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HEALTH ALERT NETWORK | HEALTH ADVISORY | December 8, 2021

FDA expands authorization of two monoclonal antibodies for treatment and post-exposure prevention of COVID-19 to younger pediatric patients, including newborns

The U.S. Food and Drug Administration revised the emergency use authorization (EUA) of bamlanivimab and etesevimab (previously authorized for pediatric patients 12 years of age and older weighing at least 40 kilograms, or about 88 pounds), to additionally authorize bamlanivimab and etesivimab administered together for the treatment of mild to moderate COVID-19 in all younger pediatric patients, including newborns, who have a positive COVID-19 test and are at high risk for progression to severe COVID-19, including hospitalization or death. This revision also authorizes bamlanivimab and etesevimab, to be administered together, for post-exposure prophylaxis for prevention of COVID-19 in all pediatric patients, including newborns, at high risk of progression to severe COVID-19, including hospitalization or death.

Pediatric Dosage for patient <40 kg is as follows:

- >20 kg to <40 kg: 350 mg bamlanivimab and 700 mg etesevimab
- >12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab
- 1 kg to 12 kg: 12 mg/kg bamlanivimab and 24 mg/kg etesevimab

Related information:

- FDA Expands Authorization of Two Monoclonal Antibodies for Treatment and Post-Exposure Prevention of COVID-19 to Younger Pediatric Patients, Including Newborns
- Letter of Authorization
- Fact Sheet for Providers
- Fact Sheet for Patients, Parents and Caregivers
- Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab and Etesevimab

Categories of Health Alert Network messages:
Health Alert Requires immediate action or attention; highest level of importance
Health Advisory May not require immediate action; provides important information for a specific incident or situation
Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##