



State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

June 26, 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: Remdesivir Distribution, Reporting, and Use for Treatment of Patients with COVID-19

As New Jersey enters Phase 2 of reopening, the New Jersey Department of Health has reassessed the distribution of Remdesivir in light of current needs and usage of this scarce pharmaceutical to-date. Enclosed is the current policy on the Distribution of Remdesivir Supplies to New Jersey Hospitals.

Key changes since the letter from NJDOH dated May 14, 2020:

- Due to adequate supplies of donated remdesivir relative to hospitalizations, NJDOH will now distribute remdesivir once per week, as needed. The remainder will be stored by NJDOH for future distributions.
- Reporting by facilities is now required twice weekly (by 10PM on Mondays and by 10PM on Thursdays) through the NoviSurvey available here: <http://healthsurveys.nj.gov/NoviSurvey/n/zz2cd.aspx>.
- The Remdesivir Advisory Committee reaffirmed its recommendations for use in eligible patients.

Questions regarding Remdesivir-related reporting and distribution should be sent to COVID.Pharma@doh.nj.gov. If an urgent need for additional remdesivir supplies arise, please contact COVID.Pharma@doh.nj.gov.

Distribution of Remdesivir Supplies to New Jersey Hospitals

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I. Background

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](#)).

Preliminary Evidence of Effectiveness

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 allowed for treatment of children (age not specified) ([ClinicalTrials.gov](#)).

As published in [NEJM](#) and reported in [STAT News](#), “The preliminary data showed that the time to recovery was 11 days on remdesivir compared to 15 days for placebo, a 31% decrease. The mortality rate for the remdesivir group was 8%, compared to 11.6% for the placebo group; that mortality difference was not statistically significant.”

Meanwhile, a separate Gilead study demonstrated that “...patients receiving a 10-day treatment course of remdesivir achieved similar improvement in clinical status compared with those taking a 5-day treatment course (Odds Ratio: 0.75 [95% CI 0.51 – 1.12] on Day 14)” ([Gilead](#)).

Distribution to States

Following issuance of the EUA, Gilead donated 607,000 doses to the U.S. government for distribution to hospitals for the treatment of in-patients with a diagnosis of severe COVID-19 disease. The Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) was tasked to distribute the drug to hospitals in states over a 6-week period. On May 5, the Office notified states, including NJ, that these select states would receive the initial distribution of remdesivir. ASPR has not stated its specific criteria for allocation to states but has stated that its assessment will be based on ethical (equity) and clinical principles (Dr. John Redd, telephone call, May 5th).

The initial distribution was determined by ASPR, but, for subsequent distributions, states were given the option of (1) continued direct distribution from ASPR to hospitals or (2) distribution from a state agency to hospitals as determined by the state. On May 6, NJDOH informed ASPR that it has decided to receive all subsequent shipments of the drug (including the shipment planned for May 7) for distribution to hospitals, as determined by NJDOH.

Development and Revision to Distribution Methodology

The NJDOH COVID-19 Professional Advisory Committee (PAC) met on May 6, May 7, and May 11 to discuss the best approach to distribute the limited supply of the drugs that will be made available to NJ. Based on those discussions and limited remdesivir data at that time, NJDOH proposed the below scarcity situation (supply<demand) methodology to distribute its allocation of remdesivir over the subsequent six weeks. However, as hospitalizations continued to decline in NJ and remdesivir-specific usage and other data demonstrated diminished demand relative to expectations, a revision to the methodology was necessary to account for excess remdesivir supply relative to demand. Both the NJDOH Professional Advisory Committee and its subcommittee, the Remdesivir Advisory Committee, recommended and informed the change in policy. This methodology is subject to further change with the emerging evidence and policymaking at state, regional, and federal levels.

Week 1 Distribution

The Week 1 remdesivir shipment included (1) 94 cases shipped directly by ASPR to St. Joseph’s and St. Mary’s hospitals, based on an initial decision by ASPR; and, (2) 179 cases that were delivered to NJDOH as of May 12. Each case includes 40 100-mg. vials of the donated drug (HHS). A 5-day course requires six vials and a 10-day course requires 11 vials. The product is scarce and the number of eligible patients based on EUA criteria alone may exceed supply, so ethical principles, data, and clinical judgments will inform the distribution of remdesivir to facilities and the use of remdesivir to eligible patients within facilities. Each case has enough product to treat ~3-7 patients depending on the treatment course of each patient. Cold chain management is required for the liquid formulation throughout the distribution process.

Initially Prioritize Research Participants

1. St. Joseph’s and St. Mary’s hospitals have agreed for most of the cases allotted to them by the federal government in Week 1 to be reallocated in accordance with this policy.
2. Some of the Week 1 shipments were distributed to the hospitals involved with Gilead’s clinical trials or were an expanded access site (Appendix B). These patients and institutions made relevant contributions to the evidence basis for remdesivir.
3. After Week 1, prior or ongoing participation by a hospital in a clinical trial or the expanded use (compassionate care) program will not factor into allocation decisions.

Supply Chain Management

The NJDOH in conjunction with the NJOEM is responsible for managing the distribution and monitoring the State’s supply of remdesivir. Given the differing expiration dates and shelf life of the liquid formulation (March 2022) and the lyophilized formulation (April 2023), the Department shall distribute the liquid formulation of remdesivir first and the powder formulations of remdesivir second.

III. Methodology for Distribution to Hospitals when Hospitalizations Exceed Supply

This methodology applies when either:

- (1) the statewide total number of COVID-19 positive + COVID-19 PUI (persons under investigation) is greater than the total number of patients that can be treated with Remdesivir available in New Jersey, or
- (2) NJDOH has fewer cases of remdesivir available to distribute to facilities than the number of eligible facilities in NJ.

Given remdesivir's limited supply and allocation to NJ, variability in number of COVID-19 patients in initial hospitalizations between facilities, and variability of disease severity in COVID-19 patients, NJDOH must consider disease burden, the universe of eligible patients, expert guidance on best practice usage of remdesivir, and ethical principles in determining the amount of drug each facility will receive.

Eligibility

1. Given the Scope of Authorization as defined in the EUA ("Remdesivir is administered in an in-patient hospital setting"), remdesivir will only be distributed by NJDOH to licensed hospital facilities.
2. Alternate care sites, ambulatory surgical centers, and non-hospital-based practices will not be eligible for distribution at this time.

Promote Equitable Access

1. During each DOH distribution, all acute care hospitals in the state caring for patients with COVID-19 infection will receive some (one or more cases) of the limited supply available to NJ.
2. This represents both the value of patients at each facility in NJ and a deterrent against privileged patients "shopping" for a facility that has this product.
3. Supply already on hand at the facility will count towards the facility's share of any distribution.

Data to Inform Fair Allocation

1. Remdesivir will be distributed to hospitals proportionally, based on the most recent census of COVID-19 positive and persons under investigation (PUI) on the designated weekly distribution day.
2. As per Sections I and J in the EUA and the memos from NJDOH to facilities dated May 12 and June 22, hospitals will provide specified information to the NJDOH on a twice weekly basis (Monday and Thursday).
 - a. NJDOH will monitor equitable availability of remdesivir. This may be used as a "tie breaker." This will be assessed through evaluation of the extent of disparities measured by the data metrics reported to NJDOH.
 - b. Hospitals will also provide information to Department of Health and Human Services (HHS) as required for the HHS determination of the allocation to the state.
 - c. Misuse may negatively affect qualification for future allocations.
 - d. Failure to report data may negatively affect qualification for future allocations.
3. Patients admitted or transferred to a facility allocated remdesivir are not guaranteed access to this scarce pharmaceutical.
4. Facilities shall reserve the pharmaceutical supply necessary to complete the full recommended treatment course for each patient started on remdesivir treatment.

5. Facilities shall report any unused inventory of donated remdesivir (e.g. due to a facility-level drug surplus or a patient withdrawal mid-treatment). Unused inventory shall count towards the facility's next proportional allocation.
 6. If hospitalizations exceed supplies at a facility and the facility believes that additional supply will be needed to meet anticipated patient remdesivir needs, additional cases may be requested from NJDOH by contacting COVID.Pharma@doh.nj.gov.
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IV. Methodology for Distribution to Hospitals when Supply exceeds Hospitalizations

This is the default methodology.

NJDOH must consider disease burden, the universe of eligible patients, expert guidance on best practice usage of remdesivir, and ethical principles in determining the amount of drug each facility will receive. Given the quantity of unused inventory at facilities, recent declines in hospitalizations, geographic variation in disease incidence over time, knowledge that the Gilead donation is limited, the expectation that COVID-19 may surge again in fall 2020, and the evolving science on remdesivir best practices, the establishment of a state reserve of remdesivir is appropriate.

Eligibility

1. Given the Scope of Authorization as defined in the EUA ("Remdesivir is administered in an in-patient hospital setting"), remdesivir will only be distributed by NJDOH to licensed hospital facilities.
2. Alternate care sites, ambulatory surgical centers, and non-hospital-based practices will not be eligible for distribution at this time.

Promote Equitable Access

1. Remdesivir supplies will be available at each acute care hospital in the state.
2. This represents both the value of patients at each facility in NJ and a deterrent against privileged patients "shopping" for a facility that has this product.
3. Supply already on hand at the facility will count towards the facility's share of the distribution.

Data to Inform Fair Allocation

1. Once per week, the Department of Health will distribute enough cases of remdesivir to ensure each facility has enough in inventory to treat a minimum of 10 patients using a 5-day course (total of 60 vials), based on their most recent reported census of COVID-19 positive + PUI (persons under investigation) and their existing inventory of remdesivir.
 - a. Facilities shall report any unused inventory of donated remdesivir (e.g. due to current facility-level drug supply or a patient withdrawal mid-treatment). Unused inventory shall count towards the facility's next allocation (e.g. if a facility already has enough on-hand to treat at least 10 hospitalized COVID-19 positive and PUI patients, no additional cases will be sent to the facility that week).
 - b. Each case has 40 vials of Remdesivir, which is sufficient to fully treat 6 patients for a 5-day course (assumes 6 vials per patient).
 - c. The remainder of cases shall be stored by NJDOH for future distribution.

2. Patients admitted or transferred to a facility allocated remdesivir are not guaranteed to receive this scarce pharmaceutical.
 3. The attending physician of record has the responsibility to determine if the patient will benefit from receiving remdesivir.
 4. Facilities shall reserve the pharmaceutical supply necessary to complete the full recommended treatment course for each patient started on remdesivir treatment.
 5. As per Sections I and J in the EUA and the memo from NJDOH to facilities dated June 22, hospitals will provide specified information to the NJDOH on a twice weekly basis (Monday and Thursday).
 - a. NJDOH will monitor equitable availability of remdesivir.
 - b. Hospitals will also provide information to Department of Health and Human Services (HHS) as required for the HHS determination of the allocation to the state.
 - c. Misuse may negatively affect qualification for future allocations.
 - d. Failure to report data may negatively affect qualification for future allocations.
 6. If hospitalizations exceed supplies at a facility and the facility believes that additional supply will be needed to meet anticipated patient remdesivir needs, additional cases may be requested from NJDOH by contacting COVID.Pharma@doh.nj.gov.
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V. Allocation of Remdesivir within Facilities

1. Standing Pharmacy and Therapeutics Committees (P&T) within individual facilities and existing hospital policies will guide allocation of remdesivir supplies within facilities. This is consistent with the use of convalescent plasma and other limited drug supplies within hospitals.
2. The product 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 (SpO₂) ≤ 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."
3. Remdesivir Advisory Committee guidance, when adopted by NJDOH, should inform usage, but is not a substitute for individualized clinical decision-making.

a. Minimum Standard of Care

1. All hospitals receiving remdesivir for use under the EUA must adhere to the Conditions of Authorization in the EUA.
2. Rights of patients admitted to general hospitals are retained, including those enumerated in N.J.S.A. 26:2H-12.8. Among these are rights pertaining to nondiscrimination, informed consent, human research, facility transfer, and confidentiality.

b. Remdesivir Advisory Committee

1. The NJDOH appointed a Remdesivir Advisory Committee (RAC)

2. Functions:
 - a. Develop statewide recommendations for the use of remdesivir 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.
 - b. Identify discrete criteria for a patient to be considered in NJDOH’s remdesivir distribution algorithm.

3. Membership:
 - a. The NJDOH appointed a Remdesivir Advisory Committee (RAC) which is a sub-committee of the COVID-19 Professional Advisory Committee (PAC).
 - b. The members of the RAC include pediatricians, critical care specialists, infectious disease physicians and others and is chaired by a member of the COVID-19 PAC.
 - c. Charge: Develop statewide recommendations for the use of remdesivir in hospitalized patients, taking into consideration the exclusion and inclusion criteria of the NIAID clinical trial (Appendix A), 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.
 - d. Remdesivir Advisory Committee recommendations, when endorsed by NJDOH, should inform usage, but is not a substitute for individualized clinical decision-making by the attending physician of record following hospital policies for use of restricted drugs.

4. Timeline:
 - a. The RAC met virtually on May 10, 2020 and developed guidance to the NJDOH.. The recommendations were integrated into a memo from NJDOH to hospitals that was issued May 14, 2020.
 - b. The RAC reconvened on June 4, reviewed their past recommendations and recent literature, and opted to retain their recommendations.
 - c. The RAC will address any future clinical issues that arise with the use of remdesivir under the EUA.

5. Key questions for the RAC to consider include, but are not limited, to:
 - a. Use by minors and pregnant women who were excluded from the NIH trial but may be eligible under the EUA. The RAC is to consider values of nondiscrimination, harm reduction, and equity.
 - b. Efficacy and effectiveness of 5-day course and of 10-day course, to inform whether a standard of greatest good for the greatest number should be applied to allocation.

c. Recommendations of the Remdesivir Advisory Committee (RAC)

(As established May 10, 2020 and reaffirmed June 4, 2020)

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.

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:
6. Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR
7. SpO2 \leq 94% on room air, OR
8. Requiring supplemental oxygen, OR
9. 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.

VI. Reporting Requirements

As communicated to acute care hospitals licensed pursuant to N.J.A.C. 8:43G in letters from NJDOH dated May 14, 2020 and June 26, 2020, the New Jersey Department of Health requires hospitals to report information on a twice weekly basis (by Mondays at 10PM and by Thursdays at 10PM) through a designated portal: <http://healthsurveys.nj.gov/NoviSurvey/n/zz2cd.aspx>. The portal designated for this purpose is a secure NoviSurvey administered by NJDOH. In section III of the EUA, Conditions of Authorization, medication usage data tracking and reporting are required of all hospitals that receive remdesivir. Under this distribution policy, facilities report to the New Jersey Department of Health:

- 1) Patient demographics (e.g. patient name, sex, age, race/ethnicity, and number of doses administered per patient)
- 2) Insurance payor
- 3) 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.