bamlanivimab/etesevimab – Emergency use authorization expansion

- On September 16, 2021, the FDA announced the emergency use authorization approval (EUA) of Eli Lilly's bamlanivimab/etesevimab, in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
  - Not fully vaccinated or who are not expected to mount an adequate immune response to complete severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination ***and***
  - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention ***or***
  - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting.

- Limitations of authorized use for bamlanivimab/etesevimab are:
  - Bamlanivimab/etesevimab is not authorized for use in states, territories, and U.S. jurisdictions in which the combined frequency of variants resistant to bamlanivimab/ etesevimab exceeds 5%
    - A list of states, territories, and U.S. jurisdictions in which bamlanivimab/ etesevimab are and are not currently authorized is available on the following FDA website: Bamlanivimab and Etesevimab Authorized States, Territories, and US Jurisdictions (fda.gov)
  - Post-exposure prophylaxis with bamlanivimab/etesevimab is not a substitute for vaccination against COVID-19
  - Bamlanivimab/etesevimab is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

- Previously, bamlanivimab/etesevimab was authorized for the treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

- The expanded EUA is based on data from part 1 of the BLAZE-2 trial, a randomized, double-blind, placebo-controlled study enrolling 966 patients who received a single dose of bamlanivimab 4,200 mg or placebo for the prevention of COVID-19 in residents and staff of skilled nursing facilities following a confirmed reported case of SARS-CoV-2 infection at the facility. The primary efficacy endpoint was the cases of symptomatic COVID-19 by day 57.
  - There were 114 cases of symptomatic COVID-19, with a lower frequency occurring in participants treated with bamlanivimab vs. placebo (residents and staff; adjusted odds ratio 0.43; $p < 0.001$).
  - Four COVID-19-related deaths were reported in the overall population; all occurred in the placebo arm (0.8%).

- The recommended dose of bamlanivimab/etesevimab for the expanded EUA use is 700 mg of bamlanivimab and 1,400 mg of etesevimab administered together as a single intravenous (IV) infusion as soon as possible after exposure to SARS-CoV-2.

Continued . . .

— Refer to the bamlanivimab/etesevimab EUA prescribing information for dosing for the treatment of COVID-19 and additional dosing recommendations

optumrx.com