YOUR GUIDE TO SOTROVIMAB:
(Injection, 500 mg, for intravenous use)
Under the Emergency Use Authorization (EUA) for Treatment of COVID-19

**Authorized Use**
Sotrovimab is an investigational medicine used to treat mild-to-moderate symptoms of COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk of progression to severe COVID-19, including hospitalization or death. Sotrovimab is still being studied, and there is limited information about its safety and effectiveness.

**Important Information About Sotrovimab**
- Sotrovimab is an investigational medicine (still being studied) and has not been approved by the FDA. The FDA has made sotrovimab available under an emergency access mechanism called an emergency use authorization (EUA).
- The EUA for sotrovimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these medicines, unless terminated or revoked (after which the products may no longer be used).

This brochure can help you learn about sotrovimab, a treatment option for COVID-19
If you are diagnosed with COVID-19, a treatment option may be right for you.
In issuing an EUA, the FDA has found it reasonable to believe that sotrovimab may be effective in reducing the risk of hospitalization or death in people who are at high risk of progression. This guide explains how it works, who might benefit from it, and what to know when considering treatment. There is limited information about the safety and effectiveness of using sotrovimab to treat people with mild-to-moderate COVID-19.
Talk to your healthcare provider if you have any questions about sotrovimab.

**IMPORTANT SAFETY INFORMATION**
Do not take sotrovimab if you have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab.

What are the important possible side effects of sotrovimab?
Allergic reactions can happen during and after infusion with sotrovimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever; difficulty breathing; low oxygen level in your blood; chills; tiredness; fast or slow heart rate; chest discomfort or pain; weakness; confusion; nausea; headache; shortness of breath; low or high blood pressure; wheezing; swelling of your lips, face, or throat; rash including hives; itching; muscle aches; dizziness; feeling faint; and sweating.

Please see additional Important Safety Information on the following pages. For additional information, see the most current Fact Sheet for Healthcare Providers, Fact Sheet for Patients, Parents, and Caregivers, and FDA Letter of Authorization for sotrovimab, or visit sotrovimab.com.
How COVID-19 spreads
COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. Though most COVID-19 illness is mild, serious illness can happen, including hospitalization or death. COVID-19 may also cause other medical conditions to become worse.

Symptoms of COVID-19
There is a wide range of COVID-19 symptoms, and they may differ from person to person. Some things, such as the new loss of taste and smell, are more unique to COVID-19, but not all people experience those symptoms. Many of the symptoms, such as congestion or runny nose, or sore throat, are similar to those associated with the common cold, allergies, or the flu.

Symptoms of COVID-19 may appear 2 to 14 days after exposure.
Possible symptoms of COVID-19 may include:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headaches
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

If you start to feel some of these symptoms, it is important to get tested as soon as possible. Testing is the only way to confirm a diagnosis of COVID-19. To find out where you can be tested, speak to your healthcare provider.

IMPORTANT SAFETY INFORMATION (cont’d)
What are the important possible side effects of sotrovimab? (cont’d)
The side effects of getting any medicine through a vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of sotrovimab. Not many people have been given sotrovimab. Serious and unexpected side effects may happen. Sotrovimab is still being studied, so it is possible that all of the risks are not known at this time.

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How sotrovimab works

Our immune system produces antibodies to fight infection. When facing a new virus, such as SARS-CoV-2 (the virus that causes COVID-19), producing antibodies takes time. Some patients cannot mount a response quickly enough to effectively attack the virus.

Sotrovimab is a monoclonal antibody. Monoclonal antibodies are produced in a lab. They can work as a substitute to your own antibodies and they can boost or mimic your immune system’s attack of the virus. Sotrovimab is designed to block the virus from attaching and entering human cells, which in turn neutralizes the virus.

In issuing an EUA, the FDA has found it reasonable to believe that sotrovimab may be effective in reducing the risk of hospitalization or death in people who are at a high risk of progression. If your doctor determines sotrovimab is right for you, it is important that you receive treatment as soon as possible.

Being treated with sotrovimab

Treatment with sotrovimab requires a 1-time, 30-minute infusion. Infusion treatment is when a drug is administered into your body through an intravenous (IV) injection. You will be observed by your healthcare provider for at least 1 hour after you receive sotrovimab.

After treatment with sotrovimab

You still may be able to infect others after receiving treatment with sotrovimab, so continue to follow safety guidelines and any additional instructions from your healthcare provider. Speak to your healthcare provider right away or seek medical attention immediately if your symptoms get worse.

IMPORTANT SAFETY INFORMATION (cont’d)

What are the important possible side effects of sotrovimab? (cont’d)

It is possible that sotrovimab could interfere with your body’s own ability to fight off a future infection of SARS-CoV-2. Similarly, sotrovimab may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.
Who sotrovimab can help

Your doctor will determine if sotrovimab is an appropriate treatment choice for you. Sotrovimab is an investigational medicine option for people aged 12 years and older with COVID-19 who:

- Have a positive COVID-19 test result
- Have had mild-to-moderate symptoms for 10 days or less
- Are at high risk of getting very sick or becoming hospitalized from COVID-19

This treatment is not for people who are hospitalized because of their COVID-19 symptoms.

Factors that put you at higher risk for progression to severe COVID-19:

- Are ≥65 years of age
- Have obesity or are overweight, with a body mass index (BMI) of >25
- Have diabetes
- Have high blood pressure
- Have heart disease
- Are pregnant
- Have chronic kidney disease
- Have an immunosuppressive disease or are receiving immunosuppressive treatment
- Have chronic lung disease, like moderate-to-severe asthma or chronic obstructive pulmonary disease (COPD)
- Have a neurodevelopmental disorder, such as cerebral palsy
- Have sickle cell disease
- Have a medical-related technological dependence, such as tracheostomy, gastrostomy, or positive pressure ventilation (not related to 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.

Talk to your doctor to see if you may be at high risk for progression to severe COVID-19.

IMPORTANT SAFETY INFORMATION (cont’d)

What are the important possible side effects of sotrovimab? (cont’d)

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a serious allergic reaction to sotrovimab or to any of the ingredients in sotrovimab
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

Please see additional Important Safety Information on the following page. For additional information, see the most current Fact Sheet for Healthcare Providers, Fact Sheet for Patients, Parents, and Caregivers, and FDA Letter of Authorization for sotrovimab, or visit sotrovimab.com.
Paying for sotrovimab
The cost of sotrovimab may vary depending on your individual insurance plan. That’s why understanding your insurance is important.

GSK may be able to help eligible commercially-insured patients with their out-of-pocket costs. Patients who have commercial insurance that does not pay the full amount of the cost of sotrovimab may also be eligible for assistance. Subject to program rules and limitations.

Please call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684) for questions regarding the co-pay program eligibility requirements and how to enroll.

Other treatment options
Like sotrovimab, the FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-emergency-use-authorities for information on the emergency use of other medicines that are not approved by the FDA to treat people with COVID-19.


Your doctor may talk with you about clinical trials you may be eligible for.

It is your choice whether or not to be treated with sotrovimab. If you decide not to receive sotrovimab, or stop it at any time, your standard medical care will not change.

Reporting side effects with sotrovimab
Tell your doctor right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088, or call the GSK COVID Contact Center at 1-866-GSK-COVID (866-475-2684).

IMPORTANT SAFETY INFORMATION (cont’d)
What if I am pregnant or breastfeeding?
There is no experience treating pregnant women or breastfeeding mothers with sotrovimab. For a mother and unborn baby, the benefit of receiving sotrovimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

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