

Expanded Use for Remdesivir

Department of Veterans Affairs (VA) Center for Medication Safety, Veterans Health Administration (VHA) Pharmacy
Benefits Management Services
March 2020

Background

Many Veterans with multiple co-morbid conditions are at risk for increased morbidity caused by the COVID-19 virus. Supportive measures remain the treatment standard however investigational antiviral treatment is being considered as an option in patients with increased morbidity through the Gilead Expanded Access Program. The Office of Research and Development will present a webinar on expanded access of investigational drugs in VA, including information on the expanded access program for remdesivir. However, until that information is presented and in addition, Pharmacy Benefits Management Services (PBM) is providing brief guidance to VISN Pharmacy Executives, Chiefs of Pharmacy, and other VA facility leaders. Listed below are steps that should be taken by sites to ensure a timely expanded use request and approval process.

Steps for requesting Expanded Use of Remdesivir

1. **Patient Identification** – review information below to ensure the patient will be allowed compassionate use according to the criteria established by the company below

Key inclusion criteria

- Hospitalization
- Confirmed SARS-CoV-2 by PCR
- Mechanical ventilation

Key exclusion criteria

- Evidence of Multi-organ failure
- Pressor requirement to maintain blood pressure
- ALT levels > 5 X ULN
- Cr Clearance <30 mL/min or on renal replacement therapy
- Remdesivir cannot be used in conjunction with other experimental antiviral agents for COVID-19
- Pregnancy or breastfeeding

2. **Contacting manufacturer:** Providers/pharmacist should contact Gilead using this link <https://rdvcu.gilead.com/> and obtain the emergency IND forms from the [FDA website](#)

- FDA contact number M-F day (8:00-4:30): 301-796-3400
- After hours / weekends: 866-300-4374

3. **Contact your facility IRB immediately**

4. **Contact PBM** to let them know that you have a patient and when the request was sent so PBM can follow-up with the company if needed and confirm request has been received.

5. For additional questions: PBM contacts: Fran Cunningham (fran.cunningham@va.gov) or Jennifer Zacher (jennifer.zacher@va.gov), ORD contacts: Karen Jeans (C.Karen.jeans@va.gov) or Steve Bartlett (stephen.bartlett2@va.gov)