



# ARIZONA DEPARTMENT OF HEALTH SERVICES

## Remdesivir Allocation Guidance

Approved by State Disaster Medical Advisory Committee (SDMAC) - 6/12/2020

### Background

With the discovery of the novel coronavirus SARS-CoV-2 and ensuing pandemic of COVID-19, there has been intense effort placed into the development, licensing and production of existing and novel therapies that effectively treat COVID-19. On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined that there is a [public health emergency](#); on March 27, 2020, the Secretary declared that circumstances exist justifying the authorization of [emergency use of drugs and biologics](#) during the COVID-19 outbreak.

On May 1, 2020 the US Food and Drug Administration issued an [emergency use authorization \(EUA\)](#) for remdesivir (RDV). RDV is a direct acting antiviral drug that inhibits viral RNA synthesis. RDV has activity in cell culture and animal models against SARS-CoV, MERS-CoV, and SARS-CoV-2. Several randomized, double-blinded, placebo-controlled trials serve as the evidence base for the EUA, but it is still considered an investigational drug and is not currently approved for any indication.

Under the EUA, distribution of the authorized RDV is controlled by the US Government. Gilead, the drug manufacturer, supplies RDV to authorized distributors or directly to a US government agency, who then distributes to hospitals and other healthcare facilities as directed by the US Government, in collaboration with state and local government authorities. Arizona's first shipment of RDV was received at the Arizona State Public Health Laboratory on May 12, 2020. Subsequent allocations have been received and distributed to counties based on an agreed-upon allocation protocol.

Since the initial Arizona distribution, RDV has been received at hospitals around the state for treatment of patients with COVID-19. The RDV covered by the EUA is only intended to treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as  $SpO_2 \leq 94\%$  on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). This is consistent with recommendations from the [NIH COVID-19 Treatment Guidelines](#), which recommends against RDV for the treatment of mild or moderate COVID-19 outside of a clinical trial.

Even with this restrictive use, hospitals have had to further refine their criteria for use in order to apply this limited resource to their large patient population. As the distribution of RDV has been organized by the state and local public health departments, hospitals and hospital organizations have asked for a shared protocol for RDV use so that a patient has equal access to RDV across all facilities ensuring that patients are treated equitably between hospitals

## Recommendation

Given the lack of readily available RDV throughout the nation and the state of Arizona, the following criteria have been developed to allocate and prioritize the limited supply of RDV to the highest priority patients.

Adapted from the Minnesota Department of Public Health:

[Ethical Framework for Allocation of Remdesivir in the COVID-19 Pandemic](#)

### *Allocation within institution*

#### *Ethical strategy for distribution within a facility:*

Clinical prognosis should ground allocation decisions. Prognosis should be understood to include both need for the resource (i.e., risk of serious morbidity or mortality if the patient were not to receive the resource), and the likelihood that the patient will benefit from access to the resource by recovery to hospital discharge. Substantial differences in prognosis are what is ethically relevant in differentiating between patients; small differences should be viewed as morally equivalent and should not be used to allocate resources to or withhold resources from patients.

### *Highest Priority Patients*

The patients receiving the highest priority for allocation of RDV are:

- Patients with laboratory-confirmed COVID-19 (by RT-PCR testing on a respiratory specimen) who are not already on RDV (e.g., for clinical trials or compassionate use) and who have three of the four characteristics:
  - < 94% oxygen saturation on room air
  - Respiratory rate > 30
  - Lung infiltrates on imaging
  - Using supplemental oxygen
- Patients should meet other clinical inclusion criteria as specified by the FDA EUA for RDV (GFR  $\geq 30$ ml/min, ALT < 5 times upper limit of normal).
- Based on the EUA and the Gilead open-label trial, the recommended dose for adults and pediatric patients weighing >40 kg not on mechanical ventilation or ECMO is a single loading dose of 200mg on Day 1 followed by 100mg once daily for Days 2 through 5 (for a total 5-day course). At five days, patients who are not mechanically ventilated or on ECMO can be evaluated for possible continuation of RDV if needed, for a possible total 10-day course.

### *Second Highest Priority Patients*

If facilities have met the needs of the highest priority group of patients, facilities should then allocate RDV based on the following criteria:

- Patients with laboratory-confirmed COVID-19 (by RT-PCR testing on a respiratory specimen) who are not already on RDV (e.g., for clinical trials or compassionate use) and who have been
  - mechanically ventilated for 5 days or less,
  - or are on ECMO for 5 days or less,
- Patients should meet other clinical inclusion criteria as specified by the FDA EUA for RDV (GFR  $\geq 30$ ml/min, ALT < 5 times upper limit of normal).
- Under the EUA for RDV, the recommended dose for adults and pediatric patients weighing >40 kg on **mechanical ventilation or ECMO** is a single loading of 200mg on Day 1 followed by 100mg once daily for Days 2 through 10 (for a total 10-day course).

In both priority groups, in addition to prognosis of surviving current illness to hospital discharge, allocation decisions should consider whether the patient is imminently and irreversibly dying, with life expectancy under 6 months and/or currently under hospice care. Given the scarcity of supply of RDV, patients in this group should not currently receive priority for access.

When patients are otherwise of equal priority within a priority group of patients (i.e., there is no substantial difference in risk and likelihood of benefit) and there is not sufficient RDV for all patients in that group, the Triage Officer or Team should use a random process to allocate the resource.

In order to maximize the benefit of this resource, no courses should be held in reserve for future use. All courses should be allocated assuming all patients need a 10-day course of treatment. At five days, patients who are not mechanically ventilated or on ECMO should be evaluated for discontinuation of RDV with extra doses reallocated to other patients.

Allocation decisions should not consider or be based upon:

- Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status;
- Ability to pay;
- Age as a criterion in and of itself (this does not limit consideration of a patient's age in clinical prognostication of likelihood to survive to hospital discharge);
- Disability status or comorbid condition(s) as a criterion in and of itself (this does not limit consideration of a patient's physical condition in clinical prognostication of likelihood to survive to hospital discharge);
- Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis), unless the patient is imminently and irreversibly dying and/or under hospice care;
- First-come, first-served (should not distinguish between patients when treatment has not yet been started on equivalent patients);
- Judgments that some people have greater "quality of life" than others;
- Judgments that some people have greater "social value" than others.