Guidance for Distribution of Remdesivir to Tennessee Hospitals on behalf of the Tennessee Department of Health: Adult and Pediatric Patients

May 26, 2020

- **The Tennessee Department of Health (TDH), acting on a recommendation from the Tennessee Hospital Association (THA), has approved a distribution process for the federal allotment of remdesivir received by the TDH**. Treatment courses will be distributed on a patient specific, first come, first served basis using the criteria described below with oversight by a panel of designated VUMC physicians ("VUMC Physician Panel").

- If a hospital has a patient for whom they think remdesivir may be appropriate ("Requesting Hospital"), they, the patient's treating physician ("Requesting Physician"), or the pharmacy contact for the Requesting Hospital ("Requesting Hospital Pharmacy Contact") should **submit a request to** https://redcap.vanderbilt.edu/surveys/?s=MD4LM9EHY9 or by emailing COVIDRX@vumc.org, if they have difficulties with the RedCap link.

- Upon completion of the RedCap survey, an email with details of the case will be sent from COVIDRX@vumc.org to designated faculty representatives in VUMC infectious diseases, pulmonary/critical care medicine, and physician leadership for case review. If needed, a VUMC representative may contact the Requesting Physician for additional details.

- Based on data from the ACTT-1 clinical trial of remdesivir for treatment of COVID-19 published in the NEJM on the May 22, 2020, the criteria for usage of remdesivir have been updated as noted below.

    - **Remdesivir will be considered for distribution if an ADULT patient (≥ 18 years old) meets all of the following indications, which were adopted by TDH:**

        - Hospitalized with confirmed positive SARS-CoV-2 PCR
        - One of the following clinical situations:
            - Patient on > 4 liters of supplemental oxygen or non-invasive ventilation AND ≤14 days since onset of symptoms *
            - Patient on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO) AND ≤ 7 days since onset of symptoms *
        - Absence of medical conditions that would limit six month survival in the absence of COVID-19
        - Absence of all of the following contraindications to remdesivir:
            - Known hypersensitivity to remdesivir
            - eGFR < 30 ml/min
            - ALT > 5 times the upper limit of normal

** Denotes change in criteria*

- **Remdesivir will be considered for distribution if a PEDIATRIC patient (< 18 years old) meets <u>all</u> of the following indications, which are adopted by TDH:**

    - Hospitalized with confirmed positive SARS-CoV-2 PCR
    - Evidence of lower respiratory tract infection **<u>or</u>** multisystem inflammatory syndrome in children (MIS-C) presenting with fever, laboratory evidence of inflammation, and dysfunction in >2 organs
    - ≤14 days since onset of symptoms
    - Receiving one of the following types of respiratory support:
        - Supplemental oxygen
        - Non-invasive ventilation
        - Invasive mechanical ventilation
        - Extracorporeal membrane oxygenation (ECMO)
    - Absence of medical conditions that would limit six month survival in the absence of COVID-19
    - Absence of all of the following contraindications to remdesivir:
        - Known hypersensitivity to remdesivir
        - eGFR < 30 ml/min
        - ALT > 5 times the upper limit of normal

** Denotes change in criteria*

- The VUMC Physician Panel will determine suitability for remdesivir and provide approval or denial for release of the medication to COVIDRX@vumc.org within a goal of 24 hours of receipt of request. This process will be monitored 8am to 5pm, 7 days per week.

- If release is **approved**, the VUMC pharmacy will contact the Requesting Hospital Pharmacy Contact and update the RedCap database.

    - Doses provided by the VUMC Pharmacy are as follows:

        - **Adults (<u>≥</u> 18 years old)**:
            - Loading dose 200 mg x 1 then 100 mg q24h x 4 days (for a total of 5 days of therapy)
            - <u>If on day 4 of therapy, the patient is on invasive mechanical ventilation/ECMO, the receiving hospital may contact COVIDRX@vumc.org to request an additional five days</u> of remdesivir 100 mg q24h to complete a total of 10 days of therapy. An updated ALT and Cr should be included in the email request.

        - **Children <u>≥</u> 40 kg**:
            - May receive either liquid or lyophilized remdesivir product
            - Loading dose 200 mg x 1 then 100 mg q24h x 4 days (for a total of 5 days of therapy)
            - <u>If on day 4 of therapy, the patient is on invasive mechanical ventilation/ECMO, the receiving hospital may contact COVIDRX@vumc.org to request an additional five days</u> of remdesivir 100 mg q24h to complete a total of 10 days of therapy. An updated ALT and Cr should be included in the email request.

        - **Children 3.5 kg to 39 kg**:
            - Must receive lyophilized remdesivir product
            - Loading dose 5 mg/kg x 1 then 2.5 mg/kg q24h x 4 days (for a total of 5 days of therapy)
            - If on day 4 of therapy, the patient is on invasive mechanical ventilation/ECMO, the receiving hospital may contact COVIDRX@vumc.org to request an additional five days of remdesivir 2.5 mg/kg q24h to complete a total of 10 days of therapy. An updated ALT and Cr should be included in the email request.

    - Logistics for delivery of drug will be coordinated between the Requesting Hospital Pharmacy Contact and the VUMC pharmacy logistics support team.
    - Recommended monitoring while patient is receiving remdesivir includes the following:
        - CBC, CMP, and INR baseline and daily
    - The Requesting Hospital is responsible for the following regulatory processes:
        - Providing the EUA Fact Sheet for remdesivir to patient/caregiver before treatment.
        - Documentation in the clinical record that the EUA Fact Sheet was reviewed with patient/caregiver.
        - Reporting all medication errors and/or serious adverse events to FDA Medwatch within 7 days of event.
        - If the therapy course provided is not completed by the patient, the Requesting Hospital should contact COVIDRX@vumc.org to arrange return of the unused product.

- If release is **denied**, the Requesting Hospital Pharmacy Contact will be notified through an automated message from COVIDRX@vumc.org.
    - The Requesting Physician may contact COVIDRX@vumc.org to request a discussion with a VUMC panel physician to appeal the decision.