

FAQs for Healthcare Providers

Sotrovimab (Monoclonal Antibody) Outpatient Treatment

Please note, as of April 13th, 2022, Alberta Health Services will be suspending the use of Sotrovimab, except in the rare circumstances that a patient is confirmed to have a non BA.2 variant. For the majority of cases, please consult the information on Paxlovid™ and Remdesivir.

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 individuals with mild to moderate COVID-19 symptoms who have a positive AHS-confirmed test for COVID-19 (confirmed by text message by AHS), are at risk for severe outcomes and are able to receive treatment **within five days** from the start of symptoms.

Treatment will be offered to patients who are most likely to develop severe COVID-19 illness and are at a greater risk of being hospitalized.

This includes:

- People who are **unvaccinated or have only received one dose of COVID-19 vaccine** and are:
 - 55 years of age or older, regardless of other health conditions
 - Indigenous and 45 years of age or older
 - Pregnant (if the benefits outweigh the risks to the fetus)
 - 18 years of age or older with a co-morbidity identified in the initial COMET-ICE study:
 - diabetes (taking medication for treatment)
 - 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
- Residents of long-term care and most designated supportive living sites (DSL4. 4D), regardless of vaccination status.
- Regardless of their COVID-19 vaccine status, immunocompromised patients, including:
 - Transplant patients (solid organ or stem cell)
 - Oncology patients that have received a dose of any IV or oral chemotherapy or other immunosuppressive treatment since December 2020
 - Patients with inflammatory conditions (e.g. rheumatoid arthritis, lupus, inflammatory bowel disease) who have received a dose of any systemic immunosuppressive treatment since December 2020.

*The COVID-19 Therapeutics Working Group notes the following treatments may be of most concern, however patients on any biologic treatment may be eligible for treatment (list adapted from the American College of Rheumatology guidance. [COVID-19 Vaccine Clinical Guidance Summary for Patients with Rheumatic and Musculoskeletal Diseases](#) (rheumatology.org):

- Rituximab, ocrelizumab
- High dose steroids (≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days)
- Other biologics: Abatacept, Belimumab (as per ACR recommendations)
- JAKs inhibitors: Tofacitinib, Upadacitinib, Baricitinib
- Immunosuppressive/immune-modulator treatments: mycophenolate, cyclophosphamide, azathioprine, cyclosporine, tacrolimus, IVIG, Methotrexate, leflunomide, sulfasalazine, apremilast

What if patients have only confirmed they have COVID-19 through a rapid/at-home test?

Eligible patients are required to have a validated AHS-confirmed test result before receiving the infusion. Patients are required to book a test and receive a positive test result before receiving Sotrovimab or Paxlovid™. If there is a delay in either booking a test, or receiving test results, patients may be tested at the Sotrovimab infusion site, in the presence of a healthcare provider, to confirm the positive result. Anyone who tests negative will not be eligible to receive Sotrovimab. Family physicians should encourage patients who are eligible and symptomatic for COVID-19 to book a test as soon as possible before calling Health Link at 1-844-343-0971.

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

Sotrovimab and Paxlovid™ have 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 or Paxlovid™ treatment.

Why are immunocompromised patients who have been vaccinated eligible for Sotrovimab treatment?

Sotrovimab treatment is intended for individuals at high risk of progressing to severe disease (hospitalization, ICU or death). Fully 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 may offer additional protection.

Can Sotrovimab be used in patients under 18 years of age?

For those aged 12 to 17, Sotrovimab may be considered if the individual meets the eligibility criteria (see above). For those with COVID-19 in this age group who are immunocompromised and

potentially eligible for Sotrovimab, a consultation with a Pediatric Infectious Disease specialist needs to occur to determine whether Sotrovimab is an appropriate treatment for the patient. Health Canada has not approved Sotrovimab use for patients under the age of 12. Children are not eligible to receive Paxlovid™.

If treatment for a pediatric patient is approved, where will it be administered?

For pediatric patients, treatment should be directed initially through the EMS MIH program. If the patient is outside of the MIH treatment area or MIH does not have capacity, a referral will be made to the closest available AHS site. At this time, our third-party provider, will not administer Sotrovimab to pediatric patients.

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?

While pregnancy was not included in the clinical trial leading to licensure of Sotrovimab, Health Canada has licensed the product for use in pregnancy. This is based on the increased risk of progression to severe COVID-19 in pregnant individuals and the overall safety profile of monoclonal antibodies. Groups like the American College of Obstetricians and Gynecologists consider treatment with monoclonal antibodies like Sotrovimab to be safe ([COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics | ACOG](#)). A specialist may be consulted if there are questions about suitability of Sotrovimab for individual patients.

How will eligible patients be identified and informed?

People in the eligible age brackets will receive information about the treatment in the text from AHS that notifies them of a positive COVID test result. If they are interested in receiving the medication or want more information, they will be asked to visit ahs.ca/opt or 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 the MAP (Monoclonal Antibody Program team where a healthcare professional will determine eligibility and obtain consent. The appointment for Sotrovimab treatment will then be booked to take place in a third-party infusion site, the patient's home, a continuing care facility, or in an AHS site.

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 and assess for eligibility. If appropriate, the patient will need to call and leave a message with **Health Link at 1-844-343-0971**. This dedicated line will call back to get patient demographics, make a chart and send the referral on to the MAP team. A physician then calls the patient to obtain consent, write a medication order and refer to the infusion team to organize an appointment time with the patient.

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 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?

Infusion locations for eligible patients will be based on their location in the province and availability of staffing:

- Most patients will receive infusions in a dedicated infusion site by a third-party provider in Calgary and Edmonton.
- Some patients will receive treatment by community paramedics in their homes or in their continuing care facility depending on availability.
- Patients may be directed to a nearby AHS site in urban or rural areas depending on current capacity.

How will people be monitored after treatment?

Within the first two days after the treatment, a healthcare provider will follow up with the patient to check on their wellbeing. After this, 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 for Sotrovimab 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 few 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.

What if the patient tests positive for COVID-19 again? Can Sotrovimab be offered more than once?

The benefits of Sotrovimab last in the body for 90 days, after which time, patients are strongly encouraged to be vaccinated against COVID-19.

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 and Paxlovid™ treatments, it is anticipated that the outcomes of patients most at risk will be improved. We anticipate that for every 20 patients infused with Sotrovimab, 1 serious outcome (hospitalization, ICU stay and/or death) can be prevented.

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, Ontario, Quebec and Nova Scotia. AHS is working with other health authorities in Canada so that we can all learn how to use using this treatment most effectively.

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

For information on Saskatchewan's program, visit www.saskatchewan.ca/monoclonal.

For information on the British Columbia program, visit [Health Care Provider Info-sotrovimab-Paxlovid.pdf \(bccdc.ca\)](#)

Residents from other provinces who are visiting or working in Alberta will be eligible to receive Sotrovimab, utilizing the same criteria and processes as Albertans.

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 and the product became available in Alberta in November 2021. For more information see [SOTROVIMAB FOR INJECTION - COVID-19](#).

I have a patient I believe is eligible for Sotrovimab or Paxlovid™ treatment. How do I refer that patient for further assessment?

For patients who may meet the eligibility criteria to receive either treatment, the patient or family member should call the dedicated Health Link line at **1-844-343-0971**. Primary care physicians, or nurse practitioners can call on behalf of patients living in Long-Term Care.

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

Sotrovimab is not indicated for patients with severe COVID-19, therefore should not be used in patients admitted for COVID. In patients admitted for other reasons or acquired COVID-19 during their hospital stay, Sotrovimab may be considered for inpatients, in alignment with the outlined formulary criteria.

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

The team of physicians who are working in the program 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

Please note that the physicians cannot enroll patients without the patient calling the dedicated Health Link line at 1-844-343-0971 to initiate the process and determine which treatment the patient may qualify for. Health Link will help create a specific chart for this program allowing physicians from anywhere in the province to assist patients in any location to obtain the medications.

For more information on Sotrovimab or Paxlovid™ treatments, visit ahs.ca/covidopt.