



Remdesivir Allocation and Distribution Frequently Asked Questions 09/24/20

1. **Question:** How was the amount of remdesivir per hospital determined for the first allotment from AmerisourceBergen?

A: Allocation was based on COVID cases entered into the HRTS COVID system on July 6th for the prior two weeks. HHS used that data to determine a distribution to each state department of health who in turn allotted vials to each hospital based on their cases. AmerisourceBergen Corporation (ABC) was notified of the amount available for purchased by each hospital and has reached out to set up the invoicing and delivery of the product.

2. **Question:** Going forward, how are future allocations to hospitals determined?

A: HHS will pull data from their reporting system each Wednesday for the prior week to determine the next purchase allocation. The State will allocate the number of vials for each hospital based on the number of positive patients entered for each site during the previous 7 days.

3. **Question:** How will the hospital know what the allocation is and communicate whether it wants to purchase the allocation or not?

A: The listed contact will receive a high priority email from the State on Thursday or Friday of each week that there is an allocation for the hospital. The deadline for emailing confirmation of allocation acceptance or declination is required by noon every Friday through 09/30/20. If a confirmation is not received by this deadline, the State will attempt to contact someone at the hospital by phone to acquire a confirmation. The deadline for statewide allocations to be submitted to the HHS and ABC is Friday afternoon of each week.

4. **Question:** Do hospitals have to enter their remdesivir data into the HHS Teletracking system?

A: No, the TDH has added the required data fields to the state HRTS system. Hospitals need to enter their data each day in the state HRTS system and the TDH will upload the data to HHS on hospital's behalf. Pharmacists should identify who is responsible for HRTS data entry at their facility and coordinate providing the remdesivir information.

5. **Question:** If a healthcare system has product at one hospital and another hospital in the same system that has never had a need for remdesivir suddenly has a patient that meets criteria, is the hospital system allowed to shift product from one hospital to another within the hospital system or should it remain only at the hospital for which it was purchased?

A: The hospital system may shift product to another hospital within the same system when necessary due to a COVID patient admission needing treatment.

6. **Question:** What if the allocation for a facility seems small compared to a rapid increase in patients meeting criteria? Is there an appeal process or a point person to contact and explain the situation? Does the TDH retain any supply for this type of need?

A: A facility that needs more medication for a rapid increase in patients and immediate need should attempt to



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borrow from a larger facility within the geographical region. Entering the accurate patient numbers daily should allow future allocations to increase with increase in patient load.

If there is difficulty in acquiring adequate medication by borrowing, the TDH will assist with arrangements for medication. Email Calita.Richards@tn.gov.

7. **Question:** For the daily reporting, “# of remdesivir vials as of 11:59 pm yesterday”, is this a count of all remdesivir vials, or should vials planned to complete initiated treatment not be included in the count?

A: This should be inventory of all vials, including vials planned to complete initiated treatment.

8. **Question:** If a site within an organization/corporation has a facility in an adjacent state that needs more remdesivir and the facility in Tennessee can spare product, may the facility with stock transfer their product out of state?

A: A quantity of product purchased by a facility that is a part of a common large corporation may be shifted to another facility that is within the same corporation, but outside of Tennessee. Product may not be shifted to facilities outside of Tennessee, unless both are within a common corporation. An email notification of the shift and the quantity shifted should be sent to Calita.Richards@tn.gov.

9. **Question:** Is a hospital required to accept and purchase a weekly allocation of remdesivir?

A: No. A hospital may decline a portion or all of a weekly allocation. It is important to remember that allocations are offered, and acceptance or declination is confirmed only once a week.

10. **Question:** Is a hospital offered the same remdesivir quantity allocation every week?

A: No. The calculation of remdesivir vials may vary from week to week, depending on the data the hospital enters in the State system daily. For the smaller hospitals, if a hospital has had even one patient entered in the system over the previous 7-day period, 6 vials will be allocated for that week and offered to the hospital. If the allocation is accepted, it will be delivered the following week.

11. **Question:** If a hospital declines purchasing a weekly allocation, will the hospital be contacted the next week for another allocation?

A: Yes, if there are positive COVID patient numbers entered in the State system within the 7 days prior to the allocation.

12. **Question:** Are unopened remdesivir vials returnable?

A: No. The HHS has stated it is not allowing sites to return unopened product to ABC, and that sites should only accept allocation deliveries for immediate use.

13. **Question:** What day of the week are the remdesivir shipments anticipated?

A: Allocations are submitted to the HHS and ABC for hospitals on Friday, and shipments of that allocation are delivered Monday - Friday of the next week. The State is not notified which sites will receive deliveries on which days of the week. The State is only notified of deliveries after they occur.

14. **Question:** Since an invoice is not accompanying the shipment of remdesivir, how will the hospital receive the



invoice for payment?

A: Amerisource was mailing the invoice separately from the shipment. The process has been changed. Invoices will be emailed from ABC to the email address listed with the State as a contact for confirming acceptance or declination of shipments. This will be effective starting at the latest 08/14/20, per ABC.

15. **Question:** When the State contacts a facility to confirm acceptance of a remdesivir purchased shipment, how will a facility be able to provide a specific Purchase Order (PO) number to be used for the shipment?

A: A generic PO of the date will typically be used for each shipment. However, if facility needs to have a specific PO used, ABC should be contacted and a credit/rebill with that specific PO can be processed.

16. **Question:** If the weekly allocation was declined and over the weekend there is a sudden increase in remdesivir usage, may a facility request a shipment?

A: It is possible that a shipment or increase in shipment may be arranged by emailing Calita.Richards@tn.gov, but this is only possible on Monday or Tuesday. This is not possible after Tuesday, and the facility definitely should attempt to borrow from a larger facility within their geographical region for an adequate supply until an allocation process occurs for shipment the following week.

17. **Question:** What steps should be taken if a delivery of a shipment occurs that was not confirmed as accepted or is a duplicate shipment delivered within one week?

A: Notify the State by emailing Calita.Richards@tn.gov with the details as soon as this occurs. Also, include whether the hospital wants to keep the shipment or not. Arrangements will be made by the State based on the direction of the hospital.

18. **Question:** What steps should be taken if a delivery is not received Monday - Friday of the week following the confirmed acceptance of allocation?

A: Notify the State by emailing Calita.Richards@tn.gov about the missed delivery. The State will contact a specific ABC individual dedicated to the remdesivir shipments about the missed delivery. The State will communicate with the hospital with updates in receiving the missed delivery.

19. **Question:** With the updated FDA guidance in expansion of remdesivir usage, will the remdesivir allocations increase?

A: No. Since the purchased remdesivir allocation phase began, there have been hospitals that have declined weekly allocations. This declining has been gradually increasing to a current rate of approximately 26% by hospitals nationwide. The remainder of State allocations that are declined have virtually shifted back to the overall national HHS inventory. Therefore, there is still adequate inventory to manage the expansion through September 2020.

20. **Question:** Will it be required for hospitals to continue entering situational data in the HRTS system after 09/30/20?

A: Yes. The data is very important in the continued response to the ongoing pandemic.



21. **Question:** Exactly when will the HHS/Amerisource purchase remdesivir allocations switch over to routine hospital commercial purchasing?
- A:** The last HHS allocation will be the week of 09/28/20, which will ship Monday - Friday the week of 10/05/20.
22. **Question:** What will be the process for hospitals to order remdesivir after 09/30/20?
- A:** The manufacture, Gilead, and Amerisource are working through the details of the future purchasing process. Gilead is currently working with the FDA in amending the EUA to allow for routine commercial sale of remdesivir. All details are not yet known. They will be shared with the State and hospitals as soon as they are finalized.
23. **Question:** Will there be limitations or allocations the remdesivir quantity a hospital may order after 09/30/20?
- A:** HHS, Gilead, and Amerisource have stated that there is plenty of remdesivir available in the US, and there will be no limitation or allocation to ordering. Product is no longer scarce. There are no concerns with providing adequate quantities for any potential surges in cases.
24. **Question:** Will hospitals be required to continue entering daily data in HRTS after 09/30/20?
- A:** Yes. There will not be any type of allocation parameters or limitations of remdesivir purchasing based on the daily information entered. However, the data is extremely important in continuing to adequately respond to the ongoing pandemic both at the State and Federal levels.
25. **Question:** Will hospitals be able to order remdesivir from their routine wholesaler after 09/30/20?
- A:** Amerisource will remain as the sole wholesaler distributing remdesivir in order to maintain best distribution management, so hospitals will continue purchasing product from Amerisource at least through the end of the year 2020. A listing of Amerisource representatives corresponding to the hospitals will be provided for future contact concerning access to the Amerisource ordering portal and communications about remdesivir orders and shipments.
26. **Question:** After 10/01/20, will remdesivir be available for purchase by any type of entity?
- A:** Remdesivir will continue to only be available for use in hospitalized patients, as stipulated in the EUA.
27. **Question:** Will Amerisource ever accept returns of remdesivir?
- A:** This is currently unknown but is being discussed.



Contacts

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