WV Remdesivir Emergency Use Checklist

This form is to be completed by requesting provider and pharmacist and must be submitted to the identified pre-positioned facility also referred to as "hub hospital," prior to remdesivir distribution. This checklist is based on currently available evidence, resources, information, emergency use authorization and expert opinion and is subject to change.

Requesting provider: _____ **Requesting pharmacist:** _____

Requesting provider phone #:_____ **Requesting pharmacist phone #:** _____

Requesting hospital: _____ **Date and time of request:** _____

Patient name: _____ **Patient Date of Birth:** _____

Medical Record Number at requesting hospital: _____

Required Testing Prior to Administration

- ☐ COVID-19 RT-PCR TEST
- ☐ Comprehensive metabolic panel (AST, ALT, bilirubin, alkaline phosphatase, electrolytes, BUN, serum creatinine, eGFR)
- ☐ Complete blood count (CBC) and coags (PT/INR)
- ☐ Vital Signs and Pulse Oximetry

Inclusion Criteria

- ☐ COVID Positive via PCR, positive test date: _____
- ☐ ID Physician Approval from pre-positioned facility: Physician Name:_____
- ☐ Time since symptom onset less than 10 days
- ☐ Approximate symptom onset date: _____

  Please mark symptoms which apply
  - Cough
  - Shortness of breath or difficulty breathing
  - Fever
  - Chills
  - Muscle pain
  - Sore throat
  - GI symptoms
  - Diarrhea
  - Other_____
- ☐ Severe disease (Please mark which apply)
  - Severe disease defined as SpO2 $\leq$ 94% on room air requiring new supplemental and escalating continual oxygen support of: ≥5 L nasal cannula (for those not previously requiring oxygen at baseline) and attempts to wean oxygen supplementation have not been successful
  - Continued need for high flow nasal cannula
  - Mechanical ventilation
  - Extracorporeal membrane oxygenation (ECMO)

Exclusion Criteria

- ☐ Weight < 40kg
- ☐ eGFR < 30 mL/min/1.73m^2 hemodialysis or hemofiltration
- ☐ Liver dysfunction on presentation defined as ALT ≥ 5 times the upper limit of normal at baseline
- ☐ Known hypersensitivity to any ingredient of remdesivir or known infusion reaction to remdesivir
- ☐ Life expectancy less than six months prior to COVID diagnosis

It MUST be documented in the patient's medical record prior to administration of remdesivir that informed consent process took place in which the risks, benefits, unknowns of the proposed treatment, and reasonable treatment alternatives were discussed with patient/surrogate and their acceptance or refusal documented **and the patient/surrogate has been provided the following:**

- ☐ The Fact Sheet for Patients and Parents/Caregivers (https://www.fda.gov/media/137565/download)
- ☐ Informed of alternatives to receiving remdesivir
- ☐ Informed that remdesivir is an unapproved drug authorized for use under EUA

If a serious and unexpected adverse event occurs and appears to be associated with the use of remdesivir, the prescribing health care provider and/or the provider's designee shall complete and submit a MedWatch form to FDA using one of the following methods:

• Complete and submit the report online: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

Or

• Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or

• Call 1-800-FDA-1088 to request a reporting form

Conditions of Authorization for the use of remdesivir from the State of West Virginia.

- You attest that all information in this submission is true to the best of your ability.
- You agree to comply with the State of West Virginia Remdesivir Protocol
- You agree to complete and submit a MedWatch form for all adverse reactions and serious adverse or unexpected adverse events that are considered to be potentially attributable to remdesivir as directed by the Emergency Use Authorization issued by the FDA for remdesivir within 7 calendar days from the onset of event (refer to EUA for reportable events).
- You agree to submit all serious adverse events and all medication errors to the State of WV by reporting the event(s) to the West Virginia Poison Center at 1-800-222-1222 as soon as possible but no later than three days after time of error or adverse reaction.

_____ _____

Requesting Provider Signature Date Requesting Pharmacist Signature Date

To be completed by Pre-positioned facility/Hub Hospital

_____ _____

ID Physician Name Date Pharmacist Name Date