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

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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)
Remdesivir History

- Developed by Gilead Sciences, Inc. with collaboration of USG
- Library of approximately 1,000 small molecules with potential for nucleoside analogues
- Initial results on Ebola virus reported in 2015
  - Studied in Democratic Republic of the Congo in 2018-2020 outbreak
  - Inferior to antibody therapy, but study gained safety information
- Two clinical trials in China for COVID-19
- Compassionate use for months in the US and Japan (including 1st patient)
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
- Candidates for treatment must be hospitalized COVID-19 patients:
  - with suspected or laboratory confirmed COVID-19 and severe disease
  - who require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
  - adults or children
- 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 patients with COVID-19 who are on supplemental O2 but do not require high-flow O2, vent, or ECMO
- 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
  - U.S. Government (USG) formally accepted 940,000 vials of donated remdesivir from Gilead Sciences, Inc.
  - 1st donation = 606,840 vials; 2nd donation = 333,160
  - Total supported more than 150,000 treatment courses

- June 28, 2020
  - HHS secured approximately 500,000 treatment courses from Gilead Sciences, Inc. from July-September
  - 100% of Gilead’s projected July production (94,200 treatment courses)
  - 90% of Gilead’s projected August production (174,900 treatment courses)
  - 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
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):
  - Previous day’s new adult admissions for confirmed COVID-19
  - Previous day’s new adult admissions for suspected COVID-19
    - Total adults hospitalized for COVID-19 (suspected and confirmed)
    - Total hospitalized for COVID-19 (confirmed only)
    - Total adults in Intensive Care Unit with COVID-19 (suspected and confirmed)
    - Total adults in Intensive Care Unit with Covid-19 (confirmed)
  - Previous day’s remdesivir used
  - Current inventory of remdesivir

- Denotes new data requested starting July 15, 2020
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
  o Week 1  (Jul 6 – 13): allocated 3,250 cases
  o Week 2  (Jul 20-26): allocated 4,244 cases
  o Week 3  (Jul 27 – Aug 2): allocated 2,979 cases
  o Week 4  (Aug 3 – 9): allocated 4,120 cases
  o Week 5  (Aug 10-16): allocated 3,269 cases
  o Week 6  (Aug 17-23); allocated 8,300 cases
• As of August 14, 2020, HHS has allocated 26,262 cases
  (1,050,480 vials; about 168,077 treatment courses) of 
  commercially available remdesivir.
Current Issues of Interest

• Unallocated/declined product by states
  o Federal government re-allocates

• Declined product 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 Declined product 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 – notify federal government via ASPR Regional Team
  o Commercial product – notification to federal government not required

• Cost of remdesivir: $3120/treatment course for all non-federal entities (including state hospitals)
ASPR Remdesivir Task Force
Office Hours

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

**Tuesdays 1:00-2:00 pm ET**

Join ZoomGov Meeting
https://hhsgov.zoomgov.com/j/1614110661?pwd=YWZ4dHZQNXI1UenZqRU9jM0tuUk5Fdz09

Meeting ID: 161 411 0661  Passcode: 897674
+16692545252,,1614110661# US (San Jose)
+16468287666,,1614110661# US (New York)

**Thursdays 1:00-2:00 pm ET**

Join ZoomGov Meeting

Meeting ID: 160 025 6024  Passcode: 284515
+16692545252,,1600256024# US (San Jose)
+16468287666,,1600256024# US (New York)
Helpful Links

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


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