

Ethical Allocation Framework for Emerging Treatments of COVID-19

Introduction

The foundational goal of this document is to develop a broad, fair, and equitable framework for how to allocate scarce, emerging COVID-19 treatments. This document addresses remdesivir (RDV) in particular, but the ethical goals of this allocation framework should inform allocation of other scarce treatments as they become available. Information in this document (such as the clinical criteria for eligibility and dosage) that apply specifically to RDV are subject to change as more data emerges on its use and effectiveness.

A committee process to determine ethical allocation frameworks is recommended by the U.S. Department of Health and Human Services.¹ An Ethical Allocation Committee was formed with the goal of developing ethical allocation guidance for emerging treatments of COVID-19. This document was developed from the recommendations of the Ethical Allocation Committee, which included members from the Pennsylvania Department of Health, Human Services, and Emergency Management Agency; physicians trained in critical care, infectious disease, geriatrics, pediatrics, and internal medicine; hospital pharmacists; experts in allocation frameworks and ethics; and stakeholders representing Pennsylvanians with disabilities, mental illness, and Medicaid beneficiaries.

Allocation of Remdesivir to Healthcare Facilities

The Department of Health has distributed RDV to acute care healthcare facilities and will continue to distribute RDV as additional supplies become available. The Department of Health has devised a formula to ensure equitable allocation to all acute care healthcare facilities.

$$\frac{\text{Total number of COVID inpatients}}{7 \text{ days}} + \frac{\text{Total number of COVID vent patients}}{7 \text{ days}} = \text{raw score}$$
$$\frac{\text{individual raw score}}{\sum \text{all raw scores}} = \text{Allocation Score}$$

Distribution of RDV to acute care healthcare facilities has been proportional to the total number of COVID-19 positive patients admitted to the facility. These details are subject to change based on emerging data. The methodology of allocation of RDV to acute care healthcare facilities was developed by the Department of Health and is outside the scope of the Ethical Allocation Committee's charge.

Ethical Goals of Allocation Framework for Emerging Treatments

Consistent with accepted standards during public health emergencies, and the [Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines](#), this framework is designed to achieve the following ethical goals:

1. To safeguard the public's health by allocating scarce treatments to maximize community benefit.
2. To create meaningful access for all patients. All patients who meet clinical eligibility criteria should have a chance to receive treatment.
3. To ensure that no one is excluded from access based on age, disability, religion, race, ethnicity, national origin, immigration status, gender, sexual orientation, or gender identity and to ensure that no one is denied access based on stereotypes, perceived quality of life, or judgements about a person's worth.
4. To ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence.

5. To proactively mitigate health disparities in COVID-19 outcomes.

Ethical Justification for Proactively Mitigating Health Disparities in COVID-19 Outcomes

Epidemiological data reveal a disproportionate burden of COVID-19 in low income communities and certain racial/ethnic minorities. For example, a recent study found that individuals who resided in a low-income area had increased odds of a hospital admission from COVID-19.ⁱⁱ Health inequities may arise from multiple causes, including higher burdens of comorbid disease, poor health care access, infeasibility of social distancing due to living in densely-populated neighborhoods and households, the higher proportion of economically disadvantaged individuals who work in jobs classified as “essential” during the pandemic, and the need to continue to work in public-facing occupations due to economic hardship. Public health interventions are commonly used to mitigate disparities in outcomes across communities. The rationale is that a core goal of public health is to redress inequities that make health and safety less accessible to disadvantaged groups—we show equal respect for all members of society by mitigating the structural inequities that cause certain communities to bear the greatest burden during the pandemic. One strategy to accomplish this is to use a metric like the Area Deprivation Index¹ to identify patients from disadvantaged communities, then give them somewhat increased chances to receive treatment in a weighted lottery (see appendix A).

Patient Eligibility to Receive Remdesivir

The U.S. Food and Drug Administration (FDA) has [issued](#) an Emergency Use Authorization (EUA) to permit the use of the remdesivir (RDV) for treatment of COVID-19. As the FDA notes, “Remdesivir is a direct acting antiviral that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication.... [However], it is reasonable to believe that the known and potential benefits of RDV outweigh the known and potential risks of the drug for the treatment of patients hospitalized with severe COVID-19.”ⁱⁱⁱ

Hospitals should allocate RDV to laboratory-confirmed COVID-19 positive patients who are not currently receiving RDV treatment (e.g. under compassionate use, a clinical trial, or previous allocations of RDV), who consent, and who are clinically eligible to receive RDV. The clinical eligibility criteria for patients to receive RDV are consistent with the FDA’s EUA for emergency use of RDV for the treatment of hospitalized COVID-19 patients:

1. The RDV covered by this authorization will be used only to treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as SpO₂ ≤ 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO); and
2. RDV is administered in an in-patient hospital setting via intravenous (IV) infusion by a healthcare provider; and
3. The use of RDV covered by this authorization should be in accordance with the dosing regimens:

Adults and pediatric patients ≥ 40kg requiring mechanical ventilation or ECMO

- Single 200mg loading dose on Day 1
- 100mg once daily for Days 2 through 10 (for a total 10-day course)

Pediatric patients ≥3.5kg and < 40kg requiring mechanical ventilation or ECMO

- Single loading dose of 5mg/kg on Day 1

¹ Area Deprivation Indices (ADIs) are practical measures used to identify geographic areas characterized by socioeconomic marginalization and limited access to services. The University of Wisconsin’s ADI has a [mapping function](#) that shows areas of relatively high disadvantage as well as areas of moderate to less disadvantage. Visitors use the Mapping function to select a state, then enter an address to view the ADI ranking for the Census block group that contains that address.

- 2.5 mg/kg once daily for Days 2 through 10

Adults and pediatric patients ≥ 40 kg **not** requiring mechanical ventilation or ECMO

- Single 200mg loading dose on Day 1
- 100mg once daily for Days 2 through 5
- If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days

Pediatric patients ≥ 3.5 kg and < 40 kg **not** requiring mechanical ventilation or ECMO

- Single loading dose of 5mg/kg on Day 1
- 2.5 mg/kg once daily for Days 2 through 5
- If the patient does not show clinical improvement, treatment may be extended for up to 5 additional days

Hospital Policies and Protocols to create an Ethical Allocation Framework

The Department of Health has developed an initial framework for the allocation of RDV. However, it is incumbent upon hospitals to develop ethical treatment policies and protocols that are consistent with the ethical goals of the allocation framework outlined in this document. Hospitals may seek further guidance from their respective ethics committees, boards, or Crisis Triage Officer Teams that are outlined in [Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines](#).

Crisis Triage Officer Teams in each hospital should be leading the implementation of the allocation framework, rather than relying on treating clinicians to determine which patients receive scarce medications. Ideally, a clinical leader in the hospital should lead the team, with assistance from key stakeholders and experts. The team should be blinded to information that is not relevant to fair application of the allocation framework, such as patients' names, religion, race, ethnicity, gender, age, sexual orientation, gender identity, presence of a disability, and immigration status. The rationale for having a separate team rather than treating clinicians make allocation decisions is to reduce bias, avoid conflicts of commitment, and minimize moral distress. The team should have expertise in implementing the allocation framework, communicating difficult news, avoiding bias, and addressing health disparities. The team leader or a designee should collaborate with the patients' treating physicians to disclose allocation decisions to patients and families.

Finally, when developing processes for the allocation of RDV it is important to determine what allocation methods should be avoided. "Completely randomized lottery" or "first-come, first-serve" processes do not satisfy the ethical goals outlined in this document, because they do not proactively mitigate health disparities in COVID-19 outcomes and do not allocate scarce resources to maximize community benefit.

For an example of a policy that aligns with the ethical allocation goals outlined in this document, please refer to Appendix A. It is important to understand that this example is one method to meet the ethical goals and does not constitute the only method.

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Appendix A: Example of Weighted Lottery Policy for Fair Allocation of Medications to Treat COVID-19ⁱⁱⁱ

Introduction: The purpose of this appendix is to provide hospitals step-by-step instructions to conduct a weighted lottery allocation policy. The following groups will receive heightened priority: 1) individuals from disadvantaged areas, defined as residing at an address with an Area Deprivation Index (ADI) score of 8 to 10 (range 1-10; with higher numbers meaning worse deprivation); and 2) essential workers, defined by the Commonwealth of Pennsylvania [list](#) of essential businesses that are required to continue physical operations during the pandemic. Individuals expected to die within a year from an end-stage condition should not be excluded from access to the weighted lottery but should receive lower priority than individuals who do not have an end-stage condition. This prioritization methodology creates meaningful access to all patients, maximizes community benefit, and proactively mitigates disparities, all consistent with the ethical goals of the framework.

Preliminary steps: The following three steps should be completed at the time that COVID-19 treatment is allocated to a hospital.

- 1. Determine the number of available courses of the COVID-19 therapy.** This information will be provided by the Commonwealth of Pennsylvania or the agency responsible for distribution.
- 2. Estimate the number of eligible patients over the time period in question for which the drug is allotted.** To accomplish this, first determine the average number of patients admitted daily over the last week who met eligibility criteria for the COVID-19 medication. Next, calculate the number of days the supply of medication is expected to last based on dosage, and the number of eligible patients.
- 3. Determine the chances for each eligible “general population” patient to receive the drug.** These chances are determined by dividing the number of available courses of medication by the projected number of eligible patients. For example, if there are 25 courses of drug available and 100 patients expected to be eligible over the time period in question, the “general population” chances to receive the drug are 25 out of 100 (25%). This number will be used in step 4 below to calculate the chances for other populations.

NOTE: There may be uncertainty or changes in the number of treatment courses available, the time period that the supply of medication needs to last, or the average number of eligible patients per day. It is appropriate to recalculate the lottery chances as new information becomes available about these parameters.

Daily Steps to Allocate Scarce COVID-19 Medications

- 1. Proactively identify eligible patients with COVID-19.** Hospitals should take proactive steps to identify eligible patients as discussed previously in this framework, rather than placing this burden solely on treating physicians, who may not be aware of the availability of the scarce drug for their patient. This approach increases the chances that all eligible patients will be offered the opportunity to be in the lottery. The Crisis Triage Officer Team may be able to screen each COVID-19 patient in the hospital, or to use EHR-based screening mechanisms to identify patients with COVID-19 who are eligible to receive the scarce therapy. The optimal approach will depend on each hospital’s resources.
- 2. Confirm each COVID-19 patient’s eligibility with the attending physician.** The Crisis Triage Officer Team should contact the attending physician of each patient with COVID-19 to confirm eligibility. This conversation should ascertain the following: 1) that the patient meets inclusion criteria to receive the scarce drug; 2) that the patient does not meet any clinical exclusion criteria for the scarce drug; and 3) the patient consents to receive the drug. Consent may also take place after the patient is selected to receive the drug in the lottery.

ⁱⁱⁱ This Appendix represents one suggested approach, but it is not the only approach to satisfy the ethical goals identified by Pennsylvania’s Ethical Allocation Committee.

3. **Determine patient’s characteristics relevant to the weighted lottery.** The Crisis Triage Officer Team should assess the three characteristics relevant to the weighted lottery:
 - a. **Is the patient from a disadvantaged community?** The allocation team should determine whether the patient resides in a disadvantaged community, defined as their residential address being in an area with score of 8, 9, or 10 on the Area Deprivation Index. This can be determined by entering the patient’s address in the Neighborhood Atlas [website](#) under the “mapping” tab.
 - b. **Is the patient an essential worker?** In conjunction with the patient’s attending physician, the Crisis Triage Officer Team should determine whether the patient meets the Commonwealth of Pennsylvania’s definition of an essential worker, as specified in this [Industry Operation Guidance document](#).
 - c. **Is the patient expected to die within a year from a chronic, end-stage condition?** In conjunction with the patient’s attending physician, the Crisis Triage Officer Team should determine whether the patient is likely to die within a year from underlying condition(s) despite successful treatment of the COVID-19 infection. The objective medical evidence supporting this determination should be documented. If needed, specialist consultation should be sought (e.g. oncology, geriatrics, palliative care) to ensure the decision is an objective medical determination. If physicians are uncertain whether the patient is likely to die within a year, they should err on the side of assuming that the patient will survive for more than a year.
4. **Conduct the lottery for each eligible patient.**
 - a. **The first step is to determine the lottery threshold for each eligible patient.** Table 1 contains a summary of the adjusted chances for each patient group, which are based on the chances of a “general community” member, with adjustments for priority considerations. Table 2 provides an example of this when there are only enough courses of treatment to treat 25 out of 100 (i.e., 0.25) general community members.

Table 1. Weighted chances to receive treatment for each patient group

Group	Chances to receive treatment
General community chances	Number of available treatment courses/ Number of eligible patients in the determined time period
Disadvantaged community member	1.25 x (general community chances)
Essential worker	1.25 x (general community chances)
Death likely within 1 year	0.5 x (general community chances)
Disadvantaged community member + Essential worker	1.5 x (general community chances)
Disadvantaged community member + death likely within 1 year	0.75 x (general community chances)
Essential worker + death likely within 1 year	0.75 x (general community chances)

Table 2. Example when the chances for treatment with the scarce COVID-19 treatment for the general community are 25 out of 100

Group- Individuals who are...	Chances to receive treatment
General community members	0.25 (25 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10	1.25 x 0.25 = 0.31 (31 out of 100)
Essential workers	1.25 x 0.25 = 0.31 (31 out of 100)
Expected to die within a year from an end-stage condition	0.5 x 0.25 = 0.13 (13 out of 100)

