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May 14, 2020

**TO:** Acute Care Hospitals Licensed Pursuant to N.J.A.C. 8:43G

**FROM:** Judith M. Persichilli, R.N., B.S.N., M.A.  
Commissioner

**SUBJECT:** Use of Remdesivir in Treatment of Patients with COVID-19

On May 1, 2020, the U.S. Food and Drug Administration (FDA) [issued an emergency use authorization](#) (EUA) for the investigational antiviral drug remdesivir (Gilead) for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease ([ABC](#); [FDA](#)). This approval was based on a National Institute of Allergy and Infectious Diseases (NIAID) sponsored adaptive, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of novel therapeutic agents in hospitalized adults diagnosed with COVID-19. The trial was limited to adults but the EUA allows for treatment of children (age not specified) ([ClinicalTrials.gov](#)).

Following issuance of the EUA, Gilead donated 607,000 doses of remdesivir to the U.S. government for distribution to hospitals for the intravenous infusion treatment of in-patients with a diagnosis of COVID-19 disease. The Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services was tasked to distribute the drug to hospitals in states over a 6-week period. On May 5, the Office notified states, including New Jersey, to receive the initial distribution of remdesivir.

On May 6, the New Jersey Department of Health (NJDOH) informed ASPR that it had decided to receive all future shipments of remdesivir to the State for distribution to hospitals, as determined by NJDOH. The shipped formulation requires cold chain management throughout the distribution process. The size of the subsequent weekly shipments is currently unknown. The product is scarce and the number of eligible patients based on EUA criteria alone may outpace the supply available to hospitals, so hospitalization data will inform the distribution of remdesivir to facilities. Every hospital in the state will be allocated some drug supply based on their recent number of hospitalized patients. Going forward, additional distribution to the state, and then equitable allocations

to hospitals will be based on the burden of disease in the state, as determined by regular assessment of hospitalizations, and by any emerging federal guidance.

The drug must only be administered to eligible patients, as defined in the [FDA Provider Fact Sheet](#):

*Treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children hospitalized with severe disease. Severe disease is defined as patients with an oxygen saturation (SpO<sub>2</sub>) ≤ 94% on room air **or** requiring supplemental oxygen **or** requiring invasive mechanical ventilation **or** requiring ECMO. Specifically, remdesivir is authorized only for the following patients who are admitted to a hospital and under the care or consultation of a licensed clinician (skilled in the diagnosis and management of patients with potentially life-threatening illness and the ability to recognize and manage medication-related adverse events: a) adult patients for whom use of an IV agent is clinically appropriate; b) pediatric patients for whom use of an IV agent is clinically appropriate.*

As remdesivir is available under an EUA, there is no assurance that this pharmaceutical will convey benefit. Hospitals should consider modifications to patient consent forms to clearly convey the EUA and to promote informed shared decision-making.

The New Jersey Department of Health requires hospitals to report information on a daily basis through a designated portal. In section III of the EUA, Conditions of Authorization, medication usage data tracking and reporting are required of all hospitals that receive remdesivir. Data required under the EUA include:

- 1) Serious adverse events
- 2) Dispensement of remdesivir (i.e. lot numbers, quantity, receiving site, receipt date)
- 3) Product storage
- 4) Patient information (e.g. patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

Facilities shall also report to the New Jersey Department of Health:

- 1) Additional patient demographics (e.g. patient sex, race/ethnicity)
- 2) Insurance payor
- 3) Patient outcomes after five-day recommended course of treatment
- 4) Unused inventory of remdesivir. Except facilities shall reserve the pharmaceutical supply necessary to complete the full recommended treatment course for each patient started on remdesivir treatment.

On May 10, a statewide Remdesivir Advisory Committee (RAC), a multi-disciplinary sub-committee of the NJDOH COVID-19 Professional Advisory Committee (PAC), met to develop guidance for use of remdesivir under the EUA. The professionally,

demographically, and geographically diverse membership of the RAC included pediatricians, critical care specialists, pulmonary physicians, and infectious disease physicians. It was chaired by a member of the NJDOH COVID-19 Professional Advisory Committee (PAC). The RAC was charged to develop the appended statewide guidance for the use of remdesivir in hospitalized patients, taking into consideration the exclusion and inclusion criteria of the NIAID clinical trial, the specifics of the EUA, the EUA provider fact sheet, and any available protocols established by hospitals participating in any of the Gilead remdesivir clinical trials. The RAC guidance should inform usage of the drug in your hospital, but is not a substitute for individualized clinical decision-making by treating physicians following hospital policies for use of restricted drugs. The recommendations of the RAC for use of the drug are included in the Appendix.

## Appendix

### Recommendations

1. The Remdesivir Advisory Committee (RAC) recommends that patients (children and adults) receive only a 5-day course of treatment, beginning as early in the disease course as possible (e.g.  $\leq 10$  days of symptoms), preferably before a patient requires mechanical ventilation.
2. The EUA permits the use of remdesivir in pregnant women but "... should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus". ([FDA Provider Fact Sheet](#))
3. Treating physicians should adhere to the requirements of the EUA and to their hospital guidelines and policies in using restricted drugs.
4. For allocation within facilities among eligible patients, the RAC recommends that remdesivir be allocated on a first-come, first-served basis.

### Inclusion Criteria:

1. All ages are eligible for use of remdesivir.
2. Patients must be hospitalized with symptoms suggestive of COVID-19 infection.
3. Generalized hospital consent to treatment is sufficient for the use of remdesivir under the EUA.
4. The patient should have suspected or laboratory-confirmed SARS-CoV-2 infection.
5. The patient may have illness of any duration, and at least one of the following:
  - o Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR
  - o SpO<sub>2</sub>  $< / = 94\%$  on room air, OR
  - o Requiring supplemental oxygen, OR
  - o Requiring mechanical ventilation.

### Exclusion Criteria:

1. Any patient previously receiving remdesivir in a clinical trial or in the expanded access (compassionate use) program.
2. Alanine Transaminase (ALT) or Aspartate Transaminase (AST)  $> 5$  times the upper limit of normal.
3. Estimated glomerular filtration rate (eGFR)  $< 30$  ml/min (including patients receiving hemodialysis or hemofiltration).
4. Anticipated discharge from the hospital within 72 hours.
5. Allergy to remdesivir.

  

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