Yale NewHaven Health

TO: **YNHHS MEDICAL STAFF AND PHARMACY STAFF**

FROM: **YNHHS COVID-19 TREATMENT TEAM**
YNHHS ANTIMICROBIAL STEWARDSHIP COMMITTEE

SUBJECT: **Review of Updated Emergency Use Authorization (EUA) Criteria for Remdesivir**

DATE: **SEPTEMBER 8, 2020**

Situation:
On August 28, 2020, The US Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) for remdesivir to consider its use for the treatment of any hospitalized patient with COVID-19. Previously, the EUA specified that remdesivir was indicated for COVID-19 inpatients who required supplemental oxygen for hypoxia.

Background:
The expansion of the remdesivir EUA to include hospitalized patients with COVID-19 and **NOT** on supplemental oxygen was based on a re-analysis of data from two prior clinical studies.

In the ACTT-1 trial, there was a numerical, but not statistically significant difference in time to improvement at day 15 in patients with mild to moderate disease (i.e., not requiring supplemental oxygen) who received remdesivir for 5 days compared to those who received placebo.

In a separate randomized, open-label multi-center clinical trial (GS-US-540-5774) of hospitalized patients with moderate COVID-19 compared treatment with remdesivir for five days versus 10 days versus standard of care. The odds of a subject's COVID-19 symptoms improving were statistically significantly higher in the five-day group at Day 11 when compared to those receiving only standard of care. However, the odds of improvement with the 10-day treatment group compared to those receiving only standard of care were not statistically significant. There was no difference in mortality at Day 28 which was less than or equal to 2 percent in all treatment groups.

Importantly, remdesivir remains a limited resource with allocation to hospitals coordinated by the US Department of Health and Human Services with a state's department of health based on the number of inpatient COVID-19 cases in the state.

Assessment:
Based the above information, the YNHHS COVID-19 Treatment Team and YNHHS Antimicrobial Stewardship Committee met to review the revised FDA EUA criteria for remdesivir use.

Recommendations:
Given the currently available data and the limited supply of remdesivir, the committees' recommendation is maintain the current remdesivir criteria for use in the YNHHS COVID-19 Adult Treatment Algorithm at this time.

Therefore, the YNHHS recommendation for remdesivir will continue to be for hospitalized patients who have an oxygen saturation ≤ 95% and require supplemental oxygen or have an increased oxygen requirement from baseline.