Remdesivir (GS-5734) UTMC Inpatient Restriction Criteria Under Emergency Use Authorization (EUA)

Inclusion Criteria

1. Admitted to a hospital with confirmed COVID-19 infection (see below)
2. Weight >/= 40 kg
3. Male or non-pregnant female adult >/ = 18 years
4. Has laboratory-confirmed SARS-CoV-2 infection as determined by polymerase chain reaction (PCR):
   - PCR positive in sample collected < 72 hours prior to administration.
5. Illness of any duration, and at least one of the following:
   - Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR
   - SpO2 < / = 94% on room air, OR
   - Requiring supplemental oxygen, OR
   - Requiring mechanical ventilation.
6. Women of childbearing potential must agree to either abstinence or use at least one primary form of contraception not including hormonal contraception from the time of presentation of EUA fact sheet through Day 29 of drug treatment.
7. NOT receiving any other COVID-19 medication or intervention
   - Convalescent plasma
   - FDA approved drug being used “off-label” for COVID-19
   - Enrolled in clinical trial/study involving study drug for COVID-19
8. EUA Patients and Parent/Caregivers Fact Sheet and process explained to patient and documented in chart.

Exclusion Criteria/Contraindications

- Serious Adverse Event and Grade 3 and 4 abnormal labs related to remdesivir
- Alanine Transaminase (ALT) or Aspartate Transaminase (AST) > 5 times the upper limit of normal
- Estimated glomerular filtration rate (eGFR) < 30 ml/min (including patients receiving hemodialysis or hemofiltration)
- Pregnancy or breast feeding
- Anticipated discharge from the hospital or transfer to another hospital which does not have remdesivir available within 72 hours
- Allergy to remdesivir
- Metastatic cancer, DNR CC, goals of care discussions/poor prognosis regardless of treatment

Adult Dosing/Duration of Therapy: optimal dosing/duration is currently unknown as drug is investigational

- **NO Invasive Mechanical Ventilation and/or ECMO**
  - 200 mg IV on Day 1 (Loading dose) x 1, followed by 100 mg IV Q24h x 4 days (maintenance dosing) for total of 5 days.
    - If patient does NOT demonstrate clinical improvement, may treat for 5 more additional days for total of 10 days.
Requiring Invasive Mechanical Ventilation and/or ECMO
- 200 mg IV on Day 1 (Loading dose) x 1, followed by 100 mg IV Q24h x 9 days (maintenance dosing) for total of 10 days.

Adverse Drug Reactions
- All Serious Adverse Events and deaths at least potentially related to remdesivir MUST be reported to FDA and Gilead within 7 calendar days.
- Increased risk of transaminase elevations
- Infusion-related reactions: hypotension, nausea, vomiting, diaphoresis, shivering. Discontinue remdesivir and provide supportive care

Place DAILY Labs Orders in CPOE For Remdesivir Monitoring
**Pre-remdesivir treatment labs also required.
- Comprehensive metabolic panel (liver function tests and serum creatinine)
- CBC with differential

UT Process
1) ID attending consult required. ID attending must review inclusion/exclusion criteria and contact Clinical Research Pharmacist or Director of Pharmacy, Acute Care Services, to review case.
2) If remdesivir use approved, ID attending to communicate to patient or caregiver (discuss and provide FDA Fact Sheet for Patients and Parent/Caregivers Emergency Use Authorization). Document in chart that the EUA patient fact sheet was provided and patient/caregiver was informed of alternatives to receiving remdesivir and that remdesivir is an unapproved drug that is authorized for use under EUA.
3) ID Attending to sign paper Remdesivir Inpatient Order and follow instructions on order for sending order to pharmacy.
4) ID attending and pharmacy will monitor patient clinical status daily. **ID attending is responsible for discontinuing/extend duration of remdesivir AND contacting pharmacy about changes to therapy. Remdesivir supply is limited.**