

REMEDESIVIR –ELIGIBILITY AND DRUG INFORMATION

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

Authorized Use:

- Remdesivir is now FDA approved 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)
 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
 - MRN
- After 4:30 PM, will need to contact the pager on the next day.
- For ICU patients at the Medical Center and HealthAlliance-Clinton Hospital only:
 - Critical Care attendings may, in consultation with the Pharmacy Department, approve remdesivir in accordance with the criteria listed below without contacting the restricted antibiotic pager (weekdays) or ID (weekends).
 - However, remdesivir must be approved by ID for ICU patients who do not meet below criteria.
- 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 <= 14 days (as proxy for newly-diagnosed within past 14 days)
 - Patients will not be eligible if:
 - AST/ALT > 5X ULN
 - Enrolled in a clinical trial that does not allow remdesivir
 - Patient's attending MD/APP feels that patient has a poor prognosis with multisystem organ failure, with an expected survival < 72 hours.
 - eGFR < 30 mL/min

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- Remdesivir is not cleared by the kidneys, but the IV formulation contains cyclodextrin. This can accumulate in renal failure leading to theoretical toxicity, but is dialyzable.
- ID/restricted antibiotic pager and nephrology should be involved in the discussion of the risks and benefits of remdesivir in patients with eGFR < 30 ml/min.
- Special Populations
 - 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 remdesivir based upon provider request. Must have OB/GYN attending approval in addition to the patient's attending physician.
 - Pediatrics: Pediatric patients will first be considered for remdesivir through clinical trial if available. If not willing to participate or ineligible for clinical trial, remdesivir will be considered based upon provider request.

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 be 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 and otherwise ready for discharge.
- 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.

Repeat Courses of Remdesivir

- Restarting remdesivir after completing a course (greater than 24 hours off therapy) **is not recommended** based upon current evidence.
- There is currently no clinical evidence evaluating a second course of remdesivir for patients with re-infection.

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).

Modified: 11/5/20

Owner(s): Magdalena Slosar-Cheah, MD and Lisa McCabe PharmD

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- 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.
- Dexamethasone is allowed while on remdesivir.
- Remdesivir is contraindicated in patients with known hypersensitivity to remdesivir.
- Consider holding remdesivir if:
 - Development of ALT levels $\geq 5 \times$ 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

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

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