

FDA urges race, ethnicity be considered in COVID-19 drug treatment



The U.S. Food and Drug Administration is recommending that health care providers consider race and or ethnicity in addition to underlying health conditions when determining if a patient should be given a COVID-19 antibody treatment.

The recommendation was made in [a fact sheet](#) given out by the agency on the emergency use authorization of the drug sotrovimab to treat mild to moderate cases of COVID-19.

“The U.S. Food and Drug Administration (FDA) has issued an Emergency

Use Authorization (EUA) to permit the emergency use of the unapproved product sotrovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults 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 fact sheet states.

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FDA officials also list a number of medical qualifications that would deem a patient as "high risk for progression to severe COVID-19" including being overweight, pregnant, 65 years of age or older, suffering from kidney disease, diabetes or cardiovascular disease.

Below that list, FDA officials wrote, in parentheses, that health care providers can use "other medical conditions" to place patients at high-risk for progression to severe COVID-19.

"Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19, and authorization of sotrovimab under the EUA is not limited to the medical conditions or factors listed above," the document reads.

The factsheet was first released in September of last year and was last updated in December.

There are some caveats to the drug's emergency use authorization, mainly that it is not recommended for patients who already have severe COVID-19 and who have been hospitalized due to the virus, require oxygen therapy due to COVID-19 or require an increase in baseline oxygen flow rate due to

COVID-19.

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