Health Update

KITSAP PUBLIC HEALTH DISTRICT

November 23, 2020

New Washington State Department of Health Use of Bamlanivimab Guidance

Please review the "Use of Bamlanivimab in Washington State" guidance document and embedded links released by WA Department of Health on November 21, 2020.

- PDF is attached and available at: https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/BamlanivimabUseinWA.pdf

General Resources

- CDC COVID-19 page: https://www.cdc.gov/coronavirus/2019-nCoV/
- DOH COVID-19 page: https://www.doh.wa.gov/Emergencies/Coronavirus
- KPHD COVID-19 page: https://kitsappublichealth.org/CommunityHealth/CoronaVirus.php
- Questions? Please contact our Communicable Disease staff at 360-728-2235

Washington State Department of Health
DOH 821-123 November 2020

Use of Bamlanivimab in Washington State

Background

On Nov. 9, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients (≥12 years old and ≥40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization. Monoclonal antibodies are laboratory-made proteins that bind to the spike protein of SARS-CoV-2 and block the virus' attachment and entry into human cells.

The issuance of an EUA is different than FDA approval. The FDA has the authority to issue an EUA for an investigational drug during a public health emergency when the known and potential benefits of the drug appear to outweigh the known and potential risks for the drug and no other approved alternatives exist.

The data supporting this EUA for bamlanivimab are based on an interim analysis from a phase two randomized, double-blind, placebo-controlled clinical trial in 452 non-hospitalized adults with mild to moderate COVID-19 symptoms. No pediatric patients were included in this study. This interim analysis showed that five (1.6%) of 309 patients receiving the monoclonal antibody and nine (6.3%) of 143 patients receiving the placebo were either hospitalized or visited an emergency department during their illness. No serious adverse effects were identified in the interim analysis. While the safety and effectiveness of this investigational therapy appear promising, the data are still very limited. Clinical trials are ongoing to collect additional data on its safety and effectiveness.

On Nov. 18, 2020, the National Institute of Health stated there are insufficient data to recommend either for or against the use of bamlanivimab for the treatment of outpatients with mild to moderate COVID-19 and that bamlanivimab should not be considered the standard of care for the treatment of patients with COVID-19. On the same day, the Infectious Disease Society of America treatment guidelines panel suggested against the routine use of bamlanivimab and stated, "In patients at increased risk (as defined by the FDA EUA), bamlanivimab is a reasonable treatment option if, after informed decision-making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events."

Bamlanivimab is approved for persons with mild or moderate COVID-19 (i.e., outpatients) early in the course of illness and is given through a one-hour intravenous infusion followed by a one-hour observation period. Administration of this drug is challenging for health care facilities to offer because it requires an appropriate space in the facility, implementation of strict infection control measures, and appropriately trained staff to administer the infusion and monitor patients to ensure safety.

Availability of bamlanivimab in Washington

The Department of Health and Human Services purchased 300,000 doses of bamlanivimab from the manufacturer and began distributing weekly allocations to states during the week of Nov. 9, 2020. During the first phase of distribution (Nov. 9-20, 2020), states were only allowed to distribute their doses to hospitals since hospitals were more likely to have the infrastructure to administer it. During these two weeks, the Department of Health (DOH) allocated doses to hospitals interested in receiving it based on the number of confirmed COVID-19 patients in the hospital that week. All hospitals received a minimum number of doses.

During the week of Nov. 23, 2020, any health care facility in Washington will be eligible to receive the medication from DOH. If the demand for medication from health care facilities in Washington exceeds the amount allocated to the state, DOH will allocate doses proportionally to facilities based on the population of the county. Doses will also be set aside for tribal clinics. Doses distributed through the government will be provided free of charge.

Any health care facility able to abide by the requirements in the provider fact sheet will be eligible to receive the medication. Facilities interested in receiving bamlanivimab from DOH should contact Jennifer Dixon at Jennifer.dixon@doh.wa.gov.

Administration of bamlanivimab in Washington

Health care providers in Washington feel differently about whether there is currently enough safety and effectiveness data to offer the drug to their patients. Some health care providers may want to offer the medication to their patients but may not be able to offer it due to a lack of available drug and/or a lack of available resources to support administration during the COVID-19 pandemic.

Health care providers administering bamlanivimab need to follow all the guidance in the provider fact sheet, including but not limited to the eligibility criteria, preparation and administration instructions, and communication requirements.

Health care providers must communicate to patients or parents/caregivers, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving bamlanivimab, including:

- FDA has authorized the emergency use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization [see Limitations of Authorized Use].
- The patient or parent/caregiver has the option to accept or refuse bamlanivimab.
- The significant known and potential risks and benefits of bamlanivimab, and the extent to which such potential risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

- Patients treated with bamlanivimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

Health care providers must document in the patient's medical record that the patient/caregiver has been:

- Given the "Fact Sheet for Patients, Parents and Caregivers",
- Informed of alternatives to receiving authorized bamlanivimab, and
- Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

Given the large number of patients who will be eligible to receive the drug and the relatively small number of doses allocated to the state, the Department of Health recommends that health care providers use a randomized selection process for all eligible patients who can have the drug safely administered. Currently, there is not enough data to narrow the criteria for use listed in the EUA.

More COVID-19 Information and Resources

Stay up-to-date on the current COVID-19 situation in Washington, Governor Inslee's proclamations, symptoms, how it spreads, and how and when people should get tested. See our Frequently Asked Questions for more information.

A person's race/ethnicity or nationality does not, itself, put them at greater risk of COVID-19. However, data are revealing that communities of color are being disproportionately impacted by COVID-19 - this is due to the effects of racism, and in particular, structural racism, that leaves some groups with fewer opportunities to protect themselves and their communities. Stigma will not help to fight the illness. Share accurate information with others to keep rumors and misinformation from spreading.

- WA State Department of Health 2019 Novel Coronavirus Outbreak (COVID-19)
- WA State Coronavirus Response (COVID-19)
- Find Your Local Health Department or District
- CDC Coronavirus (COVID-19)
- Stigma Reduction Resources

Have more questions about COVID-19? Call our hotline: **1-800-525-0127,** Monday – Friday, 6 a.m. to 10 p.m., Weekends: 8 a.m. to 6 p.m. For interpretative services, **press #** when they answer and **say your language.** For questions about your own health, COVID-19 testing, or testing results, please contact a health care provider.

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