

U.S. Department of Justice Federal Bureau of Prisons

Health Services Division

Washington, D.C. 20534

January 30, 2022

MEMORANDUM FOR ALL CLINICAL DIRECTORS

ALL HEALTH SERVICE ADMINISTRATORS ALL INSTITUTION CHIEF PHARMACISTS

FROM: (b)(6); (b)(7)(C) , D.O, Medical Director

Health Services Division

SUBJECT: Clinical Guidance on COVID-19 Outpatient

Therapeutics

The Health Services Division (HSD) recently updated the Clinical Guidance on COVID-19 Outpatient Therapeutics (formerly titled Monoclonal Antibody Therapy for COVID-19), January 2022. The guidance is issued for immediate implementation throughout the Bureau of Prisons (BOP). It will soon be available on the Sallyport COVID-19 Resources page.

This update has been issued to reflect the following changes:

- Due to the rise in omicron variant and reduced efficacy, both bamlanivimab-etesevimab and casirivimab-imdevimab (REGEN-COV) are currently not authorized for use in the US.
- Expansion of FDA approval for remdesivir (Veklury) antiviral therapy to include outpatient treatment of mild to moderate COVID-19 disease in patients who are at high risk for progression to severe disease.
- Addition of guidance for two oral antivirals molnupiravir and nirmatrelvir co-packaged with ritonavir (Paxlovid).
 Both are authorized through EUA for treatment of mild to moderate COVID-19 disease in patients who are at high risk for progression to severe disease.

Institutions are reminded of the following considerations for the use of COVID-19 therapeutics:

- Treatment has the potential to prevent progression to severe disease and decrease the number of inmates who need hospitalization in the local community.
- Per the CDC, risk factors for severe illness include many conditions present in ambulatory patients to include BMI

- >25, CKD, diabetes, 65 years old or older, immunosuppression, CVD or HTN, and COPD or other respiratory diseases.
- Treatment appears to work best when started early after the diagnosis is made in appropriately-selected patients. For that reason, it is recommended that each newly diagnosed inmate with COVID-19 be assessed for possible treatment.
- Each institution should assess their ability to administer an IV infusion and manage severe allergic reactions, including anaphylaxis. There are no special requirements for IV infusion beyond standard training and supplies.
- The BOP has issued Clinical Guidance for COVID-19
 Therapeutics which includes guidance for use of each of these medications in addition to nursing protocols. The guidance can be found here https://www.bop.gov/resources/pdfs/covid-19 oupatient therapeutics cg.pdf and will be updated shortly to reflect changes in authorized and available treatments.

Thank you for your ongoing commitment to providing quality health care to the BOP inmate population. If you have any questions regarding these guidelines, please contact RADM (b)(6); (b)(6); (b)(6); (b)(7)(C) at (b)(7)(C); (b)(6).

cc:	RADM (b)(6); (b)(7)(C) PharmD, Acting Assistant Director
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