Appendix II
WV Remdesivir Protocol

Remdesivir Flowsheet (1 page)

Remdesivir Emergency Use Checklist (2 pages)

Remdesivir Distribution Checklist

Chain of Custody Form for Transfer of WV Remdesivir Assets

Remdesivir Utilization Tracking Requirements Hub Hospital and Receiving Hospital

WV SNS Remdesivir Supply

Remdesivir Emergency Use Flowsheet

(For use at facilities requesting remdesivir)

Based upon clinical judgment, the WV Remdesivir Protocol, and WV Remdesivir "Emergency Use Checklist," a patient is deemed to meet criteria for emergency use authorization of remdesivir and the facility can comply with requirements set forth in the WV Remdesivir Protocol and Emergency Use Authorization

Call WV Coronavirus Hotline 1-800-887-4304

Hotline ensures requesting facility is on pre-approved pharmacy distribution list and then refers to Infectious Diseases (ID) physician at one of four regional pre-positioned facilities/hub hospitals

ID consult and/or discussion to occur with requesting provider and ID contact at pre-positioned facility. If ID physician deems patient meets criteria for emergency use authorization, approval will be sent by ID physician to pharmacy contact at pre-positioned facility/hub hospital

Completed Remdesivir Emergency Use Checklist sent to pre-positioned facility/hub hospital pharmacy prior to distribution

Once Emergency Use Checklist is received, pharmacy to initiate process of remdesivir distribution to requesting facility (see separate "Remdesivir Distribution Checklist")

This is based on currently available information and resources and is subject to change

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

WV SNS Remdesivir Supply
Pre-Positioned Facility (aka Hub Hospital) Remdesivir Distribution Checklist

To be reviewed with the SNS Hospital Pharmacist or designee prior to release of remdesivir vials (see WV Remdesivir Protocol, Part II Distribution). Requesting pharmacist must speak directly to a pharmacist in pre-positioned facility.

- □ Verified that patient from requesting facility has been approved.
  - Remind requesting physician that a hard copy of the emergency use checklist is needed before distribution. ID physician at Hub Hospital must provide documentation within next business day.
- □ Verified if vials needed for 5-day or 10-day course. (**Unused vials MUST be returned to Hub.**)
- □ Estimated time of arrival of the receiving facility's courier and the name of the person the drug is to be given to.
- □ Assurance that the receiving hospital will maintain the cold-storage supply chain for the drug en route.
  - Decide who will supply the cold storage transport box/carrier ahead of time
- □ Assurance that a pharmacist will be at the receiving facility to receive the drug and promptly store under refrigeration in the pharmacy (at no time will drug be allowed to be dropped off to a hospital front desk or non-pharmacy employee).
- □ Assurance that the receiving hospital has on-site facilities to compound sterile intravenous solutions.
- □ Assurance that the pharmacy agrees to assist the care provision team with reporting of administration errors and adverse drug reactions.
  - Per the EUA, adverse drug reactions are to be reported to FDA MedWatch within 7 days of event onset.
  - In addition, administration errors and serious adverse drug reactions are to be reported to the West Virginia Poison Center (1-800-222-1222) as soon as possible, but no later than 3 days after time of error or adverse reaction.
- □ Double checking that the pharmacist at the receiving hospital has no questions about EUA compounding and dosing requirements.
- □ A system is in place so the patient will not be charged for the drug.
- □ Hospital order sets are in place to allow the drug orders to be processed in the hospital order system.
- □ The pharmacist at the facility receiving the drug will inform the nurse administering the drug about administration requirements per the FDA Remdesivir EUA and to monitor for infusion reactions.

Best practices to share:

- Write administration guidelines into the order set
  - Do not administer in the same line as any other medications or solution other than saline
  - Observe for infusion related reactions (Hypotension, nausea, vomiting, diaphoresis, and shivering)
- Agreed upon infusion time is 120 mins
  - EUA allows 30 to 120 mins but 120 minutes selected to decrease risk of infusion-related reactions.
- Do not send through tube system

Pharmacist Name_____ Date/Time_____

Receiving Hospital Name_____ Pharmacist Name_____

West Virginia Center for Threat Preparedness

COVID-19 Response

CHAIN OF CUSTODY

Use a new sheet for receiving and returning

	Pre-Positioned Facility aka "Hub Hospital"	Receiving Facility
Pharmacist Name Providing the Remdesivir to the Courier		
Hospital Name		
Name of Requesting Facility Pharmacist		
Courier Name and ETA		
Pharmacist Phone:		
Date and Time Request Received		

DESCRIPTION OF PROPERTY:

MEDICATION		LOT	EXPIRATION	# of Vials
Remdesivir IV Soln.	100 mg vials			

Signatures	Date & Time
Hub Pharmacist providing the remdesivir:	
Courier picking up the remdesivir:	
Pharmacist receiving remdesivir from courier:	

IF RETURNING VIALS TO HOSPITAL HUB (Use the signature boxes below)

Signatures	Date & Time
Facility Pharmacist providing remdesivir to courier:	
Courier leaving remdesivir with Hub Pharmacist:	
Hub Pharmacist receiving remdesivir from courier:	

To be completed when transfer of WV Remdesivir Assets occurs

WV SNS Remdesivir Supply
Utilization Tracking

Pre-Positioned Facility (aka Hub Hospital)

All of the following documents are to be stored at Hub Hospital and must be retrievable upon request from the State SNS Program designee. Electronic storage is allowable as long as documents can be promptly printed when needed or sent via secure e-mail.

1. Chain-of-Custody form signed when medication was delivered by the state of WV.

For each distribution of a course of remdesivir:

2. Copy of Hub Hospital pharmacist signed Pre-Positioned Facility (aka Hub Hospital) Remdesivir Distribution Checklist for all courses sent to another facility or used by Hub Hospital's own facility.

3. Copy of signed ID Consult Clinical Approval
   If request is made with one business day of the consult the signed form can be provided the day following the initial request

4. Copy of signed WV Remdesivir Emergency Use Checklist approval form from the requesting/receiving facility (includes Hub Hospital if used at Hub facility) – both physician and pharmacist signature must be present
   Note, should be received prior to making arrangements for the courier to pick up the remdesivir.

5. Copy of Chain-of-Custody form sent with the vials to the receiving hospital.
   If being use at Hub Hospital, write "USED INTERNALLY" across the top of the Chain-of-Custody form; the remaining pieces of the form do not require completion

6. If remdesivir used within the facility, signed attestation sheet that all doses of remdesivir went to the approved patient or back into the state asset allotment.

7. Tracking sheet with information on the number of courses used and the number of remaining vials – this must be kept up-to-date in real time.
   If use is for a patient at Hub Hospital, all vials for the course should be checked out at one time.

Receiving Facility

All of the following documents are to be stored at facility receiving remdesivir and retrievable upon request from the State SNS Program designee. Electronic storage is allowable as long as documents can be promptly printed when needed or sent via secure e-mail.

1. Copy of signed facility physician WV Remdesivir Emergency Use Checklist (signed by facility physician and pharmacist)
2. Chain-of-Custody form signed when medication was handed to the courier which includes the second signature when the courier delivered to the facility hospital pharmacist
3. Chain-of-Custody form with pharmacist to courier and courier to Hub pharmacist signature when vials are sent back to the Hub Hospital due to patient discharge/death/other
4. Signed attestation sheet that all doses of remdesivir went to the approved patient or back to the Hub Hospital.