Oregon’s Federal Remdesivir Allocation: Patient Criteria and Hospital Distribution

Summary
On May 12 and May 15, 2020, the Oregon Health Authority (OHA) received allotments of remdesivir, an experimental drug for the treatment of COVID-19. Because remdesivir is experimental, OHA neither recommends nor discourages the use of remdesivir to treat COVID-19 patients. The allotments include enough remdesivir for 80 patients to receive a 10-day treatment course, which is sufficient to treat currently hospitalized patients with COVID-19 who meet criteria for eligibility. OHA anticipates additional allotments in the future, although the amount and timing are not known. This document provides background on remdesivir, outlines patient criteria, specifies the process for hospital systems to request remdesivir from OHA.

Background
On May 1, 2020, the U.S. Food and Drug Administration (FDA) announced that it issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product remdesivir, developed by Gilead Sciences Inc., for treatment of COVID-19. The FDA has issued Fact Sheets for health care providers and patients regarding the EUA for remdesivir. ¹

Remdesivir is a direct acting antiviral that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication. According to Gilead’s website, “it is not yet known if remdesivir is safe and effective for the treatment of COVID-19.”

Effectiveness Data
The EUA issued by the FDA for remdesivir states that “based on review of the topline data from the randomized, double-blinded, placebo-controlled trial conducted by NIAID (NCT04280705) and from the Gilead-sponsored open-label trial that evaluated different durations of remdesivir (NCT04292899), it is reasonable to believe that the known and potential benefits of remdesivir outweigh the known and potential risks of the drug for the treatment of patients hospitalized with severe COVID-19.” According to an April 29, 2020 NIH news release, preliminary results for the NIAID study involving 1063 individuals with advanced lung disease “indicate that patients who received remdesivir had a 31% faster time to recovery than those who received placebo (p<0.001). Specifically, the median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo.” Differences in mortality rate were not statistically significant, and full results of the study have not been published. More information about the results from the NIAID study on remdesivir can be found at https://www.niaid.nih.gov/news-events.nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19. For information about additional clinical

¹ The emergency use authorization (EUA) can be found here.
trials that are testing the use of remdesivir for the treatment of COVID-19 see www.clinicaltrials.gov.

Treatment Course
Two treatment courses for remdesivir are recommended by Gilead: a 5-day course (uses 6 vials, including loading dose on Day 1), or a 10-day course (uses 11 vials, including loading dose on Day 1):

- The 5-day course is the suggested dose for adults and pediatric patients weighing ≥40 kg NOT requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO). If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days (i.e., up to a total of 10 days).
- The 10-day course is suggested for adults and pediatric patients weighing ≥40 kg requiring invasive mechanical ventilation and/or ECMO.

Oregon Statewide Distribution Plan
Starting as early as May 16, OHA will distribute remdesivir to hospitals, upon notification of an eligible patient and receipt of a signed agreement form from the hospital. In order to maximize benefit of this resource, no courses from the initial May 2020 allocation will be held in reserve for future use.

Patient Eligibility
Inclusion Criteria:
In order to receive remdesivir from the state allocation, eligible patients must meet ALL the following criteria outlined in the FDA’s Emergency Use Authorization:

- **Patient has suspected or laboratory-confirmed SARS-CoV-2 infection**
  - Patients must have suspected SARS-CoV-2 or laboratory-confirmed SARS-CoV-2 as determined by polymerase chain reaction (PCR)
  - For suspected cases, drug can be requested with a requirement that polymerase chain reaction (PCR) test or other commercial or public health diagnostic test is in process
    - If confirmatory test is negative drug will not be administered

- **Patient is hospitalized**

- **Patient has severe COVID-19 disease** defined by one or more of the following criteria:
  - Documented low oxygen saturation (SpO2) ≤94% on room air
  - Requiring supplemental oxygen
  - Requiring mechanical ventilation or extracorporeal membrane oxygenation

Exclusion criteria:
- Patient hypersensitivity to the medication
- Patients with severe renal or hepatic impairment due to the risk of harm based on prior remdesivir trials, including:
  - Patients with severe renal dysfunction defined as glomerular filtration of < 30 ml/min, hemodialysis, peritoneal dialysis, or continuous renal replacement
Patients with severe hepatic impairment defined as documented cirrhosis or elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥5x the upper limit of normal (ULN)

- **Children and pregnant mothers** are currently eligible to receive remdesivir through compassionate use from Gilead and so will not be prioritized for the initial May 2020 allocation.

**Hospital/ provider requirements.**

Prior to proceeding with remdesivir distribution, the hospital/ provider must attest that they will comply with all the requirements of the Emergency Use Authorization (EUA) for remdesivir (including but not limited to monitoring, dosing, and reporting requirements).

**Attestation requirements**

To obtain remdesivir from OHA, providers/ hospitals will be required to agree to the following:

- Doses requested are for patient(s) who meet clinical eligibility requirements
- Written informed consent will be obtained from any patient or the patient’s legally authorized representative prior to administering remdesivir, that makes clear that remdesivir is an experimental drug.
- Hospital will report information to the State of Oregon regarding nonidentifying information on each patient receiving remdesivir as supplied by the state, including but not limited to the patient demographic characteristics, including age, sex, and race/ethnicity/disability in accordance with Oregon’s REAL-D requirements
- Comply with the requirements spelled out in the federal EUA, including reporting of adverse events
- Willingness to provide follow up information (e.g. clinical outcome) on patients treated
- Receiving hospital facility must be able to store product under appropriate conditions.
- Receiving hospital facility must return unused doses to the Oregon Health Authority within 48 hours if not used (e.g., confirmatory test on suspect patient is negative).

**Decision to treat**

- The decision for remdesivir treatment must be approached through shared decision-making with the patient or legally authorized health care representative.
- The patient or legally authorized health care representative is given the following fact sheet as required by the federal government, made available in their primary language:
  - Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19);
- Patient or legally authorized health care representative is given all information in order to provide fully informed and confirmed consent, including an understanding of risks and benefits;
- Patient or legally authorized health care representative consents to the treatment
Patient has interpreter access to ensure that all information provided is available in the patient’s primary language including ASL, and all written documents are appropriately translated; Patient/family is readily provided the option of consultation with a community health worker or other trusted community representative

**Equity Considerations**

The distribution and use of a small, federal allotment of the experimental drug remdesivir must take into consideration current inequities in the US and Oregon related to COVID-19, as well as the social and health inequities that have been prevalent for centuries. We also must account for the historical consequences for people of color and individuals with disabilities who have been impacted by lack of disclosure related to experimental drugs, procedures and testing. Any distribution and use of remdesivir must include a focus on health equity\(^2\) and take current and historical experiences into consideration.

**Treatment 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;
- Disability status or comorbid condition(s) as a criterion in and of itself;
- Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis)
- Judgments that some people have greater “quality of life” than others;
- Judgments that some people have greater “social value” than others.

**Community and Stakeholder input on Proposal Development**

OHA thanks those who gave input on this proposal development on a tight timeline, including the Governor’s Medical Advisory Board, and community members including: Tribal partners; and representatives from the Black, African American, Latino, Latina, LatinX, and Pacific Islander communities.

You can get this document free of charge in other languages, large print, braille or a format you prefer. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsoha.state.or.us.

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\(^2\) Oregon Health Authority’s definition of health equity: Oregon will have established a health system that creates health equity when all people can reach their full health potential and well-being and are not disadvantaged by their race, ethnicity, language, disability, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances. Achieving health equity requires the ongoing collaboration of all regions and sectors of the state, including tribal governments to address:

- The equitable distribution or redistributing of resources and power; and
- Recognizing, reconciling and rectifying historical and contemporary injustices.