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NH-HAN 20211227



COVID-19 Pandemic, Update # 51 *Evusheld™ COVID-19 Monoclonal Antibody Therapy*

Key Points and Recommendations:

- On December 8th, the U.S. Food and Drug Administration (FDA) issued an [Emergency Use Authorization](#) (EUA) for AstraZeneca's Evusheld™ COVID-19 monoclonal antibody product.
 - Evusheld is a combination product that includes two recombinant human monoclonal antibodies (tixagevimab and cilgavimab) targeting the spike protein of SARS-CoV-2; these monoclonal antibodies are administered as two separate consecutive intramuscular (IM) injections.
 - This long-acting monoclonal antibody therapy can be used for [pre-exposure prophylaxis](#) (PrEP) in persons 12 years of age or older, who weigh at least 40 kg, and who are either 1) moderately to severely immunocompromised (see FDA Fact Sheet below for medical conditions or treatments that might result in moderate to severe immunosuppression), or 2) not recommended to receive COVID-19 vaccination due to a history of a vaccine contraindication.
 - This product is NOT for treatment of people infected with SARS-CoV-2 and NOT for post-exposure prophylaxis (PEP).
 - Providers administering this product should review and follow the instructions found in FDA's [Fact Sheet for Healthcare Providers](#).
 - Patients and caregivers need to be provided FDA's [Fact Sheet for Patients, Parents and Caregivers](#) prior to administration.
- The PROVENT Phase 3 clinical trial found that tixagevimab/cilgavimab recipients experienced a 77% reduction in incidence of COVID-19 compared placebo and showed effect for 6 months post-administration (re-dosing can be considered every 6 months).
- Tixagevimab/cilgavimab is not a substitute for vaccination and any age-eligible person who is immunocompromised should still be vaccinated against COVID-19; tixagevimab/cilgavimab can be administered at least 2 weeks after vaccination.
- For the next two weeks, NH will be sent 216 doses of tixagevimab/cilgavimab each week, which will be allocated to NH hospitals for further use and distribution within communities. Hospitals should develop processes to take referrals for tixagevimab/cilgavimab from non-affiliate providers and healthcare organizations. After the first couple of weeks, NH DPHS will re-evaluate need and distribution.
- Given very limited initial supply, NH DPHS suggests prioritizing patients who are most immunocompromised and unlikely to mount an adequate immune response to vaccination (such persons should still be vaccinated).
- Preliminary data show that the neutralizing capability of tixagevimab/cilgavimab is 12- to 30-fold lower against the Omicron variant. The majority of infections currently being detected in NH, however, continue to be from the Delta variant.
 - CDC publishes weekly data on the proportion of SARS-CoV-2 infections due to variants in each state (see Table): <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>.
- Report any serious adverse events and medication errors that occur within 7 days of administration is required to FDA's [MedWatch](#).

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- Providers should continue to refer to the [NIH COVID-19 Treatment Guidelines](#) and the [IDSA Guidelines](#) for treatment and prevention of COVID-19.
 - Review NIH's new guidance on [use of monoclonal antibodies when Omicron is the predominant circulating variant](#).
 - Starting in January 2022, the NH Division of Public Health Services (DPHS) **Healthcare Provider and Public Health Partner** webinars will occur on the **2nd and 4th Thursday** of each month from 12:00 – 1:00 pm (**next call will be Thursday, January 13th**):
 - Zoom link: <https://nh-dhhs.zoom.us/j/94059287404>
 - Call-in phone number: (646) 558-8656
 - Meeting ID: 940 5928 7404
 - Password: 353809

- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. – 4:30 p.m.).
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call.
- To change your contact information in the NH Health Alert Network, please send an email to DHHS.Health.Alert@dhhs.nh.gov.

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From: Benjamin P. Chan, MD, MPH; State Epidemiologist
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