



Indian Health Service Fact Sheet – Distribution and Use of Remdesivir

Background: On May 9, 2020, the U.S. Department of Health and Human Services announced the allocation plan for the drug remdesivir. The allocation is from a donation by Gilead Sciences, Inc. to the United States which was finalized on May 3, 2020. The donated doses of the treatment, which received an Emergency Use Authorization from the U.S. Food and Drug Administration, will be used to treat hospitalized COVID-19 patients in areas of the country hardest hit by the pandemic. On October 22, 2020, FDA approved remdesivir for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Q: What is remdesivir?

A. Remdesivir is an approved antiviral medicine for adults and children 12 years of age and older and weighing at least 88 pounds (40 kg) for the treatment of COVID-19 requiring hospitalization. Remdesivir was shown in clinical trials in adults to shorten the time to recovery in some people. Remdesivir is still being studied in hospitalized children.

Q: How many doses of remdesivir did IHS receive? How many patients will this treat?

A: IHS received 20,000 vials of remdesivir through the HHS allocation and an additional 6,400 vials from the Department of Veterans Affairs. The recommended dosing and course of treatment varies, but this would be anticipated to treat about 4,000 patients.

Q: Where were these doses distributed?

A: Remdesivir allocated by the IHS has been distributed to all IHS requesting Areas. These include the Alaska, Albuquerque, Bemidji, Billings, Great Plains, Nashville, Navajo, Oklahoma City, Phoenix, Portland, and Tucson Areas.

Q: How were these sites chosen?

A: The Area allotments were based on requests for remdesivir from the Areas and consideration of surveillance data related to reported numbers of patients with COVID-19 that are currently hospitalized and numbers requiring intensive care unit level of care.

Q: How does IHS decide which patients get remdesivir?

A: IHS clinicians make treatment decisions based on each patient's situation. Remdesivir is available to clinicians in accordance with FDA regulations. Remdesivir can only be used to treat patients who are hospitalized.

Q: Do you have a list of sites you can share?

A: The drug was provided to the IHS Areas, where further decisions were made in regards to allocations to IHS federal and tribal hospitals

Q: Is IHS providing remdesivir to tribal and urban Indian organization facilities?

A: IHS will continue distributing, as available, the limited supply of remdesivir to I/T/U facilities, based on requests and current burden of patients with COVID-19 who meet the criteria for the drug.

Q: Can Tribes purchase remdesivir directly?

A: Remdesivir is commercially available for purchase by tribes through AmeriSource Bergen.

Q: Will IHS be receiving more remdesivir?

A: The IHS will be purchasing more remdesivir to continue to meet the needs of the Agency.

Q: Did IHS consult with Tribes before distributing remdesivir?

A: The priority of the Indian Health Service was distributing the drug as expeditiously as possible and without delay. The needs of tribes were assessed at each the IHS Area Office.

Q: Should pregnant women/children/those with specific conditions/etc. be prescribed remdesivir?

A: There is limited experience giving remdesivir to pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving remdesivir may be greater than the risk from the treatment. Treatment decisions are made between health care provider and patient based on each patient's situation.

Q: How is remdesivir administered?

A: Remdesivir is given through a vein (intravenous or IV) one time each day for up to 10 days.

Q: What is the difference between an Emergency Use Authorization (EUA) and an FDA approval?

Under section 564 of the Federal Food, Drug & Cosmetic Act (FD&C Act), the FDA may, pursuant to a determination and declaration by the HHS Secretary, authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits outweigh the known and potential risks for the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure. EUAs do not remain in effect indefinitely and FDA will consider whether a sponsor is working towards seeking FDA approval when evaluating the continued appropriateness of the EUA. FDA approves New Drug Applications (NDAs) under section 505(c) of the FD&C Act. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical that is not a biologic for sale and marketing in the U.S. In approving an NDA, FDA reviewers must

determine, among other things, that the drug is safe and effective for its labeled use(s), and that the benefits of the drug outweigh the risks; that the drug's labeling (package insert) is appropriate; and that the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. The statutory standard for an NDA approval requires substantial evidence of effectiveness, which is a higher level of evidence of effectiveness than required for an EUA.

Q: Some studies have found no benefit from remdesivir in COVID-19 patients. Why is IHS using it?

A: Remdesivir was shown in a clinical trial to shorten the time to recovery in some people. Full information regarding the data and evidence used to approve remdesivir can be found in the "[Combined Cross-Discipline Team Leader, Division Director, and ODE Director Summary Review](#)." Based on FDA's analysis of the scientific data, FDA approved remdesivir for use in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Remdesivir should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. The FDA concluded that the data met all applicable scientific and legal standards and demonstrated that remdesivir is safe and effective for the approved use. Patients have the option to accept or refuse remdesivir.

Q: How can I learn more?

- Ask your healthcare provider
- Visit <https://www.vekluryhcp.com/>
- Visit <https://www.covid19treatmentguidelines.nih.gov>
- Visit the [FDA FAQ on Remdesivir](#)
- Contact your local or state public health department
- Contact your local [IHS Area Emergency Management Point of Contact \(EMPOC\)](#)