bamlanivimab/etesevimab and REGN-COV (casirivimab/imdevimab) – Emergency use authorization revision

- On January 24, 2022, the FDA revised the emergency use authorizations (EUAs) for Eli Lilly's bamlanivimab/etesevimab and Regeneron's REGEN-COV (casirivimab/imdevimab), limiting their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.
    - At this time, bamlanivimab/etesevimab and REGN-COV are not authorized for use in any U.S. states, territories, and jurisdictions.
    - In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to bamlanivimab/etesevimab or REGEN-COV, then use of these treatments may be authorized in these regions.
- These treatments are highly unlikely to be active against the omicron variant. As of January 15, 2022, the CDC estimates that >99% of COVID-19 cases are due to the omicron variant.
- The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel recommended against the use of bamlanivimab/etesevimab and REGEN-COV because of markedly reduced activity against the omicron variant and real-time testing to identify rare, non-omicron variants is not routinely available.
- The NIH is currently recommending other therapies, Paxlovid™ (nirmatrelvir/ritonavir), sotrovimab, Veklury® (remdesivir), and molnupiravir, to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death.
- The federal government, which had paid for and is responsible for distributing these agents, has halted shipping of bamlanivimab/etesevimab and REGEN-COV.