



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

September 11, 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
- 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
 - 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



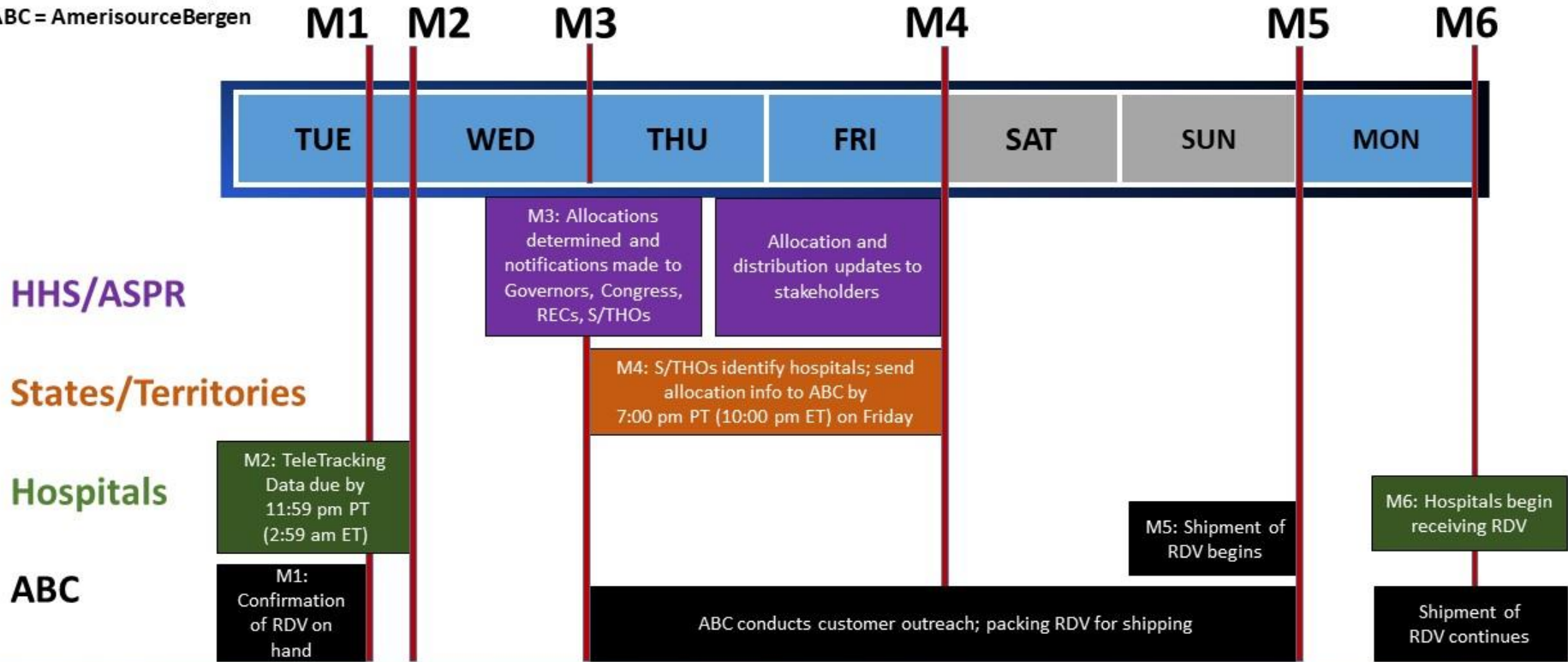
STEP 5

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

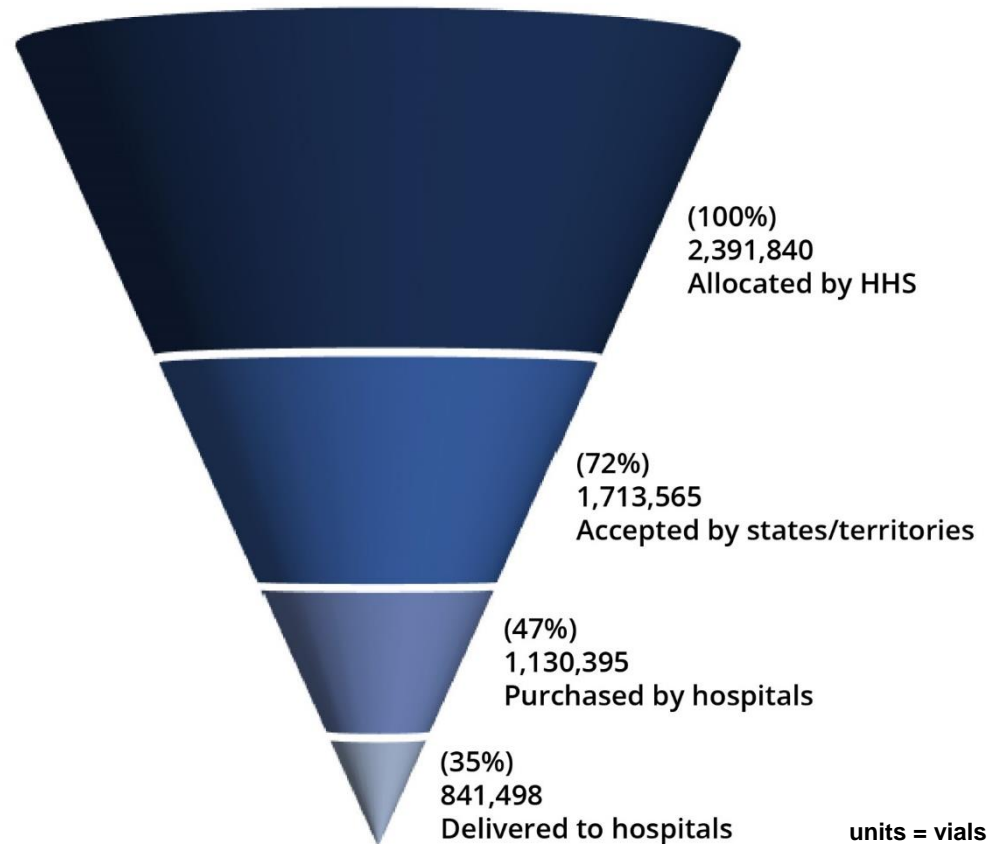
- Allocation methodology emphasizes *recent* COVID-19 cases and increases in cases in states/territories
- Data requested from hospitals via TeleTracking (part of HHS Protect) in support of allocation determinations:
 - ❖ Previous day's new adult admissions for confirmed COVID-19
 - ❖ Previous day's 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); 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



Helpful Links

- 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/or 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
- Product not purchased by hospitals
 - States/territories encouraged to confirm w/hospitals' willingness to purchase remdesivir
 - States/territories encouraged to have reallocation process in place
 - 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
 - Donated product – states notify federal government via ASPR Regional Teams
 - Commercial product – notification to federal government not required
- Supply and Demand
- What happens beyond October?