What You Need to Know: Remdesivir for the Commercial Marketplace

On Sunday, June 28, 2020, the U.S. Department of Health and Human Services (HHS) signed a Memorandum of Agreement with Gilead Sciences, Inc. (the manufacturer of remdesivir) and AmerisourceBergen (the distributor of remdesivir) to secure approximately 500,000 treatment courses of remdesivir for use in American hospitals. This represents 100 percent of Gilead's projected production for July (94,200 treatment courses), 90 percent of production for August (174,900 treatment courses), and 90 percent of production in September (232,800 treatment courses), in addition to an allocation for clinical trials. At the end of this three-month period, the federal government will assess the COVID-19 environment to determine the best path forward relative to future distributions.

In alignment with the current terms of the Emergency Use Authorization (EUA) for remdesivir, HHS will oversee the drug's allocation and distribution process.

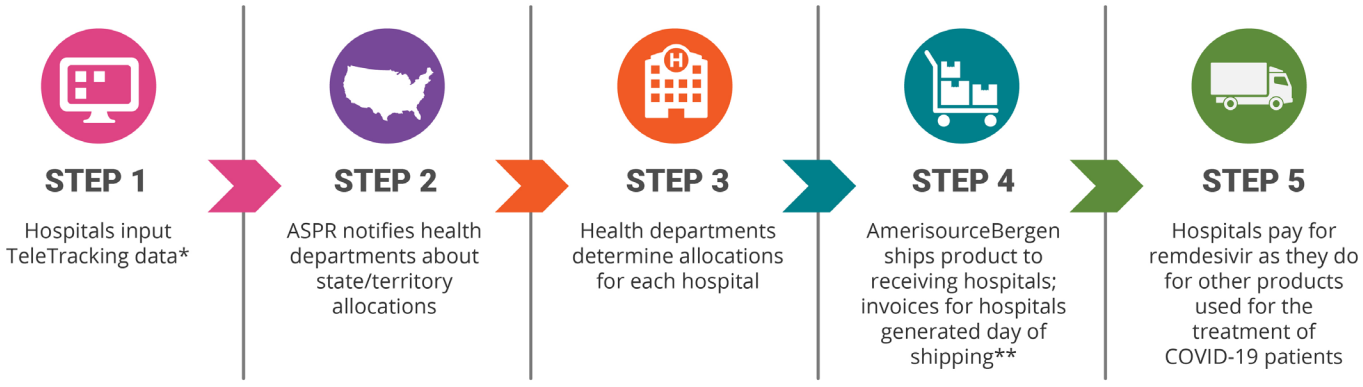
Allocation and Distribution Strategy

To achieve the federal government's priority of distributing the limited doses of available remdesivir in a fair and equitable manner, the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) will oversee the allocation of the commercially available drug using the same process employed for the donated lots of remdesivir. States and territories should continue providing any remaining donated remdesivir to hospitals in their jurisdictions at no cost.

Step 1: Beginning Monday, July 6 and every two weeks thereafter through September, hospitals will input TeleTracking data by 8:00 pm ET regarding their COVID-19 confirmed and suspected positive patients.

Step 2: HHS/ASPR will notify state/territorial health departments about their allocated amounts of remdesivir based on their respective COVID-19 hospital

Allocation & Distribution of Remdesivir: A Five-step Process



**Data input likely to occur every other Monday, beginning Monday, July 6*
***Shipments likely to occur every other Monday, beginning the week of Monday, July 13*

burden. Just as the donated remdesivir was calculated, a state/territory's percentage of the country's COVID-19 hospitalized patients will equal that state's allotted percentage of commercially available remdesivir for a given distribution week.

Step 3: Health departments will determine how much remdesivir hospitals within their respective jurisdictions may purchase based on the state/territory's allocation. Health departments will communicate information regarding receiving hospitals and drug amounts to AmerisourceBergen. Neither AmerisourceBergen nor Gilead are involved in allocation decisions for the remdesivir.

Step 4: Hospitals identified by their state/territorial health department to receive an allocation of remdesivir will be contacted by AmerisourceBergen to coordinate shipments. AmerisourceBergen will generate invoices to hospitals upon shipping. Receiving hospitals will be responsible for payment of the drug, as they are for other products used for the treatment of their COVID-19 patients.

Step 5: Beginning the week of Monday, July 13 and every two weeks thereafter through September, AmerisourceBergen will ship remdesivir directly to receiving hospitals.

Payment and Reimbursement

Hospitals will pay no more than the wholesale acquisition cost (WAC) set by Gilead, which amounts to approximately $3,200 per treatment course. A treatment course of remdesivir is, on average, 6.25 vials.

The drug will be billed per the standard relationship between AmerisourceBergen and the receiving hospital. Hospitals that do not have an account with AmerisourceBergen should email sales@asdhealthcare.com to complete this process.

Generally, patients do not pay directly for hospital-administered drugs like remdesivir; rather, for Medicare and most private insurers, the drug's cost is incorporated into payments made by the insurer.

HHS is using a portion of the $100 billion CARES Act Provider Relief Fund to reimburse healthcare providers, at Medicare rates, for COVID-related treatment of the uninsured. Hospitals can apply for reimbursement of hospitalization costs through this program. Private insurers (including Humana, Cigna, UnitedHealth Group, and the Blue Cross Blue Shield system) have committed to waive cost-sharing payments for treatment related to COVID-19 for plan members.

About Remdesivir

Under the EUA, the investigational drug remdesivir is approved for distribution and use by licensed health care providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine.

Remdesivir as a treatment for COVID-19 continues to be evaluated in clinical trials and is available through expanded access and compassionate use mechanisms for certain patient populations. Preliminary results of a clinical trial supported by the National Institutes of Health suggest that the drug may be associated with faster recovery compared with patients in the study who did not receive the drug.

For more information about remdesivir and the EUA, visit www.phe.gov. This site will be updated regularly to reflect the current state-by-state dashboard of allocations.