VERMONT
DEPARTMENT OF HEALTH

Health Advisory
May 28, 2020

TO: Vermont Hospitals
FROM: Mark Levine, MD, Commissioner of Health

Remdesivir Allocation to Vermont Hospitals

BACKGROUND:

Remdesivir was issued an Emergency Use Authorization on May 1, 2020 by the FDA for the treatment of coronavirus disease 2019 (COVID-19). The Vermont Department of Health is working with the University of Vermont Medical Center (UVMMC) to safely store and distribute the State's limited federal allocation of Remdesivir. UVMMC's main pharmacy is facilitating the distribution. Once the clinical criteria listed below have been met, clinicians should utilize the attached request form per the outlined protocol described in this advisory to obtain Remdesivir for their patient.

REQUESTED ACTION:

- **Understand the current criteria for consideration of use of Remdesivir:**
  - Positive COVID-19 test
  - O_2 sat ≤ 94%, or the need for supplemental O_2, mechanical ventilation, or ECMO
  - CrCl ≥ 30ml/min
  - AST & ALT ≤ 5x upper limit of normal
  - The use of IV medication is appropriate
- **Complete these requirements prior to administration:**
  1. It must be documented that the patient (or caregiver) received the EUA patient fact sheet and fact sheet has been explained to the patient.
  2. The physician must document that they have read the EUA physician fact sheet.
  3. It must be documented that the patient has been informed about alternative treatments.
  4. It must be documented that the patient has been informed that Remdesivir is not an FDA approved medication.
- **Conduct the following daily laboratory monitoring for patients receiving Remdesivir:**
  - Creatinine and creatinine clearance
  - AST, ALT
  - CBC
  - Electrolytes
- **Prescribe an appropriate dosage of Remdesivir:**
  - **Adults and children weighing > 40kg:**
    - 200 mg IV on day 1,
    - then 100 mg IV daily for up to 10 days
  - **Children 3.5kg - ≤ 40kg (lyophilized powder formulation):**
    - 5mg/kg IV on day 1,

        - then 2.5mg/kg IV daily for up to 10 days.
    - Five days of therapy is recommended for patients not requiring invasive mechanical ventilation or ECMO but can be extended up to ten days if no clinical improvement is seen at day 5. Ten days of therapy is recommended for intubated patients.

- **Discontinue Remdesivir if** AST or ALT ≥ 5x upper limit of normal. Remdesivir may be restarted when transaminase < 5x upper limit of normal. Discontinue Remdesivir if transaminase elevation is accompanied by signs or symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.

- **Hospitals should request Remdesivir through the following process:**
    1. The clinician notifies the clinical pharmacy that a request for Remdesivir is being made. The clinician should:
        a. Verify adequate storage space (12" x 9" x 8" per case) at controlled room temperature for lyophilized powder or refrigeration (36°F - 46°F) for concentrated solution with the ability to monitor temperature for each.
        b. Verify that the shipment can be received 24 hours per day, 7 days per week.
    2. The clinician calls UVMMC main pharmacy at 802-847-2880 to speak with a pharmacist.
    3. A Remdesivir Request Form must be completed in full and faxed to the UVMMC pharmacy at 802-847-4832.
    4. The requesting hospital must secure courier service to transport Remdesivir from the UVMMC pharmacy to their location.
    5. Following receipt of Remdesivir from the UVMMC pharmacy:
        a. Pharmacy must confirm receipt of product and document receipt of same as well as receipt at proper temperature.
        b. Pharmacy must put medication into proper storage area while ensuring appropriate segregation and maintain an inventory of receipt and dispensing.
        c. Pharmacy must segregate storage and develop inventory accountability record.
        d. Clinician must ensure patient selection criteria for treatment and appropriate monitoring is being followed.
    6. Integrate treatment orders into hospital electronic medical record.
    7. Health care facilities and clinicians receiving Remdesivir must track serious adverse events that are considered to be potentially attributable to Remdesivir use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form, or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178). Call 1-800-FDA-1088 for questions. Submitted reports should state, "use of Remdesivir was

under an EUA" at the beginning of the question "Describe Event" for further analysis.

RESOURCES:

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734™)
- Fact Sheet for Patients And Parent/Caregivers Emergency Use Authorization (EUA) Of Remdesivir For Coronavirus Disease 2019 (COVID-19)
- Pharmacy Guide: Remdesivir for Injection (100 mg) Lyophilized Powder

If you have any questions please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: Provides important information for a specific incident or situation may not require immediate action.
Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.