Indian Health Service Fact Sheet – Distribution and Use of Bamlanivimab

Background: On November 10, the U.S. Department of Health and Human Services announced the allocation plan for the drug bamlanivimab. The allocation is from Eli Lilly and Company to the United States which was finalized on November 12, 2020. The doses of the treatment, which received an Emergency Use Authorization from the U.S. Food and Drug Administration, will be used to treat non-hospitalized patients with confirmed COVID-19 who are experiencing mild to moderate symptoms and are at high-risk for severe symptoms and hospitalization in areas of the country hardest hit by the pandemic. The National Service Supply Center will oversee allocation of the drug and coordinate its distribution in Indian Country.

Q: What is bamlanivimab?
Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19. Therefore, the FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization.

Q: How many doses of bamlanivimab did IHS receive? How many patients will this treat?
A: IHS received 300 vials of bamlanivimab. The recommended dosing and course of treatment varies, but this would be anticipated to treat about 300 patients.

Q: Where were these doses distributed?
A: Distribution will occur upon request. IHS is currently working with IHS, tribal and urban Indian health programs sites to assess capabilities for administration. Sites interested in receiving doses should contact the IHS National Supply Service Center.

Q: How does IHS decide which patients get bamlanivimab?
A: IHS clinicians make treatment decisions based on each patient's situation. Bamlanivimab is available to clinicians in accordance with FDA regulations. Bamlanivimab can only be used to treat patients who are non-hospitalized with confirmed COVID-19 who are experiencing mild to moderate symptoms and are at high-risk for severe symptoms and hospitalization.

Q: Do you have a list of sites you can share?
A: Information will be provided as it becomes available

Q: Is IHS providing bamlanivimab to tribal and urban Indian organization facilities?

A: IHS is monitoring the limited supply of bamlanivimab to be distributed to IHS federal, urban Indian organization and tribal clinics, based on requests and current burden of patients with COVID-19.

Q: Can Tribes purchase bamlanivimab directly?
A: Bamlanivimab is not commercially available for purchase by tribes. Under the Emergency Use Authorization, distribution of bamlanivimab is monitored by the U.S. government for use consistent with the terms and conditions of the Emergency Use Authorization. The manufacturer will supply bamlanivimab to authorized distributors, or directly to a U.S. government agency, who will distribute the drug to hospitals and other healthcare facilities as directed by the U.S. government, in collaboration with state and local government authorities, as needed.

Q: Will IHS be receiving more bamlanivimab?
A: Currently, we have no information about future availability of bamlanivimab. We continue to work closely with HHS to communicate the needs of the Indian health system.

Q: Did IHS consult with Tribes before distributing bamlanivimab?
A: The priority of the Indian Health Service was distributing the drug as expeditiously as possible and without delay. The needs of tribes were assessed by the IHS Area Office.

Q: Should pregnant women/children/those with specific conditions/etc. be prescribed bamlanivimab?
A: There is limited experience giving bamlanivimab to pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from the treatment. Treatment decisions are made between health care provider and patient based on each patient's situation.

Q: How is bamlanivimab administered?
A: It is recommended that bamlanivimab be administered as soon as possible after positive viral test for COVID-19 and within 10 days of symptom onset. Bamlanivimab is administered as a single dosevia IV infusion over 60 minutes. More information about administration is available in the Health Care Provider Fact Sheet.

Q: What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. The issuance of an Emergency Use Authorization is different from FDA approval.

Bamlanivimab has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality

of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Q: Some studies have found no benefit from bamlanivimab in COVID-19 patients. Why is IHS using it?

A: There are limited clinical data for bamlanivimab. Bamlanivimab was shown in a clinical trial to shorten the time to recovery in some people. Patients have the option to accept or refuse bamlanivimab.

Q: How can I learn more?

- Ask your healthcare provider
- Visit www.bamlanivimab.com
- Visit https://www.covid19treatmentguidelines.nih.gov
- Visit the FDA FAQ on Bamlanivimab
- Contact your local or state public health department
- Contact your local IHS Area Emergency Management Point of Contact (EMPOC)