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.

Q: What is remdesivir?
Remdesivir is an investigational antiviral medicine to treat certain people in the hospital with COVID-19. Remdesivir is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using remdesivir to treat people in the hospital with COVID-19. Remdesivir was shown in a clinical trial to shorten the time to recovery in some people. There are no medicines approved by the FDA as safe and effective to treat people in the hospital who have COVID-19. Therefore, the FDA has authorized the emergency use of remdesivir for the treatment of COVID-19 under an Emergency Use Authorization.

Q: How many doses of remdesivir did IHS receive? How many patients will this treat?
A: IHS received 6,000 vials of remdesivir. The recommended dosing and course of treatment varies, but this would be anticipated to treat about 750 patients.

Q: Where were these doses distributed?
A: The majority of the remdesivir allocated by IHS to date has been distributed to the IHS Navajo Area and Phoenix Area. Other areas receiving remdesivir are the Alaska Area, Albuquerque Area, Great Plains Area, Oklahoma City Area, and Tucson Area.

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 be distributing the limited supply of remdesivir to IHS federal and tribal hospitals, based on requests and current burden of patients with COVID-19 who are hospitalized and/or in an ICU. Urban Indian Organizations will not be included, as they do not operate hospitals. Remdesivir is currently approved under the Emergency Use Authorization only for hospitalized patients.

Q: Can Tribes purchase remdesivir directly?
A: Remdesivir is not commercially available for purchase by tribes. Under the Emergency Use Authorization, distribution of remdesivir is controlled by the U.S. government for use consistent with the terms and conditions of the EUA. The manufacturer will supply remdesivir to authorized distributors, or directly to a U.S. government agency, who will distribute the drug to hospitals and other healthcare facilities as directed by the U.S. government, in collaboration with state and local government authorities, as needed.

Q: Will IHS be receiving more remdesivir?
A: Currently, we have no information about future availability of remdesivir. We continue to work closely with HHS to communicate the needs of the Indian health system.

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. Tribes were not formally consulted, but their needs were assessed.

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

Q: What is an Emergency Use Authorization (EUA)?
The United States FDA has made remdesivir available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. The issuance of an Emergency Use Authorization is different from FDA approval.

Remdesivir has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality

of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for remdesivir is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Q: Some studies have found no benefit from remdesivir in COVID-19 patients. Why is IHS using it?
A: There are limited clinical data for remdesivir. Remdesivir was shown in a clinical trial to shorten the time to recovery in some people. Patients have the option to accept or refuse remdesivir.