**Remdesivir Memo (1-14-2022)**

Remdesivir (Veklury) was approved by the U.S. Food and Drug Administration (FDA) in 2020 for treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization.

In December 2021, a clinical trial, PINETREE, was published that demonstrated the safety and efficacy of off-label use of remdesivir for treatment of mild or moderate COVID-19 illness in non-hospitalized patients at high risk for hospitalization or death (see Table).[1] Patients in the trial were treated in infusion centers, skilled nursing facilities, and through home infusion services.[1] The treatment regimen requires 3 infusions over 3 days.

| Primary Endpoint (by day 28) | Remdesivir (n=279) | Placebo (n=283) |
|---|---|---|
| COVID-19 hospitalization or death from any cause | 0.7%<br>HR 0.13 (95% CI, 0.03 to 0.59)<br>NNT 22 | 5.3% |
| Abbreviations: CI = confidence interval; HR = hazard ratio; n = number of study participants; NNT = number needed to treat to prevent one COVID-19 hospitalization or death from any cause over 28 days. | | |

Patients received their first infusion 3-6 days after symptom onset.[1] As with other COVID-19 treatments under Emergency Use Authorization by the FDA, efficacy of the drug is time sensitive.

The U.S. National Institutes of Health (NIH) currently recommends remdesivir as one of four treatment options for treatment of mild or moderate COVID-19 infection due to the Omicron variant.[2] The recommended NIH therapies are: 1) oral Paxlovid™ (nirmatrelvir; ritonavir); 2) intravenous sotrovimab; 3) intravenous remdesivir; and 4) oral molnupiravir.

Paxlovid™, sotrovimab, and molnupiravir are currently available only through federal allocation, which is initially very limited, and Oregon's allocation does not meet the current demand. Remdesivir is a commercially available product. For this reason, Oregon Health Authority recommends that its use for treatment of patients with laboratory-confirmed COVID-19 at high risk of progression to severe illness should be allowed without prior authorization, until supply of other treatments is sufficient to meet demand.

References:


1. Gottlieb RL, Vaca CE, Paredes R, Mera J, Webb BJ, et al. Early remdesivir to prevent progression to severe Covid-19 in outpatients. *N Engl J Med*. 2021 Dec 22. doi: 10.1056/NEJMoa2116846. Online ahead of print.
2. Statement on Therapies for High-Risk, Nonhospitalized Patients. COVID-19 Treatment Guidelines, National Institutes of Health. Available at: https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/. Accessed 6 January 2022.