How do hospitals in Virginia receive remdesivir?

The supply of donated remdesivir was exhausted as of the beginning of July, 2020. Recently, the U.S. Department of Health and Human Services (HHS) signed a Memorandum of Agreement (MOA) with Gilead Sciences, Inc. (the manufacturer of remdesivir) and AmerisourceBergen (the distributor of remdesivir) to secure the remaining remdesivir for treatment of COVID-19 for patients in U.S. hospitals. This remdesivir is made available to hospitals at commercial marketplace pricing, wholesale acquisition cost (WAC), under the previously issued FDA EUA.

HHS provides oversight of the allocation of the commercially available remdesivir to each state/territory similar to the no-cost donated remdesivir. AmerisourceBergen’s specialty pharmaceutical distributor, ASD Healthcare, is responsible for shipping directly to the hospitals. This arrangement removes VDH pharmacy as the end distributor to the hospital sites. The state will continue to provide oversight of remdesivir to individual hospitals/healthcare sites by providing AmerisourceBergen with the site information and the amount of remdesivir allocation for each site.

When did the change go into effect?

The press release regarding the future remdesivir availability was issued by HHS on June 29, 2020 and HHS released additional guidance on July 8, 2020 for the remdesivir State Product Management on the HHS Public Health Emergency website.

To date, Virginia has received 2 allocations and is expecting weekly to biweekly allocations for Virginia through the end of September.

Who will make the allocation decision?

HHS determines the total number of remdesivir vials to be allocated to each state. VDH is responsible for determining the allocated amount of remdesivir to individual hospitals and provide the information to AmerisourceBergen.

Hospitals must input Tele-Tracking data to HHS regarding the status of COVID-19 confirmed and suspected positive patients. Virginia receives the allocated amount of remdesivir based on the data of confirmed and suspected COVID-19 positive patients within the Tele-Tracking database.

Is there a plan to ensure that the distribution amount is determined based on current positive patients?

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) provides oversight of the allocation of the
commercially available drug using the same process employed for the donated lots of remdesivir to all the states and will be based on the COVID-19 hospital burden that is inputted in the HHS Tele-Tracking database.

As previously established for the no-cost remdesivir allocation, the distribution plan takes into account community-level needs and the limited supply with input from the Virginia Emergency Support Team Unified Command, the Virginia Hospital and Healthcare Association (VHHA) and the Governor’s office. VDH continues to work with VHHA to determine the hospitals to receive the allocation using a random selection model based on confirmed COVID-19 positive patients, those under investigation for COVID-19 and the hospital’s current need and desire to purchase remdesivir. Hospitals that do not choose to purchase remdesivir in the current round will not be excluded from future allocations. This process ensures an equitable and fair allocation of remdesivir for hospitals throughout the state.

Can the shipment be made to either one site for a healthcare setting to use within multiple owned hospitals or a centralized distribution center?

Yes, if a hospital is selected and confirmed to purchase remdesivir, someone with VDH will contact the hospital pharmacy point of contact to verify the shipping address and contact information. Should a hospital/health system choose to change the shipping method, someone should contact VDH Pharmacy Services.

Which formulation of remdesivir will be available?

Both, the concentrated solution and the lyophilized powder formulations of remdesivir may be available within an allocation. If a hospital is interested in the concentrated solution, the hospital must reach out to VDH Pharmacy Services as AmerisourceBergen has stated that they will ship lyophilized powder formulation without any special requests.

What is the final cost of the remdesivir vials?

The final cost is $520 per vial. The drug is billed per the standard relationship between AmerisourceBergen and the receiving hospital.

What purchase quantity will be available to hospitals in order to ensure the appropriate treatment dose?

After the allocation information is provided to AmerisourceBergen from VDH, the hospital point of contact will be contacted by AmerisourceBergen to confirm their final remdesivir order/ship quantity. The process for remdesivir allocation and distribution is scheduled to last through the end of September, 2020. Hospitals may be able to receive quantities less than 40 vials (1 case) based on the random selection model. Each selection is considered 1 allotment of 6 vials.

How and when will the hospital receive the notification of an order?
AmerisourceBergen receives allocation information from each state and will be responsible for the final order confirmation of the hospital, order creation, and order fulfillment as well as inventory and shipment reporting to HHS and VDH. VDH pharmacy no longer acts as the end distributor of remdesivir to the hospital sites. AmerisourceBergen’s specialty pharmaceutical distributor, ASD Healthcare, is now responsible for notifying and distributing the shipment of remdesivir directly to the hospital sites. AmerisourceBergen provides a shipping confirmation report back to VDH.

**What do hospitals needs to do to set up an account with AmerisourceBergen/ASD Healthcare?**

AmerisourceBergen must work initially to set up an account with any hospitals that do not have an existing account. The steps for setting up an account are as follows. The Direct Bill Account Questionnaire has been provided in order to set up an account. The completed form should be emailed to accountsetup@asdhealthcare.com. Once ASD has received the information, ASD will pre-populate the application and send it to the contact at the hospital within 1-2 days for review and execution. The application process may be expedited if the hospital can include state pharmacy license, W9 and tax exemption certificate (if applicable), along with the completed questionnaire.

Contact for AmerisourceBergen:
Remdesivir hotline: 877-987-4987
Email: remdesivir@amerisourcebergen.com

**How do hospitals receive reimbursement for the drug?**

Generally, patients do not pay directly for hospital-administered drugs like remdesivir; rather, for Medicare and private insurers, such as Humana, Cigna, UnitedHealth Group, and the Blue Cross Blue Shield system, the drug’s cost is incorporated into payments made by the insurer.

In order to ensure equity among those that are under/uninsured, hospitals can utilize the CARES Act Provider Relief Fund to receive reimbursement for the remdesivir. 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 and reimbursement of hospitalization costs through this program for those that are uninsured.

**Are hospitals able to transfer inventory at cost to other hospitals within the state?**

Hospitals may transfer remdesivir to other hospitals within the state of Virginia.

**Are hospitals able to transfer inventory at cost to other hospitals outside the state?**

Hospitals should not transfer remdesivir to other hospitals outside the state. HHS is utilizing data within each state to allocate remdesivir. The allocation of remdesivir is for use by hospitals within Virginia.
Will hospitals be able to transfer inventory at cost? Can states purchase to hold for surges in cases?

VDH did request the ability to purchase remdesivir but this request has not been approved.

What statistics are available about the success within Virginia from the donated supply?

At this time, VDH does not have statistics on the results concerning the remdesivir treatment outcomes.

Additionally, what outcome data do we have about remdesivir from the clinical trials, specifically with it shortening length of stay?

On June 1, 2020, Gilead Sciences announced results from the Phase 3 SIMPLE trial in hospitalized patients with moderate COVID-19 pneumonia. This open-label study evaluated 5-day and 10-day courses of the investigational antiviral remdesivir plus standard of care, versus standard of care alone. The study demonstrated that patients in the 5-day remdesivir treatment group were 65 percent more likely to have clinical improvement at Day 11 compared with those in the standard of care group (OR 1.65 [95% CI 1.09-2.48]; p=0.017).

VDH is working to compile any information collected from the no cost remdesivir distribution and summarize it to make it available to hospitals.

Do hospitals need to continue to report the status of the remdesivir inventory to VDH?

No, the survey and inventory tracking closed effective Monday, July 27 and will no longer be required. Hospitals must continue to report information into VHASS and to the HHS Tele-Tracking database.

Who is the best point of contact for VDH Pharmacy Services?

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