

# 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>U.S. Food and Drug Administration EUA Letter of Authorization</u>, <u>Fact Sheet for Patients and Parent/Caregiver</u>, 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 (creatine 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.