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Remdesivir:
Treatment Guidelines, Oregon's Federal Allocations and Hospital Distribution

Information in this document changes regularly. Make sure to revisit https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2389C.pdf for updates.

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.[1] Remdesivir is a direct-acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication. The FDA has issued Fact Sheets for health care providers and patients regarding the EUA for remdesivir.

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 1,063 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 case fatality rates were not statistically significant.

For additional information about clinical data on remdesivir, see www.covid19treatmentguidelines.nih.gov/antiviral-therapy/remdesivir/. For information about clinical trials that are testing the use of remdesivir for the treatment of COVID-19 see www.clinicaltrials.gov.

Treatment Course

[1] The emergency use authorization (EUA) can be found here.

Two possible treatment courses for remdesivir were originally recommended by Gilead for the treatment of hospitalized patients with SARS-CoV-2 infection: 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 July 24 ,2020 NIH COVID-19 Treatment Guidelines recommend the following regarding remdesivir:

- Because remdesivir supplies are limited, the Panel recommends that remdesivir be prioritized for use in hospitalized patients with COVID-19 who require supplemental oxygen but who are not on high-flow oxygen, noninvasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

- The Guidelines Panel recommends using remdesivir for 5 days or until hospital discharge, whichever comes first.

- If a patient who is on supplemental oxygen while receiving remdesivir progresses to requiring high-flow oxygen, noninvasive or invasive mechanical ventilation, or ECMO, the course of remdesivir should be completed.

- There are insufficient data on the optimal duration of remdesivir therapy for patients with COVID-19 who have not shown clinical improvement after 5 days of therapy. In this group, some experts extend the total remdesivir treatment duration to up to 10 days.

For additional information on the NIH Remdesivir treatment Guidelines, visit https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/remdesivir/.

Oregon Remdesivir Distribution

Oregon received several allotments of donated remdesivir in May and June 2020 which have now been distributed to Oregon hospitals for the treatment of patients with COVID-19.

On June 29, 2020, the federal government announced that remdesivir is now commercially available to U.S. hospitals for purchase through September 2020, as negotiated with Gilead. As part of the new federal allocation process, OHA receives notice of the state's weekly allotment from the federal government and must indicate the amount of remdesivir doses that individual Oregon hospitals *may* purchase. These shipments are made directly to hospitals by the distributor, AmerisourceBergen.

OHA is using data from a rolling, 2-week period of recent COVID-19 patient hospitalizations by facility to determine hospital distributions. We will reassess our approach for the distribution of remdesivir as needed. We encourage hospitals to coordinate with each other if needed, should a hospital receive an insufficient number of doses to treat its hospitalized patients.

Contraindications to Remdesivir

Treating providers should review the remdesivir EUA and NIH clinical treatment guidelines before prescribing remdesivir, with attention to the following contraindications:

- 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 or need for hemodialysis, peritoneal dialysis, or continuous renal replacement therapy (CRRT)
    - Patients with severe hepatic impairment, defined as documented cirrhosis or elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥5x the upper limit of normal

Decision to treat

- The decision for remdesivir treatment should be approached through shared decision-making with the patient or legally authorized health care representative. Providers should review the Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Veklury® (remdesivir).
- As required by the federal government, the patient or legally authorized health care representative must be given, in their primary language, the Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Remdesivir for Coronavirus Disease 2019 (COVID-19).
- The patient or legally authorized health care representative must be given all the information necessary to make an informed choice, including information about the potential risks and benefits of the treatment.
- Verbal consent must be documented in the patient's chart, reflecting that the associated potential risks and benefits were discussed with the patient or legally authorized health care representative.
- The patient or legally authorized health care representative must have interpreter access to ensure that all information provided is available in the patient's primary language, including ASL if needed, and that all written documents are appropriately translated.The patient or legally authorized health care representative should be readily provided the option of consultation with a community health worker or other trusted community representative.

Equity Considerations

The distribution and use of the investigational drug remdesivir must take into consideration 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. The

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.

Document Accessibility: For individuals with disabilities or individuals who speak a language other than English, OHA can provide information in alternate formats such as translations, large print, or braille. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsoha.state.or.us.

[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.