FAQs for Patients/Public

Alberta Health Services (AHS) is offering some Albertans sotrovimab to treat mild to moderate COVID-19 symptoms. Eligible patients will get the treatment from the EMS Mobile Health Unit (MIH) in their homes or at an AHS site.

**Sotrovimab is not a replacement for immunization against COVID-19. Albertans are strongly encouraged to get the COVID-19 vaccine.**

**What is sotrovimab?**
Sotrovimab is a monoclonal antibody - a type of protein that attaches to the surface of the coronavirus that causes COVID-19. Sotrovimab prevents the virus from entering healthy cells in your body.

**Has sotrovimab been approved for use?**
Health Canada has authorized the use of sotrovimab to treat mild to moderate COVID-19 that has been confirmed by testing. Sotrovimab is used to prevent symptoms from getting worse in people who have a high risk of needing to go to the hospital for COVID-19.

Health Canada has authorized sotrovimab based on limited clinical testing in humans and quality information. Learn more on the Health Canada consumer information summary for sotrovimab.

**What is sotrovimab used for?**
Health Canada has authorized sotrovimab to treat mild to moderate COVID-19 that has been confirmed by testing. Sotrovimab is used to prevent these mild to moderate symptoms from getting worse in people who have a high risk of needing to go to the hospital for COVID-19.

**Who can get sotrovimab?**
In Alberta, sotrovimab is approved for adults who:
- have a positive polymerase chain reaction (PCR) test for COVID-19
- have mild to moderate COVID-19 symptoms
- can receive the treatment within five days from when symptoms started

Treatment will be given to patients who are most likely to get severe COVID-19 illness and are at a greater risk of being hospitalized. This includes:
- Unvaccinated people who have not received any doses of a COVID-19 vaccine and are:
  - 55 years of age and older, regardless of other health conditions
  - 18 years of age and older with one of the following health conditions:
    - diabetes requiring medication
    - obesity (BMI >30)
    - chronic kidney disease (estimated glomerular filtration rate, <60 ml per minute per 1.73 m2 of body-surface area)
    - congestive heart failure (New York Heart Association class II, III, or IV)
- chronic obstructive pulmonary disease, and moderate-to-severe asthma
  - pregnancy
- Vaccinated or unvaccinated patients who are immunocompromised due to one of the following reasons:
  - have received a transplant (solid organ or stem cell)
  - are an oncology patient who has received a dose of any IV or oral chemotherapy or other immunosuppressive treatment since December 2020
  - are a patient with inflammatory conditions (e.g. rheumatoid arthritis, lupus, inflammatory bowel disease) receiving a dose of any systemic immunosuppressive treatment since December 2020.

Sotrovimab is not a replacement for immunization against COVID-19. **Albertans are strongly encouraged to get fully immunized against COVID-19.** If you receive sotrovimab, you should wait 90 days after your treatment before getting a COVID-19 vaccine.

**Why is this medication limited to people with COVID symptoms for less than five days?**
Sotrovimab works best when it is used in early infection, before the virus has moved beyond a mild to moderate infection. If you have [symptoms of COVID-19](https://www.health.gov.ab.ca/en/topics/coronavirus/covid-19-topics/symptoms), it’s important to get tested as soon as possible. This gives AHS time to determine if you are eligible for treatment with sotrovimab.

**Why are immunocompromised patients who have been vaccinated eligible for sotrovimab treatment?**
Sotrovimab treatment is intended for individuals that are at high risk of progressing to severe disease (hospitalization, death). Vaccinated individuals are expected to develop an immune response that places them at a low risk for severe COVID-19. However immunocompromised individuals may not respond fully to vaccines, and therefore providing access to sotrovimab treatment can better protect them.

**How were the health conditions for unvaccinated individuals selected?**
Aside from pregnancy, the age cut off and health conditions are based on the evidence from the COMET-ICE study used to approve sotrovimab.

**How come pregnancy is included if pregnant patients were not included in the study?**
Pregnancy was included based as pregnant individuals are at a higher risk than the general population to progress to severe COVID-19. Groups like the American College of Obstetricians and Gynecologists, recommend treatment with monoclonals like sotrovimab ([COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics | ACOG](https://www.acog.org/Certification-and-Licensure/FAQs-Clinical-Practice-Topics/COVID-19)). The decision to proceed with treatment can be discussed with your doctor. A specialist may be consulted if you have more questions.

**How will eligible patients be identified and informed?**
If you are 18 years of age or older and test positive for COVID-19, you will hear about treatment with sotrovimab in the same text message from AHS that notifies you of your positive COVID-19 test result. You may also hear about sotrovimab from your family doctor or another healthcare provider.

If you are unvaccinated or immunocompromised and are interested in getting the treatment or learning more about sotrovimab, follow the instructions in the text message. You will be asked visit [ahs.ca/covidopt](https://ahs.ca/covidopt) to determine if you are eligible for sotrovimab treatment. If you meet the criteria outlined on the website, you should then leave a message for Health Link at 1-844-343-0971. Health Link staff will call you back and ask...
you some questions before referring you to a health professional who will determine if you are eligible, get your consent and book your appointment.

If you are a transplant patient, tell your medical specialist or specialized healthcare team if you test positive for COVID-19. A member of your healthcare team will answer your questions, determine if you are eligible for treatment, get your consent, and refer you for appointment booking. Transplant patients should notify their medical specialist or specialized healthcare team if they test positive for COVID-19. A member of the healthcare team will answer questions, assess for eligibility, obtain consent and refer for appointment booking.

**How is Sotrovimab given?**
Sotrovimab is given intravenously by a qualified health professional. The medicine is given over 60 minutes (1 hour). You will be watched closely for another 60 minutes after getting the treatment. You can expect the appointment to last about 2.5 hours, including setup time.

**Where will the treatment be given?**
Treatment will be provided to eligible patients either at a clinic or by EMS MIH in your home, in the areas they service, depending on your location in the province. Details on appointment booking at that clinic will be provided to eligible patients.

**How will I be monitored after receiving the treatment?**
If you are treated with sotrovimab, a healthcare provider will call you several times in the first five days after you get sotrovimab. You will also get an information sheet.
After five days, you should watch your health. Tell your doctor about any side effects or COVID-19 symptoms that get worse. Or call Health Link at 811 to speak to a registered nurse. For urgent help, call 911. You should also follow up with your family doctor or healthcare provider 10 days after your COVID-19 symptoms started.

**What are the possible side effects of sotrovimab?**
Current clinical trials have found relatively mild side effects in less than one out of every 100 people who get sotrovimab. Side effects that have been found include:
- diarrhea
- headache
- shortness of breath
There was also one case of an allergic reaction in the 430 people involved in the study.

Since there is limited clinical data about sotrovimab, you might have unexpected side effects that have not been reported. EMS MIH will monitor you during the treatment and one hour after you receive sotrovimab. They will provide treatment as needed to manage any side effects you have.
For more details on avoiding potential side effects and what to watch for, see the Health Canada consumer information summary.

**What should be done if COVID-19 symptoms get worse?**
Even with sotrovimab treatment, your COVID-19 symptoms may continue or get worse.
- Monitor your health and tell the healthcare provider who calls you in the first five days after your treatment about your symptoms.
- Call Health Link at 811 or your healthcare provider if you have more questions or concerns.

Date: November 29, 2021
Call 911 right away if you have severe symptoms such as:
  o difficulty breathing
  o severe chest pain
  o feelings of confusion
  o loss of consciousness

Learn more about managing your COVID-19 symptoms.

Can I get vaccinated for COVID-19 after I get sotrovimab?
Yes. But you should wait 90 days after getting sotrovimab or other monoclonal antibody treatments before getting a COVID-19 vaccine. Sotrovimab is not a replacement for immunization against COVID-19. Albertans are strongly encouraged to get fully immunized against COVID-19.

Will sotrovimab be offered to pregnant women and children?
At this time, AHS is still determining if sotrovimab should be given to pregnant women and children over 12 years old, outside of those who are currently eligible for treatment.

Why is Alberta using this drug?
Sotrovimab can prevent mild to moderate COVID-19 from becoming more severe and requiring people to be admitted to the hospital. Sotrovimab can be especially helpful for patients who might otherwise have a high risk of being hospitalized due to COVID-19.

Is sotrovimab being used elsewhere?
Yes. Outpatient monoclonal antibody treatments like sotrovimab are currently being used in many areas of the United States, as well as in Saskatchewan and Ontario. AHS is reaching out to other health authorities in Canada to learn how they are using this treatment.

Do I need to pay for this treatment?
No. The treatment is covered and paid for by Alberta Health. If you are eligible for the treatment, you do not need to pay for it.

Why hasn’t this drug been considered before now?
Sotrovimab is a new treatment for COVID-19. The clinical trial was only recently finished. Health Canada gave it interim authorization on July 30, 2021. For more information, see the Health Canada consumer information summary for sotrovimab.

For more information on the AHS rollout of sotrovimab, visit ahs.ca/covidopt

Date: November 29, 2021