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

October 1, 2020

UNCLASSIFIED

Background

- Currently no Food and Drug Administration (FDA)-approved COVID-19 treatment
- Veklury 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 fully commercially available
  - Gilead Sciences, Inc. – manufacturer
  - AmerisourceBergen – distributor
- HHS/ASPR led allocation and distribution on behalf of USG
  - Donated product (May 4 – June 29, 2020)
  - Commercially available product (July 6 – September 30)

About Veklury and the EUA

- Investigational drug (NOT experimental)
- 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 and October 1, 2020
    - August 28 – expanded use to all hospitalized patients
    - October 1 – removed requirement of USG allocation oversight

NIH Treatment Recommendations

- 5-day treatment course (200 mg loading dose x 1; 100 mg x 4)
- NIH Panel recommends use for 5 days or until hospital discharge, whichever comes first If a patient is on supplemental O2 while receiving remdesivir and progresses, treatment course should be completed
- 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

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
  - Agreement expired September 30, 2020
  - Distributed more than 161,000 treatment courses to states, territories and federal agencies

What happens now?

- Updated EUA removes requirement for USG allocation oversight
  - In line with data regarding overall state/territory acceptance of allocations (60%)
  - In line with data regarding overall purchases by hospitals (24%)

- As of October 1, hospitals can purchase directly from AmerisourceBergen in unrestricted amounts

- Cost of drug will NOT change
  - ~$3200/treatment course
  - ~$520/vial

What happens now?

- HHS/ASPR continues to monitor data input by hospitals into HHS Protect

- 160,982 of the initial 500,000 treatment courses secured as part of the June 28th agreement distributed to states

- Remaining treatment courses
  - USG purchasing a portion for Strategic National Stockpile
  - USG purchased portion for NIH
  - Remaining available for commercial sale

- Confident supply will meet current/future U.S. needs

Helpful Links

- www.PHE.gov/remdesivir
  current EUA, allocation dashboard, background information, direct ordering guidance

- NIH COVID-19 Treatment Guidelines

ASPR Remdesivir Task Force Office Hours

- Office Hour will occur today
- Last office hours are Oct 6 and Oct 8

Oct 6
Tuesday 1:00-2:00 pm ET

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

Meeting ID: 161 411 0661 Passcode: 897674

Oct 8
Thursday 1:00-2:00 pm ET

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

Meeting ID: 160 025 6024 Passcode: 284515