https://drive.google.com/file/d/1ROZzJ4iRnHuOqKw1xwFtvmLgYefrGpax/view?usp=sharing

On January 21, 2022, the U.S. Food and Drug Administration (FDA) expanded the approval for
remdesivir to include outpatient use in adults and pediatric patients ≥12 years old and ≥40 kg.

When used in an outpatient setting, remdesivir (Veklury) is given as an intravenous (IV) infusion once daily on three consecutive days.

Remdesivir (Veklury) is not state-distributed at this time and must be ordered directly from the manufacturer.

Expansion of approval for non-hospitalized patients

The FDA has expanded the approved indication for remdesivir (Veklury) to include its use in adults and pediatric
patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds):

● with positive results of direct SARS-CoV-2 viral testing,
● who are not hospitalized and have mild-to-moderate COVID-19, and
● who are at high risk for progression to severe COVID-19, including hospitalization or death.

The treatment course of remdesivir (Veklury) should be initiated as soon as possible after diagnosis of symptomatic
COVID-19 has been made and within seven days of symptom onset. The expanded prescribing information is available at
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214787Orig1s010Lbl.pdf.

The approval of remdesivir (Veklury) for use in non-hospitalized patients is supported by a randomized,
placebo-controlled clinical trial that included 562 non-hospitalized patients with mild-to-moderate COVID-19 who were

at high risk for progression to severe COVID-19, including hospitalization or death. The main outcome measured in the
trial was whether a patient was hospitalized for any COVID-19 related reason or died from any reason within 28 days of
treatment. Overall, two of 279 patients who received remdesivir (Veklury) (0.7%) required COVID-19 related
hospitalization compared to 15 of 283 patients who received a placebo (5.3%). There were no deaths in either group.