# Information about the COVID-19 Sotrovimab Monoclonal Antibody Treatment

Disclaimer: as of April 5, 2022, the U.S. Food and Drug Administration has revoked approval of the COVID-19 monoclonal antibody (mAb) treatment called sotrovimab in all U.S. states and territories. This is due to an increase in COVID-19 cases caused by the Omicron BA.2 sub-variant and data showing that sotrovimab is unlikely to be as effective against it.[1]

Like many other viruses, the SARS-CoV-2 virus that causes COVID-19 is evolving and changing over time. This means that what made the virus susceptible to certain treatments or vaccines may change. As COVID-19 becomes an endemic disease, meaning that it is still present but not causing significant disruption in our daily lives, the virus will continue to change and new variants will arise.

In the future, new variants may arise that may once again be treatable with sotrovimab.

On May 26, 2021, the US Food and Drug Administration approved the COVID-19 monoclonal antibody (mAb) treatment called sotrovimab made by GlaxoSmithKline LLC, making it available for emergency use during the COVID-19 pandemic.[2] This fact sheet contains information about the sotrovimab treatment to help you make informed decisions about treatments for COVID-19 that may help reduce your risk of severe illness.

## How does sotrovimab work?

Sotrovimab provides your immune system with antibodies to protect you from COVID-19. The antibodies recognize and attack the virus and stops it from entering the cells in your body. The treatment is given to you as soon as possible after testing positive for COVID-19.

## Who is sotrovimab for?

Sotrovimab has been authorized for treating mild to moderate cases of COVID-19. Those that receive the treatment must be 12 years of age or older, weigh at least 40kg/88lbs, and be at high risk for progressing to severe COVID-19 and/or hospitalization.[3]

Before receiving sotrovimab, you should talk with your provider to discuss potential risks and benefits if you[4]

- have any allergies.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- have any serious illnesses.
- are taking any medications (prescription, over the counter, vitamins, herbal products, and traditional medicines).

Sotrovimab is not authorized for use in people who[3]

- are already hospitalized due to COVID-19.
- require oxygen therapy due to COVID-19.
- require an increase in baseline oxygen flow rate due to COVID-19 for those on chronic oxygen therapy because of a pre-existing medical condition.

You are considered high-risk if you meet at least one of the following criteria[3]:

- are 65 years of age or older
- have a body mass index (BMI) equal to or over 25
- are pregnant
- have a chronic kidney disease
- have diabetes
- have an immunosuppressive disease
- are currently receiving immunosuppressive treatment
- have a cardiovascular disease such as congenital heart disease
- have hypertension
- have sickle cell disease
- have a chronic lung disease such as
- chronic obstructive pulmonary disease
- moderate to severe asthma
- interstitial lung disease
- cystic fibrosis
- pulmonary hypertension
- have a neurodevelopmental disorder such as cerebral palsy
- have a medical-related technological dependence such as a tracheostomy or gastrostomy

## How is sotrovimab given?

Sotrovimab is administered as a single dose through intravenous (IV) infusion over 30 minutes.[4] Patients are monitored during the infusion and for at least one hour afterward.[4]

## What are the possible benefits of receiving sotrovimab?

The known and potential benefits of receiving Sotrovimab as a treatment for COVID-19 include[2,4]

- reduced risk of severe COVID-19 symptoms.
- reduced risk of hospitalization.
- reduced risk of death from COVID-19.

## What are the possible side effects of receiving sotrovimab?

Sotrovimab is still being studied for its safety and effectiveness, and not all side effects are currently known.[4]

Possible temporary side effects of sotrovimab treatment include[3]

- allergic reactions including anaphylaxis
- rash
- diarrhea
- chills
- worsening of existing COVID-19 symptoms

Possible temporary side effects of getting any medicine by infusion may include[4]

- brief pain
- bleeding
- bruising of the skin
- soreness
- swelling
- possible infection at the injection site

It is also possible that sotrovimab may interfere with your body's ability to fight off a future COVID-19 infection.[4] Similarly, sotrovimab may reduce your body's immune response to a COVID-19 vaccine.[4]

Although not all side effects are currently known, the known and potential benefits of sotrovimab outweigh the known and potential risks and continues to be monitored by the FDA.

## Can I be vaccinated for COVID-19 if I am treated with sotrovimab for COVID-19?

Currently, there is no data on the safety and effectiveness of COVID-19 vaccines in people who received a COVID-19 mAb treatment like sotrovimab.

The Advisory Committee on Immunization Practice recommends that you wait 90 days after receiving a COVID-19 mAb treatment to get vaccinated to avoid any possible interactions between the treatment and vaccine. This is the recommended wait time because data suggest that reinfection of COVID-19 is uncommon within 90 days.[5]

## Should I continue to follow CDC guidelines?

You should continue to practice all safety measures to stop the spread of COVID-19, even if you have received the sotrovimab treatment. This is important because receiving this treatment does not protect you against future COVID-19 infections.

To protect yourself and your community we recommend

- continuing to wear a mask.
- continuing to social distance.
- continuing to wash your hands.
- following all public health guidelines and recommendations.

### Resources


1. FDA updates Sotrovimab emergency use authorization. U.S. Food and Drug Administration. Updated April 5, 2022. Accessed April 5, 2022. www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization
2. Office of the Commissioner. Coronavirus (COVID-19) Update: FDA Authorizes Additional Monoclonal Antibody for Treatment of COVID-19. U.S. Food and Drug Administration. Published May 26, 2021. Accessed August 6, 2021. www.fda.gov/news-events/pressannouncements/coronavirus-covid-19-update-fda-authorizes-additionalmonoclonal-antibody-treatment-covid-19
3. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Sotrovimab. U.S. Food and Drug Administration. Accessed August 6, 2021. www.fda.gov/media/149534/download
4. Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Sotrovimab for Treatment of Coronavirus Disease 2019 (COVID-19). U.S. Food and Drug Administration. Accessed August 6, 2021.www.fda.gov/media/149533/download
5. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC. Published August 6, 2021. Accessed August 6, 2021. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19vaccines-us.html