

## Subject: Veklury® (remdesivir) is the First FDA-Approved Medication for COVID-19

On October 22<sup>nd</sup>, Veklury (remdesivir) was approved by the U. S. Food and Drug Administration (FDA) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization.<sup>1</sup> This signifies the first medication to be approved by the FDA for the treatment of COVID-19. The FDA notes that Veklury should only be administered in a hospital or in a health care setting that can provide acute care equivalent to inpatient hospital care.

COVID-19 is a viral respiratory infection caused by SARS-CoV-2 which can present as asymptomatic, a mild infection, upper respiratory tract infection, lower respiratory tract infection including pneumonia, or as acute respiratory distress syndrome (ARDS).<sup>2</sup> Veklury is an antiviral agent.<sup>3</sup> The approval of Veklury is based on three clinical trials which showed efficacy in treating hospitalized patients diagnosed with COVID-19. The most common adverse reactions associated with Veklury include nausea and liver enzyme elevations. The American College of Occupational and Environmental Medicine (ACOEM) does recommend remdesivir but only for the supervised treatment of selected patients with COVID-19.<sup>3</sup>

First Script® will continue to provide Smart Prior Authorization (PA) messaging recommending denial until the relationship of the drug to the compensable injury is established. This drug is only approved for hospitalized COVID-19 patients under strict medical supervision and is not indicated to treat patients in the outpatient setting.

If you have any questions or concerns about why this drug is being prescribed for your injured worker and whether it is related to a work injury, please either contact us at Ask The Pharmacist ([askthepharmacist@cvty.us.com](mailto:askthepharmacist@cvty.us.com)) or seek another available clinical resource for further research.

For more information, please contact your Account Manager or Account Pharmacist.

1. Commissioner, Office of the. "FDA Approves First Treatment for COVID-19." U.S. Food and Drug Administration, FDA, 22 Oct. 2020, [www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19](https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19).
2. Coronavirus (COVID-19) Clinical Practice Guideline. Accessed at: <https://www.dir.ca.gov/dwc/mtus/mtus.html>
3. Veklury Highlights of Prescribing Information. Accessed at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/214787Orig1s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214787Orig1s000lbl.pdf)