U.S. Department of Justice

Federal Bureau of Prisons

Washington, D.C. 20534

November 17, 2020

MEMORANDUM FOR ALL CLINICAL DIRECTORS
ALL HEALTH SERVICES ADMINISTRATORS
ALL CHIEF PHARMACISTS

Jeffery D. Allen, M.D. 2020.11.17 16:05:38 -05'00'

FROM: Jeffery D. Allen, M.D., Medical Director
Health Services Division

SUBJECT: Emergency Use Authorization for Bamlanivimab

On November 9, 2020, the U.S. Food and Drug Administration issued an emergency use authorization for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.

Bamlanivimab is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions. Additional details can be found on the FDA website at https://www.fda.gov/media/143602/download, and on the Fact Sheet for Health Care Providers at https://www.covid19.lilly.com/bamlanivimab/hcp.

Bamlanivimab should be administered as soon as possible after a positive SARS-CoV-2 viral test result but no later than 10 days after symptom onset. A single dose is administered through intravenous infusion while under observation by clinical health care staff within their scope of practice. Because a premixed solution is not commercially available, preparation of bamlanivimab requires dilution of the concentrated solution in an infusion bag of 0.9% sodium chloride prior to administration. See the above links for additional information regarding preparation, administration, storage and stability.

Limited quantities of bamlanivimab are being made available to the Federal Bureau of Prisons (BOP) and will be distributed initially to Medical Centers and Care Level 3 institutions via

the BOP Central Fill and Distribution (CFAD) pharmacy. Care Level 1 and 2 institutions that wish to obtain bamlanivimab should contact their Regional Medical Director and Regional Chief Pharmacist for additional guidance. As experience is gained with this new treatment for COVID-19 and the medication becomes more available, a plan will be developed for expanded distribution and use within the BOP. Please note: bamlanivimab is not available through the BOP Prime Vendor and is not available for purchase outside the above process.

Informed consent is needed from the patient prior to use of bamlanivimab as described in the Fact Sheet for Health Care Providers at the above link. As part of the informed consent requirement the Fact Sheet for Patients, Parents and Caregivers must be given to each patient and may be accessed in both English and Spanish versions at https://www.covid19.lilly.com/bamlanivimab.

All use of bamlanivimab will be documented in BEMR. A non-formulary authorization is required. Bamlanivimab use needs to be tracked and recorded in the institutional Pharmacy and Therapeutics (P&T) meeting minutes. There is also a mandatory reporting requirement for all medication errors and serious adverse events potentially related to bamlanivimab.

Questions related may be directed to (b)(6); (b)(7)(C) BOP Chief Pharmacist by email at (b)(6); (b)(7)(C) or by phone at (b)(6); (b)(7)(C)

cc: (b)(6); (b)(7)(C)

HSD Branch Chiefs
Chief Professional Officers
Regional Medical Directors
Regional Health Services Administrators
Regional Chief Pharmacists
Central Processing Pharmacy Services