Remdesivir Allocation Criteria

Remdesivir is a very limited resource. To receive remdesivir from the State of South Dakota, health care facilities must meet all federal criteria described in the U.S. Food and Drug Administration EUA Letter of Authorization, Fact Sheet for Healthcare Providers, Fact Sheet for Patients and Parent/Caregiver, as well as State of South Dakota criteria listed below.

I. Mandatory Requirements:
   a. Remdesivir is for treatment of laboratory-confirmed COVID-19 in adults and children hospitalized with severe symptoms.
   b. Remdesivir is authorized only for patients under the care or consultation of a licensed clinician skilled in the diagnosis and management of patient with potentially life-threatening illness and the ability to recognize and manage medication-related adverse events.
   c. All patients must have an estimated glomerular filtration rate (eGFR) determined before dosing; remdesivir is not recommended in adult and pediatric patients (>28 days old) with eGFR less than 30mL/min or in full-term neonates (≥7 days to <28 days old) with serum creatinine greater than or equal to 1mg/dL unless the potential benefit outweighs the potential risk.
   d. Hepatic testing should be performed in all patients prior to starting remdesivir and daily while receiving remdesivir; alanine transaminase (ALT) elevations have been observed.
   e. Serious Adverse Events reporting is required.

II. Treatment Initiation:
   a. A treatment course of 5 days is recommended for adults and pediatric patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation; 200mg loading on day 1 followed by 100mg daily for days 2-5.
   b. A treatment course of 10 days is recommended for adults and pediatric patients requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation; 200mg loading on day 1 followed by 100mg daily for days 2-10.

III. Patient Monitoring Requirements:
   a. The following laboratory tests should be performed prior to receiving remdesivir and daily while receiving remdesivir:
   b. Serum chemistries
   c. Hematology
   d. ALT and AST
   e. Bilirubin
   f. Alkaline phosphatase
   g. Renal function tests (creatinine and creatinine clearance)

IV. Required Facility Plan for Remdesivir Use:
   a. Facilities must also have a documented plan for the use of remdesivir including:
   b. Patient selection criteria
   c. Patient exclusion criteria
   d. Ethics statement

Please contact the South Dakota Department of Health at 605-773-3368 during business hours or at 1-800-592-1861 afterhours to request remdesivir.

06/10/2020