

FAQs for Healthcare Providers

Sotrovimab (Monoclonal Antibody) Outpatient Treatment

What is Sotrovimab?

Sotrovimab is a monoclonal antibody - a type of protein that attaches to the spike protein of the coronavirus that causes COVID-19. It prevents the virus from entering healthy cells within the body.

Has sotrovimab been approved for use?

Health Canada provided interim authorization in July 2021 for use of sotrovimab in Canada to treat mild to moderate COVID-19 with the aim of preventing worsening of symptoms for those at risk of hospitalization. HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION.

Sotrovimab is currently not approved for patients who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19, or who require an increase in baseline oxygen flow rate due to underlying non-COVID-19 related comorbidity. Sotrovimab is contraindicated in those who are known to be hypersensitive to monoclonal antibodies or the infusion ingredients.

Sotrovimab is NOT a replacement for COVID-19 vaccination. Albertans are strongly encouraged to get fully vaccinated against COVID-19.

What are the eligibility criteria for Alberta patients?

Sotrovimab is approved for outpatient use in Alberta for adults with mild to moderate COVID-19 symptoms who have a positive PCR test for COVID-19, are at risk for severe outcomes and are able to receive treatment within five days from the start of symptoms. Because there is currently a limited supply of medication, the treatment will be rolled out in a phased approach starting with people who are at the highest risk of progressing to severe illness and hospitalization:

- People aged 55 years and older who have not received any doses of a COVID-19 vaccine.
- OR
- Immunosuppressed people, initially those who have received Solid Organ Transplants or Stem Cell Transplants, regardless of vaccination status.

Why is this medication limited to people who can receive treatment within five days of onset of symptoms?

Sotrovimab has been shown to be most effective when administered in the early phases of infection and viral replication, while symptoms remain mild to moderate (i.e. no shortness of breath at rest and no requirement for supplemental oxygen). If people have COVID-like symptoms, they are advised to get tested as early as possible to allow sufficient time to determine potential eligibility for sotrovimab treatment.

How will eligible patients be identified and informed?

People aged 55 and older will receive information about the treatment in the text from AHS that notifies them of a positive COVID test result. If they are unvaccinated and interested in receiving the medication or want more information, they will be asked to call Health Link at 1-844-343-0971. Health Link staff will call back and ask some initial screening questions and refer them to [EMS Mobile Integrated Health team \(MIH\)](#) where a healthcare professional will determine eligibility and obtain consent. The appointment for sotrovimab treatment will then be booked to take place in the patient's home or continuing care facility, or in a dedicated clinic site for those patients located in the Fort McMurray area (since there is no current MIH coverage for this area).

Physicians should advise their patients to call the Health Link at 1-844-343-0971 directly if they believe they are eligible to receive treatment.

Transplant patients should notify their specialized healthcare team if they test positive for COVID-19. A member of their specialized team would then answer their questions, assess for eligibility, obtain consent, and refer to EMS MIH to book the appointment.

How is Sotrovimab administered?

Sotrovimab is administered as a single intravenous 500 mg infusion by a qualified health professional. The infusion is administered over 60 minutes and the patient is closely monitored for an additional 60 minutes after the infusion. The expected total administration time is about 2.5 hours, including set-up. Details may be found in the AHS parenteral [monograph](#).

Where will the treatment be provided?

In the first phase, infusion location for eligible patients will be based on their location in the province:

- [EMS MIH](#) will provide treatment to most eligible patients in their homes or in their continuing care facility. For a complete list of areas services by [EMS MIH](#), visit the website and click on the WHERE tab.
- Patients in Fort McMurray and surrounding areas including Anzac and Fort Mackay will receive their treatment at an AHS clinic located in Fort McMurray.

Access will be expanded to more areas of the province, including more rural communities, as soon as possible.

How will people be monitored after treatment?

For the first five days after the treatment, a healthcare provider will follow up with the patient to check on their wellbeing. After this five day period, patients should continue to monitor their health and report any perceived adverse effects or worsening COVID-19 symptoms to their healthcare professional or Health Link by calling 811. For urgent assistance, call 911. All patients should follow up with their family physician or healthcare provider 10 days after onset of their COVID-19 symptoms.

What are the potential adverse effects?

Current clinical trials report relatively mild side effects at a rate of less than 1%. Side effects reported in the clinical trial include diarrhea, headache and shortness of breath. In addition, there was one case of anaphylaxis. However, since there is limited clinical data, unexpected side effects may occur that have not previously been reported. The healthcare provider administering treatment will monitor for side effects during

administration and for one hour following the treatment and will provide care as required. For more details on avoiding potential side effects and what to watch for, refer to [Health Canada's website](#).

What should be done if COVID-19 symptoms continue to worsen?

Even with sotrovimab treatment, COVID-19 symptoms may continue or get worse. Patients will be advised to:

- Monitor their health and report any symptoms or concerns to the healthcare provider who follows up with them in the five days following their treatment. They can also call [Health Link at 811](#) or their healthcare provider if they have questions or concerns.
- **Call 911 immediately** if they experience severe symptoms of COVID-19 such as:
 - difficulty breathing
 - severe chest pain
 - feelings of confusion
 - loss of consciousness

More information on how to manage COVID-19 symptoms can be found at [Symptoms and testing | Alberta.ca](#).

Can patients receive COVID-19 vaccinations after sotrovimab treatment?

According to Public Health guidelines, COVID-19 vaccines should be delayed for at least 90 days after the receipt of SARS-CoV-monoclonal antibodies provided for treatment of COVID-19 infection.

Timing of administration and potential interference between COVID-19 vaccine and monoclonal products as part of COVID-19 treatment are currently unknown and administering these products close together may reduce the effectiveness of the COVID-19 vaccine.

The advice is also based on the estimated half-life of such therapies and [evidence](#) suggesting that reinfection is uncommon within the 90 days after initial infection.

This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses.

Why is Alberta providing access to this drug? How many patients could benefit?

Sotrovimab may help prevent mild to moderate COVID-19 from progressing. By providing access to sotrovimab treatment, it is anticipated that the outcomes of patients most at risk will be improved.

Is sotrovimab being used elsewhere?

Outpatient monoclonal antibodies are offered in a many areas of the United States. Outpatient sotrovimab clinics have recently been started in Saskatoon and Regina. AHS is reaching out to other health authorities to understand how they are using this treatment.

Why hasn't this drug been considered before now?

This is a new drug and the clinical trial was only recently completed. Health Canada provided interim approval on July 30, 2021 based on the evidence from this trial. For more information see <https://covid-vaccine.canada.ca/info/sotrovimab-en.html>.

I care for a patient in Saskatchewan or British Columbia; do these patients have access to treatment?

At this time, Saskatchewan is administering sotrovimab to targeted patients. For information on Saskatchewan's program, visit www.saskatchewan.ca/monoclonal. AHS is not aware of a program in British

Columbia at this time.

I have a patient I believe is eligible for sotrovimab treatment. How do I refer that patient on for further assessment?

For patients who are aged 55 and older, patients or family members should call Health Link directly at 1-844-343-0971. For transplant patients, contact the specialist involved with the patient's care to discuss a referral.

I have a patient admitted to an AHS facility for care. Are they eligible for sotrovimab?

Not at this time. Casirivimab/imdevimab (REGEN-COV), another monoclonal antibody, is available for AHS inpatients. Details can be found in the [AHS Formulary](#).

I have additional questions about the monoclonal antibody program. Who can I speak with?

The team of physicians who are doing patient follow ups are available to answer questions about the program. They are available between 8 a.m. and 8 p.m. daily and can be reached through RAAPID.

- North: 1-800-282-9911 or 780-735-0811
- South: 1-800-661-1700 or 403-944-4486

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