FDA updates Sotrovimab emergency use authorization

Update [4/5/2022] 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

This statement updates the statements below.

The Centers for Disease Control and Prevention (CDC) Nowcast data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) 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. Data included in the health care provider fact sheet (https://www.fda.gov/media/149534/download) show 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.

Health care providers should use other approved or authorized products (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs) as they choose appropriate treatment options for patients.

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

Update [3/30/2022] FDA limits use of Sotrovimab to treat COVID-19 in additional U.S. regions due to the BA.2 Omicron sub-variant

This statement updates the statements below.

The Centers for Disease Control and Prevention (CDC) Nowcast data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) from March 29, 2022 estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in three additional Health and Human Services (HHS) regions (5, 9, and 10). Due to these data, FDA has added these regions to the list of states and territories where sotrovimab is not authorized at this time.

Sotrovimab is not authorized at this time in the following states and territories:

- Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (Region 1) (as of 3/25/2022)
- New Jersey, New York, Puerto Rico, and the Virgin Islands (Region 2) (as of 3/25/2022)

- Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin (Region 5) (as of 3/30/2022)
- Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau (Region 9) (as of 3/30/2022)
- Alaska, Idaho, Oregon, and Washington (Region 10) (as of 3/30/2022)

Sotrovimab remains authorized in U.S. regions where the CDC Nowcast point estimate for the proportion of the Omicron BA.2 variant remains below 50%. FDA will continue to monitor BA.2 in all U.S. regions and may revise the authorization further to ensure that patients with COVID-19 have effective treatments available. Health care providers in regions where sotrovimab remains authorized should strongly consider the use of other approved or authorized products (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs), and monitor the frequency of BA.2 in their region (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) as they choose appropriate treatment options for patients.

Update [3/25/2022] FDA limits use of Sotrovimab to treat COVID-19 in some U.S. regions due to the BA.2 Omicron sub-variant

This statement updates and replaces the original statement below from 2/25/22.

The U.S. Food and Drug Administration is continually monitoring how authorized and approved treatments for COVID-19 are affected by changing variants—currently Omicron and the Omicron sub-variants, such as BA.2. Today, considering the most recent data available, FDA is announcing that sotrovimab is no longer authorized for use at this time in the following states and territories:

- Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont (Health and Human Services [HHS] Region 1)
- New Jersey, New York, Puerto Rico, and the Virgin Islands (HHS Region 2)

New data included in the health care provider fact sheet (/media/149534/download) shows that the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Based on Centers for Disease Control and Prevention Nowcast data, the BA.2 sub-variant is estimated to account for more than 50% of cases in the states and territories in Regions 1 and 2 listed above (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) as of March 19, 2022.

There are several other therapies (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs) – Paxlovid, Veklury (remdesivir), bebtelovimab, and Lagevrio (molnupiravir) – that are expected to be effective against the BA.2 sub-variant, and that are

authorized or approved to treat certain patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death. Health care providers should assess whether these treatments are right for their patients.

We will continue to monitor BA.2 in all U.S. regions and may revise the authorization further to ensure that patients with COVID-19 have effective treatments available. Health care providers should also monitor the frequency of BA.2 in their region (https://covid.cdc.gov/covid-data-tracker/#variant-proportions) as they choose appropriate treatment options for patients.

[2/25/2022] On February 23, 2022, FDA revised the emergency use authorization for sotrovimab to clarify that sotrovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a variant that is not susceptible to this treatment. However, sotrovimab is currently authorized in all U.S. regions until further notice by FDA. For other limitations and conditions, refer to the emergency use authorization (EUA) (https://www.fda.gov/media/149532/download).

FDA will continue to monitor conditions to determine whether use in a geographic region is consistent with the scope of authorization, referring to available information, including information on variant susceptibility and CDC regional variant frequency data (https://covid.cdc.gov/covid-data-tracker/#variant-proportions).

This EUA authorizes sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and certain pediatric patients 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. Sotrovimab should be administered by a qualified health care provider as a single intravenous infusion (IV) as soon as possible after positive viral test for COVID-19 and within seven days of symptom onset.