

January 5, 2022

Re: Request federal management and distribution of remdesivir for early outpatient treatment to avoid hospitalizations and deaths

We request that the federal government manage remdesivir, an existing antiviral COVID-19 drug, as a critical agent for the COVID-19 public health emergency (PHE), similar to monoclonal antibody infusions.

Remdesivir is now FDA-approved and is no longer being distributed free of charge by the federal government, thus limiting access for community infusion centers. Resuming federal distribution of this drug would make it accessible for the outpatient emergency response teams who have been administering the now scarce monoclonal antibody infusions. Effective treatment for COVID-19 infection has made significant progress over the past two years, but at this moment in time, availability of effective monoclonal antibodies and newer therapeutic agents are limited. The widely available monoclonal antibodies from Regeneron and Lilly lack significant activity against the now predominant omicron variant. Sotrovimab (GSK), the monoclonal antibody with activity against omicron, is in short supply. Oral anti-virals, monupiravir and Paxlovid, are becoming available, but are also in very short supply.

Given the current surge of the highly transmissible omicron variant and the shortage of evidenced-based therapeutic products, improving outpatient remdesivir access has the potential to improve patient care, as well as reduce hospitalizations and deaths. A recent multicenter study, [Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients](#), published in the New England Journal of Medicine, showed that early remdesivir given in outpatients daily for three days resulted in an 87% lower risk of hospitalization or death.

Remdesivir offers the potential to offset this current shortage of other treatment agents during this time of surging infection rates in the United States due to the omicron variant. While 62% of people in the US are fully vaccinated, only 20% of eligible persons have gotten boosters. Vaccination with a booster protects against death and severe illness, but breakthrough omicron infections are increasingly common.

Remdesivir is a vital option for patients with COVID-19 and could play a critical role in preventing disease progression and reducing hospitalizations, especially among those most at risk of serious complications or death.

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