Sotrovimab – Emergency use authorization revision

- On April 5, 2022, the FDA announced that GlaxoSmithKline's sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant.

- The CDC's Nowcast data from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions.

    - The authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant.
    - Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

- The FDA recommends using other approved or authorized products, Paxlovid™ (nirmatrelvir/ritonavir), Veklury® (remdesivir), bebtelovimab, and Legevrio™ (molnupiravir), to treat patients with mild-to-moderate COVID-19 who are at high risk for progressing to severe COVID-19, including hospitalization or death.

- The FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

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