![Ontario Health logo]

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

Last updated: January 31, 2022

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.
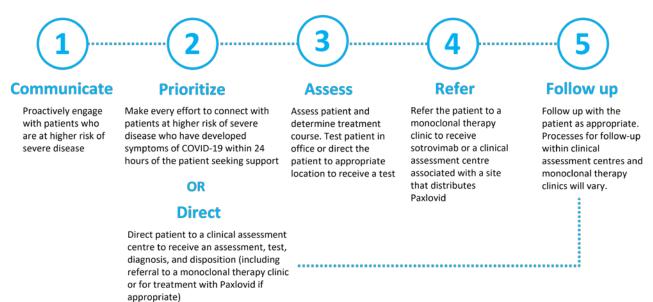
> **Key resource: Therapeutic Management of Adult Patients with COVID-19**
>
> This guidance follows the recommendations outlined in Therapeutic Management of Adult Patients with COVID-19, developed by the Ontario COVID-19 Drugs and Biologics Clinical Practice Guidelines Working Group on behalf of the Ontario COVID-19 Science Advisory Table.
>
> This guidance specifically focuses on outpatient therapies for people at higher risk of severe disease (Tier 1 and Tier 2).

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 Communicate
Proactively engage with patients who are at higher risk of severe disease

2 Prioritize
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

OR

Direct
Direct patient to a clinical assessment centre to receive an assessment, test, diagnosis, and disposition (including referral to a monoclonal therapy clinic or for treatment with Paxlovid if appropriate)

3 Assess
Assess patient and determine treatment course. Test patient in office or direct the patient to appropriate location to receive a test

4 Refer
Refer the patient to a monoclonal therapy clinic to receive sotrovimab or a clinical assessment centre associated with a site that distributes Paxlovid

5 Follow up
Follow up with the patient as appropriate. Processes for follow-up within clinical assessment centres and monoclonal therapy clinics will vary.

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

[Therapeutic Management of Adult Patients with COVID-19](#) provides full details on which patients are considered at higher risk of severe disease and may be eligible for outpatient therapies.

In short, the following individuals are at higher risk of severe disease and may be eligible for outpatient therapies:

- Immunocompromised individuals aged 18 and over regardless of vaccine status *(examples of immunocompromised individuals are presented in the guidance linked above)*
- Unvaccinated individuals over 60
- Unvaccinated First Nations, Inuit, and Métis individuals over 50
- Unvaccinated individuals over 50 with one or more risk factors
    - Risk factors include obesity (BMI ≥ 30), dialysis or stage 5 kidney disease (eGFR < 15mL/min/1.73 m^2), diabetes, cerebral palsy, intellectual disability of any severity, sickle cell disease, receiving active cancer treatment, solid organ or stem cell transplant recipients

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](#).

Ontario Health

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 clinical assessment centre (preferably one of the 15 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 late January 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.

Ontario Health

Note that although this guidance document focuses on sotrovimab and Paxlovid, [fluvoxamine](#) and budesonide may also be considered if sotrovimab and Paxlovid are not appropriate or are not available.

- **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 [sotrovimab](#) and [Paxlovid](#) 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 7 sites (called monoclonal therapy clinics) across the province. Clinic locations and contact information are presented in the common referral form distributed with this document. 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 (with the exception of 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.

Ontario Health

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.

Ontario Health

Paxlovid

Sites and referral process

Paxlovid is currently distributed at 15 sites in Ontario. Many of them are associated with clinical assessment centres. A list of the 15 sites and contact information has been distributed with this document. 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 15 sites that distribute Paxlovid, refer them to a local clinical assessment centre. The 15 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 15 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 patient testing and referral for Paxlovid.

Ontario Health

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 [product monograph](#) 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: [Assessment, monitoring and management of COVID-19: Monitoring and follow-up](#) (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.

Ontario Health