



**ASPR**

# **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

August 27, 2020

**UNCLASSIFIED**

# 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](#)
  - Investigational drug (not experimental)
  - EUA provides guidelines for use and allocation of drug
- Product initially donated to USG; now commercially available
  - Gilead Sciences, Inc. – manufacturer
  - AmerisourceBergen – distributor
- HHS/ASPR oversees allocation and distribution on behalf of USG
  - Donated product (May 4 – June 29, 2020)
  - 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
- 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

# 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

## Allocation & 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



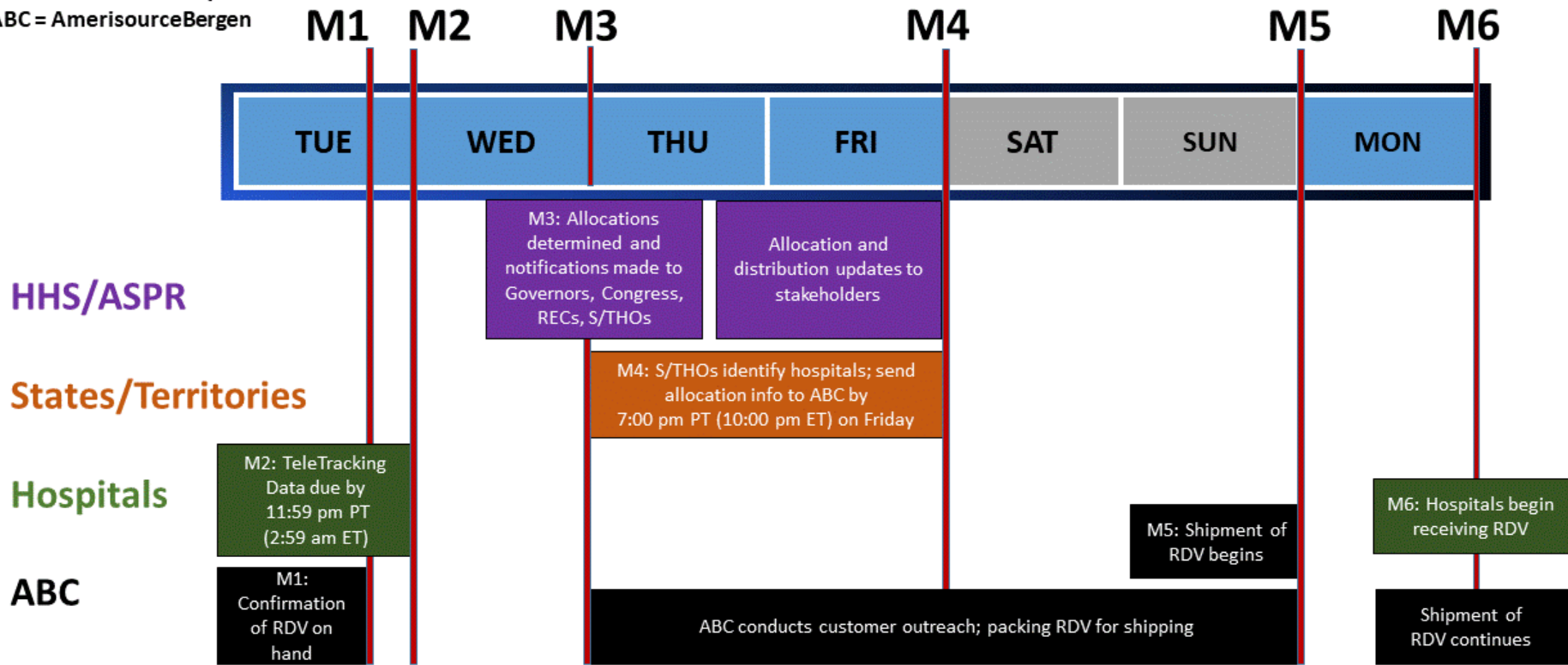
### STEP 5

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





# 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); allocation determinations underway**
- As of August 26, HHS has allocated 38,262 cases (244,877 treatment courses) of commercially available remdesivir.

# Statistics of Note

- Percentage of **hospitals reporting** last week = **93.9%**
- Percentage of product declined by **states** for Weeks 1-6 = **13.3%**
- Percentage of product declined by **hospitals** for Weeks 1-6 = **23.94%**

# 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](#)
- [ASPR Regional Team](#)  
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 other Task Force members available

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

**Join ZoomGov Meeting**

<https://hhs.gov.zoomgov.com/j/1614110661?pwd=YWZ4dHZQNlUenZqRU9jM0tuUk5Fdz09>

**Meeting ID: 161 411 0661 Passcode: 897674**

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

**Join ZoomGov Meeting**

<https://hhs.gov.zoomgov.com/j/1600256024?pwd=SXMtYU3ZjRGdwkPL21CYi9JemdsUT09>

**Meeting ID: 160 025 6024 Passcode: 284515**

# Current Issues/Concerns

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