

Guidance for primary care providers – Access to outpatient therapies for COVID-19 (sotrovimab and Paxlovid)

Last updated: March 2, 2022

Updates to this document: March 2, 2022

This document was revised on March 2, 2022, to reflect the following changes:

- The Ontario COVID-19 Science Advisory Table has issued revised guidelines, <u>Therapeutic Management of Adult Patients with COVID-19</u>, on February 23, 2022. These revised guidelines redefine which patients are eligible for treatment with sotrovimab and Paxlovid, with consideration to number of vaccine doses, age, and risk factors.
- Ontario Health and the Ministry of Health have expanded the number of sites distributing Paxlovid in Ontario to facilitate access. The most current list of sites distributing Paxlovid (including contact information for referring clinicians) is available here.
- The referral form for sotrovimab has been updated and is available here.

This document outlines how primary care providers can access outpatient therapies for people at higher risk of severe disease, specifically sotrovimab (a monoclonal antibody) and Paxlovid (an oral antiviral).

As supply of sotrovimab and Paxlovid is currently limited, Ontario is distributing these therapeutics through a limited number of sites across the province and prioritizing individuals who are at higher risk of severe outcomes from COVID-19 infection. The sites distributing sotrovimab and Paxlovid may differ.

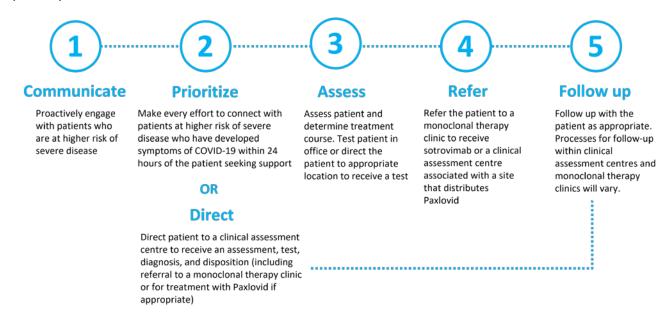
Key resource: Therapeutic Management of Adult Patients with COVID-19

This guidance follows the recommendations outlined in <u>Therapeutic Management of Adult Patients</u> with <u>COVID-19</u>, developed by the Ontario COVID-19 Drugs and Biologics Clinical Practice Guidelines Working Group on behalf of the Ontario COVID-19 Science Advisory Table.

This guidance specifically focuses on outpatient therapies for people at higher risk of severe disease.

Pathway for primary care providers

The general pathway for primary care providers is presented in the graphic below and in detail throughout this document. Local pathways may appropriately vary based on availability of services and pre-existing pathways.



1. Proactively communicate with patients at higher risk for severe disease

Both sotrovimab and Paxlovid must be administered within a short window after symptom onset (7 days for sotrovimab; 5 days for Paxlovid). Proactively informing potentially eligible patients that they should contact a health care professional if they develop symptoms of COVID-19 can help ensure they receive timely treatment.

Identify patients at higher risk for severe disease

<u>Therapeutic Management of Adult Patients with COVID-19</u> provides full details on which patients are considered at higher risk of severe disease and may be eligible for outpatient therapies.

In short, individuals may be considered at higher risk of severe disease and may be eligible for outpatient therapies if they:

- are immunocompromised (have an immune system that is weakened by a health condition or medications)
- are unvaccinated or partially vaccinated (have received only one or two doses of a vaccine)
- have one or more risk factors, such as a long-term medical condition or being of older age
- are Indigenous, Black, or a member of another racialized community



Proactively engage with patients at higher risk for severe disease

Patients at higher risk for severe disease should be informed that they should contact a health care professional to talk about possible therapies and extra monitoring if they develop symptoms of COVID-19.

Consider engaging with patients:

- During appointments
- Via email or telephone (after identifying patients at higher risk for severe disease via EMR search)
- By updating the practice's website or online booking portal

Tool: I think I have COVID. When should I call my doctor?

This resource from the Department of Community and Family Medicine at the University of Toronto and the Ontario College of Family Physicians provides plain-language instructions on when patients should call their primary care provider, including specific instructions for patients at higher risk.

Additional resources to help the public make sense of the latest guidance around COVID/Omicron are available at ConfusedAboutCovid.ca.

2. Prioritize appointments for patients who may be eligible for outpatient therapies, or direct them to a clinical assessment centre if an expedited appointment is not possible

Primary care providers should make every effort to connect with patients at higher risk of severe disease who have developed symptoms of COVID-19 within 24 hours of the patient seeking support.

If a primary care provider is not able to connect with the patient either virtually or in person within 24 hours, the patient should be directed to book an appointment with a <u>clinical assessment centre</u> (preferably one of the sites that are distributing Paxlovid if this treatment is not contraindicated for the patient). The clinical assessment centre will provide assessment and testing, diagnose the patient, and support disposition planning, including directing the patient to outpatient therapies (if appropriate and available).

To support booking appointments for these patients within 24 hours, primary care offices may incorporate screening questions into the appointment booking process.



Tool: Script to support staff in identifying patients who may be eligible for outpatient treatment

A script to support staff in identifying patients who may be eligible for outpatient treatment is available at the link above. Patients flagged as potentially eligible will either be seen by their primary care provider within 24 hours or directed to a COVID-19 clinical assessment centre.

3. If feasible, assess and determine an appropriate treatment course with the patient, with consideration to local availability of therapies

If the primary care provider is able to see the patient either virtually or in person within 24 hours, they should assess the patient and determine an appropriate treatment course, referencing the recommendations outlined in Therapeutic Management of Adult Patients with COVID-19.

Consideration should be given to:

- Local availability of therapies. Information on the sites that are providing sotrovimab and sites distributing Paxlovid is presented in the following section. As of February 2022, the supply of sotrovimab is more limited than that of Paxlovid. Primary care providers considering sotrovimab should contact their local monoclonal therapy clinic to confirm that supply is available.
 - Note that although this guidance document focuses on sotrovimab and Paxlovid, <u>fluvoxamine</u> and budesonide may also be considered if sotrovimab and Paxlovid are not appropriate or are not available. Remdesivir is not typically provided on an outpatient basis due to challenges related to administration.
- Patient eligibility and contraindications. For Paxlovid in particular, drug-drug interactions leading to
 potentially serious and/or life-threatening reactions are possible due to the effects of ritonavir on
 the hepatic metabolism of certain drugs. The product monographs for <u>sotrovimab</u> and <u>Paxlovid</u>
 provide full details on interactions and contraindications.

Tool: Nirmatrelvir/Ritonavir (Paxlovid): What Prescribers and Pharmacists Need to Know

This resource, developed by the Ontario COVID-19 Science Advisory Table and University of Waterloo School of Pharmacy, summarizes key information that can help primary care providers determine whether Paxlovid is right for their patients.



4. Testing and referral process for patients receiving sotrovimab or Paxlovid

Processes for testing and referral for patients to receive sotrovimab or Paxlovid may vary based on local context. Primary care providers should follow any local processes for testing and referral to ensure patients can receive these therapeutics in a timely manner. Contact your local clinical assessment centre to understand their referral process.

Patients must have a positive COVID-19 test result (either PCR or an ID NOW or rapid antigen test administered by a health care professional) to receive sotrovimab or Paxlovid. General recommendations for testing to ensure timely results are outlined below. Note that symptomatic people for whom COVID-19 treatment is being considered are eligible for molecular testing (PCR or rapid molecular testing) according to the current testing guidelines.

Sotrovimab

Sites and referral process

Sotrovimab is available at 8 sites (called monoclonal therapy clinics) across the province. Clinic locations and contact information are presented in the common referral form, available here. Primary care providers considering sotrovimab should contact their local monoclonal therapy clinic to confirm that supply is available before referring patients. To refer patients, fax or email the referral form to the desired site.

Sotrovimab is generally provided on an outpatient basis only at monoclonal therapy clinics (although regional processes may vary, such as in the Ontario Health North region – see below). If it is not feasible for your patient to travel to receive sotrovimab, consider if the patient would be eligible for Paxlovid instead.

Testing

Patients must have a positive COVID-19 test to be referred to receive sotrovimab at a monoclonal therapy clinic. Testing is not provided at the monoclonal therapy clinics.

The preferred order of COVID-19 testing options to ensure test results are available as quickly as possible is as follows:

- ID NOW or other rapid molecular test administered by a health care professional
- A rapid antigen test administered by a health care professional, with concurrent lab-based PCR if the rapid antigen test is negative
- A lab-based PCR test

Therefore, primary care providers referring patients to monoclonal therapy clinics should:

• Administer ID NOW or other rapid molecular test, or a rapid antigen test if available in their office and if the patient is at the office in person; or



 Direct the patient to book an appointment at a clinical assessment centre. The clinical assessment centre will assess the patient, test according to the preferred order outlined above, and refer the patient to the monoclonal therapy clinic if appropriate and available.

A note for primary care providers in the Ontario Health North region – Sotrovimab

The Ontario Health North region uses a distribution model involving local hospitals to administer sotrovimab for patients who cannot travel to the two monoclonal therapy clinics in the North.

Primary care providers in the North region may:

- Direct the patient to book an appointment at a clinical assessment centre if there is one in your community. The clinical assessment centre will assess the patient, test according to the preferred order outlined above, and refer the patient to the monoclonal therapy clinic if appropriate and available; or
- If there is no clinical assessment centre in your community, contact an assessment centre to arrange for patient testing and reach out to your local hospital to access treatment.

Paxlovid

Sites and referral process

Paxlovid is currently distributed at a number of sites in Ontario. Many of them are associated with clinical assessment centres. A list of the distributing sites and contact information is available here. These sites are leading the distribution of Paxlovid for their community and surrounding areas. Contact the site to understand their referral process.

If a patient cannot travel to a clinical assessment centre associated with one of the sites that distribute Paxlovid, refer them to a local clinical assessment centre. The distributing sites will work with the other clinical assessment centres to provide Paxlovid on an individual basis for eligible patients.

Testing

Patients must have a positive COVID-19 test to receive Paxlovid.

The preferred order of COVID-19 testing options to ensure test results are available as quickly as possible is as follows:

ID NOW or other rapid molecular test administered by a health care professional



- A rapid antigen test administered by a health care professional, with concurrent lab-based PCR if the rapid antigen test is negative
- A lab-based PCR test

Therefore, primary care providers referring patients to receive Paxlovid should:

- Administer ID NOW or other rapid molecular test, or a rapid antigen test if available in their office and if the patient is at the office in person; or
- Refer the patient to a clinical assessment centre that is associated with one of the distributing sites distributing Paxlovid. These clinical assessment centres will assess the patient, test according to the preferred order outlined above, and prescribe Paxlovid to the patient if appropriate and available.

A note for primary care providers in the Ontario Health North region - Paxlovid

There may be patients in the North region who are not within traveling distance to a clinical assessment centre. Providers caring for these patients may contact their local assessment centre to arrange for testing and referral for Paxlovid.

Medication reconciliation

Drug-drug interactions leading to potentially serious and/or life-threatening reactions are possible due to the effects of ritonavir (a component of Paxlovid) on the hepatic metabolism of certain drugs. The <u>product monograph</u> provides details on interactions and contraindications.

To ensure safety, consultation with a pharmacist who can get a complete medication and natural health product list from the patient is recommended prior to prescribing Paxlovid. A thorough medication reconciliation will be completed at the clinical assessment centre or at a supporting location (e.g., a hospital). Support your patients to bring a list of their medications (including prescription and over-the-counter medicines, vitamins, and herbal supplements) and any important medical conditions to their appointment. There may be medication holds or changes that will need to be resumed after the patient finishes Paxlovid.



5. Follow-up

The follow-up provided after treatment with sotrovimab or Paxlovid will vary depending on local arrangements. Particularly for Paxlovid, patients will need close monitoring for drug interactions and side effects. Follow-up may include:

- Handoff back to primary care for ongoing monitoring (e.g., via COVID@Home)
- Connection with a **COVID-19** remote care monitoring program or virtual care

Contact the site distributing Paxlovid to your patient for details on follow-up.

Tool: <u>Assessment, monitoring and management of COVID-19: Monitoring and follow-up</u> (tab 6)

This resource, developed by Hamilton Family Medicine, summarizes information on monitoring and follow-up based on risk level to guide primary care providers who are monitoring their patients at home.

