The Secretary of the Department of Health and Human Services has declared a public health emergency that justifies the emergency use of remdesivir to treat coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 infection. In response, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the unapproved product, remdesivir, for the treatment of COVID-19.

**Drug Name (and synonyms):** Remdesivir (RDV; GS-5734™)

**Authorized Use:**
- Remdesivir is authorized for use under an EUA only for the treatment of adult or pediatric patients who are admitted to the hospital with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19.
- Severe disease is defined as patients with an oxygen saturation (SpO2) ≤94% on room air or requiring supplemental oxygen, non-invasive/invasive mechanical ventilation, and/or extracorporeal membrane oxygenation (ECMO).

**Criteria for Use at UMass Memorial Health Care:**
- Patient should meet eligibility criteria below. To request remdesivir for any hospital/campus approval may obtained:
  1. Monday- Friday 8:00 AM – 4:30 PM: Restricted antibiotic pager 4963 (long range 508-987-3649)
     - After 4:30 PM, will need to contact the pager on the next day.
  2. Saturday, Sunday and Holidays 8:00 AM – 4:30 PM: Weekend ID Consult – please see On-Call Schedule on the Hub, or contact ID consult at community sites
  3. Weekdays and Weekends: ID attending seeing the patient
     - Text through the Hub Pager Directory, if available. Please include within the page:
       - Call Back Number
       - Remdesivir EUA
       - MRN

- **Criteria for Eligibility:**
  - Any patient with oxygen saturation < 94% on room air, requiring supplemental oxygen or non-invasive/invasive mechanical ventilation associated with COVID-19
  - Positive SARS-CoV-2 test (NAAT or PCR) documented in the system
  - Confirmed COVID, placed on precautions in <= 10 days (as proxy for newly-diagnosed within past 10 days)
  - Patients will not be eligible if:
    - eGFR < 30 mL/min
    - AST/ALT > 5X ULN
    - Enrolled in a clinical trial that does not allow EUA remdesivir (i.e. ACTT-2) Patients may receive up to 2 doses of EUA prior to enrollment in ACTT-2
    - Patient’s attending MD/APP feels that patient has a poor prognosis with multisystem organ failure, with an expected survival < 72 hours.
• Special Populations
  o Pregnancy: There have been no adequate and well-controlled studies of remdesivir use in pregnant women conducted to date. Remdesivir should be used during pregnancy only if potential benefits justify potential risks for the mother and fetus. Pregnant patients may qualify for EUA based upon provider request. They are also eligible to receive compassionate use through Gilead. Must have OB/GYN attending approval in addition to the patient’s attending physician.
  o Pediatrics: Pediatric patients will first be considered for remdesivir through clinical trial. If not willing to participate or ineligible for clinical trial, EUA will be considered based upon provider request. They are also eligible to receive compassionate use through Gilead.

Mechanism of Action:
• Remdesivir is a nucleotide prodrug that is intracellularly metabolized into an analog of adenosine triphosphate that inhibits viral RNA polymerases and has broad spectrum activity against members of the filoviruses (e.g., Ebola virus, Marburg virus, coronaviruses).

Treatment Regimen / Lab Monitoring:
All patients should have eGFR calculated and LFTs drawn prior to first dose. All patients should have LFTs and eGFR monitored daily while receiving drug. Timing of remdesivir will be up to the discretion of the campus and pharmacy hours.

Recommended dosing for adult patients (regardless of invasive mechanical ventilation status):
- Day 1: Loading Dose of remdesivir 200 mg IV in 250 mL 0.9% NS
- Days 2-5: Maintenance dose of remdesivir 100 mg IV in 250 mL 0.9% NS

Treatment Duration:
• An initial treatment course of 5 days will approved. Therapy is approved for 5 days, not 5 doses.
• Treatment course may be shortened if patient improves and is ready for discharge. Patient should not be kept in hospital to complete 5 days if they have substantially improved.
• Treatment for up to 10 days can be considered in mechanically ventilated patients not improving provided there is adequate supply available. Restricted pager must be re-consulted if an additional 5 days is requested.

How supplied / Route of Administration:
• Pharmacy will prepare and dispense remdesivir 200mg and 100mg doses in 0.9% Sodium Chloride 250mL.
• Prepared IV bag Storage: Room Temperature (4 hrs expiration), Refrigerated (24 hrs expiration).
• Remdesivir must be given as an IV Infusion run over 30 to 120 minutes.
• Flush IV line with at least 30 mL 0.9% Normal Saline after infusion.
Possible Side Effects:
- Infusion related reactions: hypotension, N/V, diaphoresis, and shivering.
  - If signs and symptoms of a clinically significant infusion reaction occur, immediately discontinue administration and initiate appropriate treatment.
- GI symptoms: constipation, heartburn, loss of appetite, N/V, loose stool, or upset stomach.
- Other symptoms: headache, itching, unusual feelings in the ear, dizziness, and shaking of the leg and arm.
- ALT and AST elevation.
- Prothrombin time prolongation without any clinically significant change in INR or evidence of hepatic effects. The mechanism of these elevations is currently unknown.

Prohibited Medications / Precautions:
- Convalescent plasma therapy is allowable provided all other requirements are met.
- Remdesivir is contraindicated in patients with known hypersensitivity to remdesivir.
- Consider holding remdesivir if:
  - Development of ALT levels ≥ 5 x ULN
  - Development of eGFR < 30 mL/min
  - Any serious adverse events and Grade 3 and 4 abnormal laboratory results thought to be related to study drug

Patient/Caregiver Education
- The provider must:
  - Document in the chart that a discussion was had with the patient or caregiver regarding the patient factsheet for remdesivir
    - The factsheet is linked to the medication record in the MAR
    - FDA Remdesivir Patient/Caregiver Factsheet
    - FDA Healthcare Provider Factsheet
  - Let the patient/caregiver know this medication is not FDA approved, but it is being used under emergency use authorization by the FDA and there are alternative therapies
  - This is NOT a clinical trial
  - If providing this information will delay the administration of remdesivir to a degree that would endanger the lives of patients, the information must be provided to the patients as soon as practicable after remdesivir is administered

Pharmacy Contacts for Approval of Remdesivir – Approval should only be given between 8:00 AM – 4:30 PM

<table>
<thead>
<tr>
<th>Pharmacy Contact</th>
<th>Weekday Hours</th>
<th>Sat-Sun Hours</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leominster Pharmacy</td>
<td>6a-10p</td>
<td>6a-10p</td>
<td>978-466-2530</td>
</tr>
<tr>
<td>Clinton Pharmacy</td>
<td>8a-4:30p</td>
<td>8a-12p</td>
<td>978-368-3774</td>
</tr>
<tr>
<td>Marlborough Pharmacy</td>
<td>7a-11p</td>
<td>7a-6p</td>
<td>508-486-5999</td>
</tr>
<tr>
<td>University Pharmacy</td>
<td>24/7</td>
<td>24/7</td>
<td>774-441-8800</td>
</tr>
<tr>
<td>Memorial Pharmacy</td>
<td>24/7</td>
<td>24/7</td>
<td>508-994-6356</td>
</tr>
</tbody>
</table>

Modified: 6/25/20
Owner(s): Maureen Campion PharmD and Lisa McCabe, PharmD