



Remdesivir (GS-5734™) =MEDICATION TRANSFER GUIDANCE=

Background:^{1,2,3}

COVID-19 is a novel illness with high morbidity and mortality for which there is a lack of currently available approved treatments. Limited data support the safety and efficacy of remdesivir, which has been made available under an FDA Emergency Use Authorization (EUA). HHS has been coordinating regular allotments of remdesivir to the IHS National Supply Service Center in support of increasing utilization at IHS inpatient facilities.

Issues:

1. Many IHS facilities utilize private-sector partners to provide inpatient/ICU care for their patients. This often holds true also for moderately/severely ill COVID-19 patients with indications for treatment with remdesivir.
2. Agency-level guidance for the transfer of remdesivir from an IHS facility to accompany a patient to a non-IHS inpatient facility enhances both access and consistency for IHS beneficiaries.
3. No current regulatory or manufacturer guidelines limit transfer of remdesivir from one facility to another.
4. No current regulatory or manufacturer guidelines describe the need for return of unused remdesivir (due to early discontinuation or death) back to an IHS program from an outside facility.

Guidance:^{4,5}

1. IHS facilities may establish local policies, consistent with the following stipulations, for the transfer of remdesivir between an IHS pharmacy and the pharmacy of a non-IHS inpatient facility:
 - a. For the treatment of a specific registered IHS patient,
 - b. Following confirmation of a positive test for SARS-CoV-2,
 - c. After verification that the patient meets remdesivir treatment criteria.
2. Remdesivir transfers to non-IHS facilities, for each patient, require:
 - a. Direct communication between the transferring and receiving physician and pharmacist.
 - b. Ensuring that a full treatment course will be supplied and completed following initiation of remdesivir (with the exception of documented adverse drug event or discharge).
 - c. The transport service must be able to ensure proper medication storage and safety during transport.
 - i. In the concentrated solution, remdesivir must be kept at refrigerated temperatures (2-8 degrees Celsius) until use.
 - ii. In the lyophilized powder form, it must be kept at controlled room temperature (below 30 degrees Celsius until use).
 - d. Adherence to all documentation and reporting requirements of the EUA, including informed consent.
3. For inventory control, the transferring IHS facility must maintain records of all remdesivir transfers, including:
 - a. Those dictated by the EUA (i.e., lot number, quantity, receiving site, receipt date),
 - b. Receiving facility, including attending physician and pharmacist accepting patient/medication,
 - c. Product storage,
 - d. Patient information (e.g., patient name, DOB, disease manifestation, number of doses transferred).
4. The non-IHS (receiving) facility must agree to adhere to EUA stipulations, including notification of FDA MedWatch regarding any adverse drug reactions. Please include the words "Indian Health Service" prominently in the FDA MedWatch submission either at the top of the report or in section G (reporter's information).
5. The non-IHS (receiving) facility must agree not to bill the patient or the IHS for the transferred remdesivir.

References:

1. U.S. Food and Drug Administration. Fact Sheet for Health Care Providers. [Emergency Use Authorization of Remdesivir. \(GS-5734\)](#).
2. IHS National Pharmacy and Therapeutics Committee. [Emerging Treatments Update: Remdesivir](#). Available online. Accessed May 14, 2020.
3. Beigel J, et al. [Remdesivir for the Treatment of COVID-19 – Preliminary Report](#). NEJM 2020, May 22. DOI: 10.1056/NEJMoa2007764.
4. Goldman JD, et al. [Remdesivir for 5 or 10 Days in Patients with Severe COVID-19](#). NEJM. 2020, May 27. DOI: 10.1056/NEJMoa2015301.
5. IHS National Pharmacy and Therapeutics Committee. Treatment Prioritization Strategy: Remdesivir. Available at www.ihs.gov/NPTC. Accessed June 5, 2020.