Update and Guidance on U.S. Government Allocation and Distribution of Remdesivir

Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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Overview

• Background
• About Remdesivir and the Emergency Use Authorization
• Treatment Recommendations
• U.S. Government Agreements
• Allocation and Distribution
• Current Status
• Issues/Concerns/Questions
Background

• Currently no Food and Drug Administration (FDA)-approved COVID-19 treatment
• Remdesivir authorized for use through FDA Emergency Use Authorization
  o Investigational drug (not experimental)
  o EUA provides guidelines for use and allocation of drug
• Product initially donated to USG; now commercially available
  o Gilead Sciences, Inc. – manufacturer
  o AmerisourceBergen – distributor
• HHS/ASPR oversees allocation and distribution on behalf of USG
  o Donated product (May 4 – June 29, 2020)
  o Commercially available product (July 13 – current)
About Remdesivir and the EUA

- Investigational drug that went through National Institutes of Health (NIH) clinical trial
- FDA issued EUA allowing administration to hospitalized patients with COVID-19
- EUA allows for distribution and use by licensed health care providers
- EUA updated/expanded August 28, 2020
- Candidates for treatment must be hospitalized COVID-19 patients:
  - adults/children
  - with suspected or laboratory confirmed COVID-19
- Administered intravenously according to one of two courses:
  - 5-day course (requires 6 vials of remdesivir)
  - 10-day course (requires 11 vials of remdesivir)
  - Average course = 6.25 vials
  - 1 case = 40 vials; 1 case treats approximately 6.4 patients
NIH Treatment Recommendations

• 5-day treatment course (200 mg loading dose x 1; 100 mg x 4)
• Recommended for hospitalized patients with COVID-19
• NIH Panel recommends use for 5 days or until hospital discharge, whichever comes first (AI)
• If a patient is on supplemental O2 while receiving remdesivir and progresses, treatment course should be completed
U.S. Government Agreements

• May 3, 2020
  o U.S. Government (USG) formally accepted 940,000 vials of donated remdesivir from Gilead Sciences, Inc.
  o 1st donation = 606,840 vials ; 2nd donation = 333,160
  o Total supported more than 150,000 treatment courses

• June 28, 2020
  o HHS secured approximately 500,000 treatment courses from Gilead Sciences, Inc. from July-September
  o 100% of Gilead’s projected July production (94,200 treatment courses)
  o 90% of Gilead’s projected August production (174,900 treatment courses)
  o 90% of Gilead’s projected September production (232,800 treatment courses)
Allocation and Distribution of Remdesivir: A Five-step Process

**STEP 1**
HHS/ASPR determines allocation amounts for states and territories.

**STEP 2**
HHS/ASPR notifies health departments regarding allocation amounts.

**STEP 3**
Health departments determine allocations for hospitals in their jurisdictions.

**STEP 4**
AmerisourceBergen coordinates shipping directly with receiving hospitals; generates invoice upon shipping.

**STEP 5**
Hospitals pay for remdesivir as they do with other products used for the treatment of COVID-19 patients.
Weekly Allocation/Distribution Cycle for Commercial Remdesivir

**M = Milestone Activity**

**ABC = AmerisourceBergen**

**HHS/ASPR**

**States/Territories**

**Hospitals**

**ABC**

**M1: Confirmation of RDV on hand**

**M2: TeleTracking Data due by 11:59 pm PT (2:59 am ET)**

**M3: Allocations determined and notifications made to Governors, Congress, RECs, S/THOs**

**M4: S/THOs identify hospitals; send allocation info to ABC by 7:00 pm PT (10:00 pm ET) on Friday**

**M5: Shipment of RDV begins**

**M6: Hospitals begin receiving RDV**

**ABC conducts customer outreach; packing RDV for shipping**

**Shipment of RDV continues**
Allocation and Distribution

- Allocation methodology emphasizes recent COVID-19 cases and increases in cases in states/territories
- Data requested from hospitals via TeleTracking (part of HHS Protect) in support of allocation determinations:
  - Previous day’s new adult admissions for confirmed COVID-19
  - Previous day’s new adult admissions for suspected COVID-19
  - Previous day’s remdesivir used
  - Current inventory of remdesivir
Current Status

- Last donated remdesivir shipped week of June 29, 2020
- Product now commercial ($3,120/course)
- Currently in Week 6 of commercial remdesivir allocations
  - Week 1 (Jul 6 - 13): allocated 3,250 cases
  - Week 2 (Jul 20 - 26): allocated 4,244 cases
  - Week 3 (Jul 27 - Aug 2): allocated 2,979 cases
  - Week 4 (Aug 3 - 9): allocated 4,120 cases
  - Week 5 (Aug 10 - 16): allocated 3,269 cases
  - Week 6 (Aug 17 - 23): allocated 8,300 cases
  - Week 7 (Aug 24 - 30): allocated 12,000 cases
  - Week 8 (Aug 31 - Sep 6): allocated 11,000 cases
  - Week 9 (Sep 7 - Sep 13): allocated 10,250
  - Week 10 (Sep 14 – 20): allocated 16,927
- As of Sep 10, HHS has allocated 76,644 cases (3,065,760 vials; about 490,522 treatment courses) of **commercially available** remdesivir
Statistics of Note

- Percentage of hospitals reporting data into HHS Protect Sep 2-8: **95.7%** (4918 out of 5139 hospitals reported at least once over the 7-day period)

- Allocation, acceptance and purchase by HHS/ASPR, State/Territorial Health Departments, Hospitals for Jul 6 - Sep 8

  - (100%) 2,391,840 Allocated by HHS
  - (72%) 1,713,565 Accepted by states/territories
  - (47%) 1,130,395 Purchased by hospitals
  - (35%) 841,498 Delivered to hospitals

units = vials
Helpful Links

- [www.PHE.gov/remdesivir](http://www.PHE.gov/remdesivir) allocation dashboard, remdesivir background information, FAQs regarding allocation and distribution process

- [NIH COVID-19 Treatment Guidelines](https://www.nih.gov/coronavirus)

- [ASPR Regional Team](https://aspr.hhs.gov) consult the ASPR Regional Team in your area should you have remdesivir-related questions
ASPR Remdesivir Task Force
Office Hours

• Twice during each distribution week
• Dial in anytime during the hour
• Ask questions/gain clarification
• Dr. Redd and/or other Task Force members available

Tuesdays 1:00-2:00 pm ET
Join ZoomGov Meeting
https://hhsgov.zoomgov.com/j/1614110661?pwd=YWZ4dHZQNXIUenZqRU9jM0tuUk5Fdz09
Meeting ID: 161 411 0661  Passcode: 897674

Thursdays 1:00-2:00 pm ET
Join ZoomGov Meeting
Meeting ID: 160 025 6024  Passcode: 284515
Current Issues/Concerns

• Unallocated/declined product by states
  o Federal government re-allocates
• Product not purchased by hospitals
  o States/territories encouraged to confirm w/hospitals’ willingness to purchase remdesivir
  o States/territories encouraged to have reallocation process in place
  o Product not purchased by hospitals should be used to address urgent needs of other hospitals within respective state/territory
• Transfer of remdesivir across state lines
  o Donated product – states notify federal government via ASPR Regional Teams
  o Commercial product – notification to federal government not required
• Supply and Demand
• What happens beyond October?