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 28, 2020

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~~
  - adults or children
  - ~~who require supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)~~
- 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

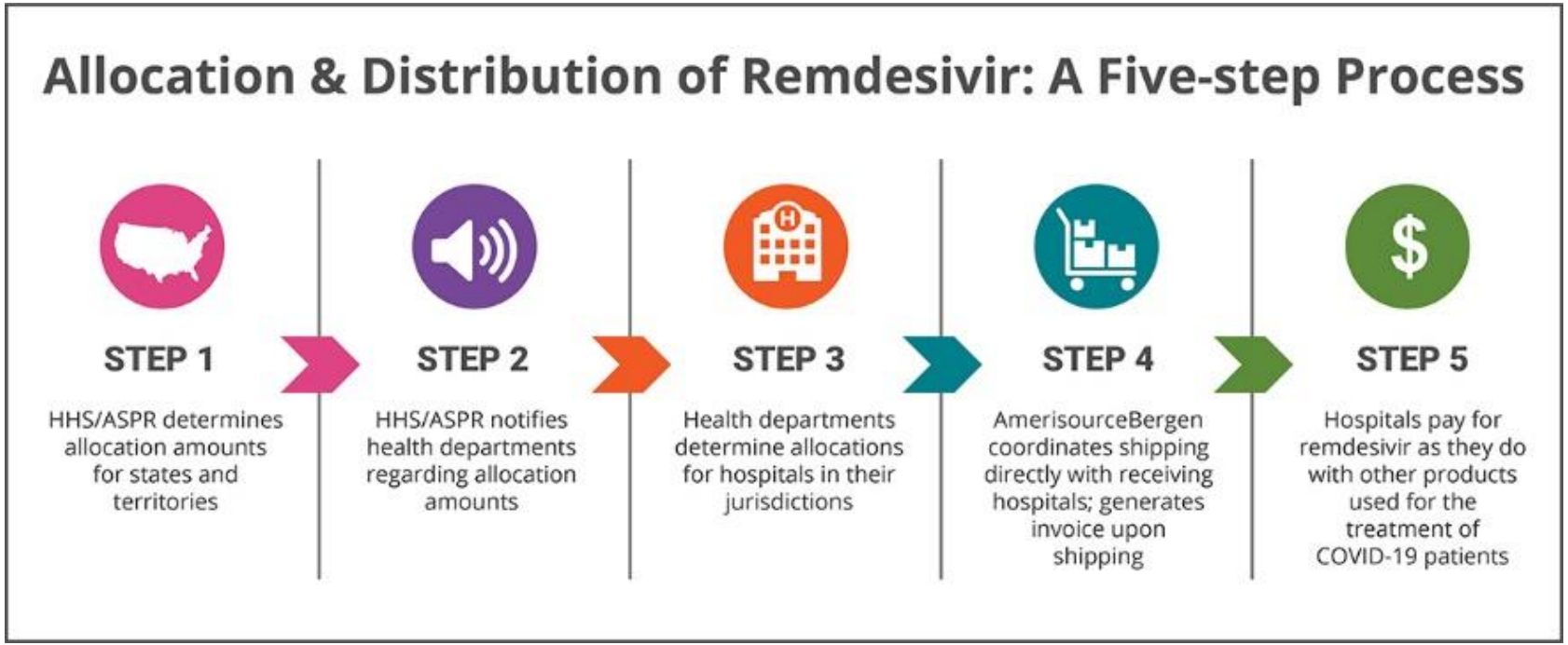
- 5-day treatment course (200 mg loading dose x 1; 100 mg x 4)
- Recommended for hospitalized patients with COVID-19 ~~who are on supplemental O2 but do not require high-flow O2, vent, or ECMO~~
- NIH Panel recommends use for 5 days or until hospital discharge, whichever comes first (AI)
- If a patient 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

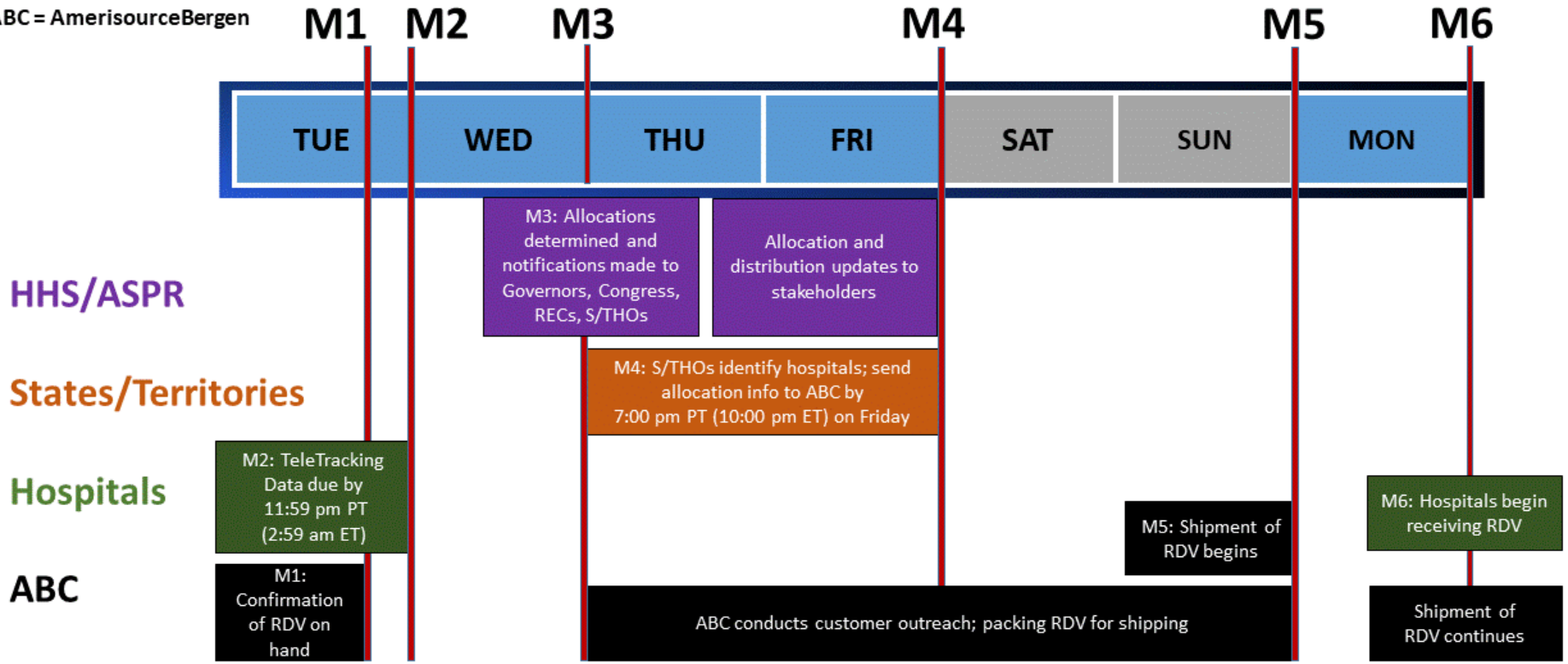
- June 28, 2020
  - HHS secured approximately 500,000 treatment courses from Gilead Sciences, Inc. from July-September
  - 100% of Gilead's projected July production (94,200 treatment courses)
  - 90% of Gilead's projected August production (174,900 treatment courses)
  - 90% of Gilead's projected September production (232,800 treatment courses)

Allocation and Distribution



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**
- As of August 28, HHS has allocated 49,262 cases (315,277 treatment courses) of commercially available remdesivir.

Statistics of Note

Percentage of **hospitals reporting** data into HHS Protect Aug 19-25: **94.6%**

Week	% of product declined by states/territories	% of product not purchased by hospitals
1	8.65	8.53
2	10.95	4.04
3	18.15	3.86
4	30.03	2.59
5	28.23	12.44
6	39.51	26.68

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 other Task Force members available

Tuesdays 1:00-2:00 pm ET

Join ZoomGov Meeting
https://hhsgov.zoomgov.com/j/1614110661?pwd=YWZ4dHZQNXlUenZqRU9jM0tuUk5Fdz09

Meeting ID: 161 411 0661 Passcode: 897674

Thursdays 1:00-2:00 pm ET

Join ZoomGov Meeting
https://hhsgov.zoomgov.com/j/1600256024?pwd=SXMyU3ZjRGdwbkpPL21CYi9JemdsUT09

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
- Extended deadline for getting hospital information to AmerisourceBergen
- Supply and Demand
- What happens beyond October?