDESIVIR E-IND 100mg, using VA drug code IN160 (IV additive name is the same as above but just not the 100mg).
- The following information is **required** to be reported once treatment is initiated:
 - Sites must report the number of doses administered per patient and the number of excess doses on-hand from that patient’s treatment course to the VHAPBM RemdesivirOrderForm mail group.
 - If excess vials remain from the treatment course, sites must store appropriately in pharmacy until further direction is received from PBM. Stock must NOT be used to initiate treatment for another patient, as there is no assurance that additional stock will be available to complete the treatment course. Excess inventory will be rebalanced across the VA system.

Additional information: [FDA EUA Fact Sheet for Health Care Providers](#) [Remdesivir FAQ](#)