

New Mexico Medical Advisory Team (MAT) Assessment

MAT Workgroup Name: Clinical Care

Date: April 8, 2020

Question or request:

1. What action should the Governor take to acquire Remdesivir or other experimental drugs as treatment for COVID-19 patients?

Recommendation/s:

- Work with Gilead, the manufacturer of Remdesivir to obtain approval for UNMH and Presbyterian to participate in the clinical trial of this medication for COVID-19
- Be aware that Remdesivir will be used for study patients only. Remdesivir is currently only available to patients through formal clinical trials and organizations must be participating in a clinical trial to obtain this medication from Gilead under the FDA's expanded use guidelines. While the University of New Mexico and Presbyterian are on wait lists for participation in clinical trials of Remdesivir, availability of the medication is very limited and therefore should not be considered a valid treatment for COVID-19 patients statewide.
- Be aware that experimental treatment options including Tocilizumab (IL-6) and IL-1R antibody studies are also available for off-label treatment of COVID-19 at the discretion of the prescribing provider. These treatments will be available shortly at UNM and may be used in acute respiratory distress in patients in the intensive care unit. However, this treatment can be more complex and require additional monitoring.

Assessment:

Several clinical trials of Remdesivir as a treatment for COVID-19 are ongoing.^{8,9,10,15} Remdesivir has been shown to inhibit the virus in vitro. Remdesivir appears very promising based on in vitro data, but there is no efficacy data in humans at this point, it must be given intravenously, and it was inferior to anti-ebolavirus monoclonal antibody therapy in a recent trial in Africa.^{16,17,21} The drug is only available to those participating in the clinical trials and must be requested by Gilead directly under the FDA's expanded use guidelines. Gilead submitted an investigational new drug filing through the FDA, and the drug is no longer available for compassionate use.

In the clinical trial setting, Remdesivir is recommended only for those over the age of 18 who have a confirmed PCR SARS-CoV-2 infection within the past 3 days, infiltrates on chest imaging, require supplemental oxygen or mechanical ventilation, have respiratory physical exam findings and SpO₂ ≤ 94% on room air.^{18,19} Given the limited availability of this medication and restrictions on use to only those patients enrolled in a clinical trial, we do not recommend wide scale rollout of this treatment across the state.

Red flags and concerns:

Additional studies are needed to understand the role of Remdesivir in treating COVID-19 patients. The Clinical Care workgroup will continue tracking existing studies and will update this recommendation as additional information becomes available.

Contributors: There was moderate consensus on these recommendations among the following contributors.

- Cristina Beato, MD (UNM)
- Jon Femling, MD, PhD (UNM)
- Richard Larson, MD, PhD (UNM)
- Ebany Martinez-Finley, PhD, MBA (Presbyterian)

New Mexico Medical Advisory Team (MAT) Assessment

- Greg Mertz, MD (UNM)
- Justin Schmetterer, PharmD (Presbyterian)
- Renee Mercier, PharmD (UNM)
- Nestor Sosa, MD (UNM)
- Norbert Topf, MD (Presbyterian)

Resources/Reference:

Wang M, Cao R, Zhang L et al. Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro. *Cell Res.* 2020; 30:269-271. (PubMed 32020029) (DOI 10.1038/s41422-020-0282-0)

Ko, W. C., Rolain, J. M., Lee, N. Y., Chen, P. L., Huang, C. T., Lee, P. I., & Hsueh, P. R. (2020). Arguments in favor of remdesivir for treating SARS-CoV-2 infections. *Int J Antimicrob Agents.*

Nebraska Medical Center COVID-19 Antiviral and Pharmacotherapy Information Available from: <https://www.nebraskamed.com/sites/default/files/documents/covid-19/antiviral-and-pharmacotherapy-information.pdf>. [Accessed April 7, 2020]

Gilead Sciences Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment Available from: <https://clinicaltrials.gov/ct2/show/NCT04292730> [Accessed April 7, 2020]