

## CABINET FOR HEALTH AND FAMILY SERVICES DEPARTMENT FOR PUBLIC HEALTH

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Steven J. Stack, MD Commissioner

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Hospitals and Clinicians,

The Kentucky Department of Public Health (KDPH) has received a limited quantity of remdesivir from Health and Human Services (HHS) for distribution to hospitals for the treatment of hospitalized patients with severe disease related to COVID-19.

Remdesivir is an experimental anti-viral drug that has activity against SARS-CoV-2 in cell cultures and animal models. It has not been approved by the Food and Drug Administration (FDA) for any indication and is considered an investigational drug. On May 1, based on preliminary data from clinical trials of RDV in patients with severe COVID-19, the FDA issued an Emergency Use Authorization (EUA) for the use of RDV for treatment of COVID-19.

## NIH COVID-19 Treatment Panel Recommendations:

- 1. Based on preliminary clinical trial data the Panel recommends the investigational antiviral agent remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease defined as SpO2 ≤ 94% on ambient air, requiring supplemental oxygen, mechanical ventilation or extracorporeal membrane oxygenation (BI).
- 2. The Panel does not recommend remdesivir for treatment of mild or moderate COVID-19 outside of a clinical trial (AIII).

## KDPH request process for remdesivir:

- Requests for allocations of remdesivir will be made by the attending physician or their designee.
- This request should meet current FDA / Gilead guidelines; no further vetting or triage for use will be conducted by KDPH.
- All allocations of remdesivir will be on a first come, first served basis until supply is exhausted.



- Attending physician or designated authority will complete a remdesivir survey via a ReadyOp form at <a href="https://ky.readyop.com/fs/4hb7/1c7f">https://ky.readyop.com/fs/4hb7/1c7f</a> prior to allocation request.
- Remdesivir (5 or 10 day course) will be shipped direct to the requesting hospital by UPS. Orders placed before
  4pm EST will be shipped same day for next early AM delivery. Requested allocation will be made by the facility
  via a ReadyOp form at the following link: <a href="https://ky.readyop.com/fs/4hbc/4042">https://ky.readyop.com/fs/4hbc/4042</a>
- Upon discharge of patient, complete the patient outcome form at the following link: https://ky.readyop.com/fs/4hb8/48cf

## For additional information:

- NIH: https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/
- FDA: Emergency Use Authorization (EUA) for Emergency Use of Remdesivir. May 1, 2020
- https://www.fda.gov/media/137564/download
- FDA: Fact Sheet for Health Care Providers for Emergency Use Authorization (EUA) of Remdesivir <a href="https://www.fda.gov/media/137566/download">https://www.fda.gov/media/137566/download</a>
- Gilead: Fact Sheet for Patients and Parent/Caregivers for Emergency Authorization (EUA) of Remdesivir <a href="https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-patients-and-caregivers">https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-patients-and-caregivers</a> 01may2020.pdf?la=en&hash=18BE014A3864EB86EE43E87917514525

Thank you for all you are doing to help Kentuckians during this public health emergency.

Sincerely yours,

Steven J. Stack, MD Commissioner