FAQs for Healthcare Providers

Nirmatrelvir/ritonavir (Paxlovid™) Outpatient Treatment

What is Paxlovid™?

Paxlovid™ is a combination of two antiviral drugs, nirmatrelvir and ritonavir (brand name PAXLOVID™), taken orally to treat adults with mild to moderate COVID-19 who are at high risk of progressing to serious disease, including hospitalization or death. Nirmatrelvir works by stopping the virus from replicating, while ritonavir slows nirmatrelvir metabolism, thus prolonging its action.

Has Paxlovid™ been approved for use?

On Jan. 17, 2022, Health Canada authorized the use of Paxlovid™, which is the first oral treatment for COVID-19. For more information, visit the Health Canada Consumer Information Summary.

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

Which patients are most likely to benefit from Paxlovid™ treatment?

Paxlovid™ is approved for outpatient use in Alberta for individuals with mild to moderate COVID-19 symptoms who have a positive test for COVID-19, are at risk for severe outcomes and can receive treatment **within five days** from the start of symptoms.

Treatment with nirmatrelvir-ritonavir should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset in adult patients who have either of the following:

Patients considered high risk for severe outcomes

Criteria: Age 18 or older AND Immunocompromised*

- **Severe immunosuppression, such as:**
  - recipient of solid organ transplant
  - treatment for a malignant hematologic condition
  - bone marrow-, stem cell transplant-, or transplant-related immunosuppressant use
  - receipt of an anti-CD20 drugs or B-cell depleting drugs (such as rituximab) in the past 2 years
  - Severe primary immunodeficiencies
- **Moderate immunosuppression, such as:**
  - treatment for cancer, including solid tumors
  - treatment with significantly immunosuppressing drugs (e.g., a biologic in the past 3 months, oral immune-suppressing medication in the past months, oral steroid [20 mg/day of prednisone equivalent taken on an ongoing basis] in the past month, or immune-suppressing infusion or injection in the past 3 months).
  - advanced HIV infection (treated or untreated)

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- moderate primary immunodeficiencies
- renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis and dispensing of a steroid, eGFR < 15 mL/min/1.73 m2)

Please note that Paxlovid™ is also approved for patients in hospital who have incidental or hospital acquired COVID-19 if they meet the criteria above. Please consult the AHS Provincial Drug Formulary for further information on inpatient use.

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

Paxlovid™ 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-19 symptoms, they are encouraged to get tested as early as possible to allow sufficient time to determine potential appropriateness for either Paxlovid™ or an alternate outpatient treatment like Remdesivir.

Can Paxlovid™ be used in patients under 18 years of age?

Paxlovid™ is not licensed for patients under 18 years of age at this time. Pediatric patients can be considered for Remdesivir treatment. More information is available in the Remdesivir FAQs.

How were the guidelines developed?

Guidelines were partly based on evidence from the EPIC-HR study of Paxlovid™, and partly on expert consensus derived from cohort studies and a thorough analysis of provincial data showing risk factors for severe disease among Albertans testing positive for COVID-19.

In the case of a facility outbreak, can Paxlovid™ be ordered for patients prior to confirmation of COVID-19 infection or onset of symptoms?

No. Paxlovid™ is only approved for use in patients with symptomatic confirmed COVID-19. It is not approved for use as prophylaxis.

My patient is on other medications. Can they take Paxlovid™?

Paxlovid™ does interact with other medications. Patients will be required to produce a list of medications, including all over-the-counter and herbal medications, at the time of their assessment. For a complete list of drug interactions, visit the Health Canada Consumer Information Summary.

How is Paxlovid™ administered?

Paxlovid™ is taken orally in pill form. One dose is a combination of two nirmatrelvir (pink) tablets and one ritonavir (white) tablet, taken twice a day for five days.

How is Paxlovid™ administered for patients with reduced renal function?

Paxlovid was not studied in patients with eGFR below 30 mL/min/1.73m^2. However, guidance based on expert consensus and cohort studies is provided below.

	eGFR > 60mL/min	eGFR ≤ 60mL/min and ≥ 30mL/min	eGFR < 30mL/min	Dialysis

Paxlovid 150mg/100mg (Nirmatrelvir/Ritonavir)	300 mg nirmatrelvir + 100 mg ritonavir both twice a day for 5 days	150 mg nirmatrelvir + 100 mg ritonavir both twice a day for 5 days	300 mg nirmatrelvir + 100 mg ritonavir both on day 1, then 150 mg nirmatrelvir + 100 mg ritonavir once a day for 4 more days	300 mg nirmatrelvir + 100 mg ritonavir both on day 1 then 150 mg nirmatrelvir + 100 mg ritonavir once a day for 4 more days, to be dosed aer dialysis[1]

[1]If dialysis paent weighs < 40kg, the dose should be reduced to 150 mg nirmatrelvir + 100 mg ritonavir on day 1 then 150 mg nirmatrelvir + 100 mg ritonavir every 48 hours for 2 more doses, to be given aer dialysis.

How will high risk patients be identified and informed?

Patients who fall into the high-risk categories will receive information in a text from AHS that notifies them of a positive COVID-19 test result if they've had a lab-confirmed test. Alternatively, if patients have tested positive through a Rapid Antigen Test taken at home, they can contact their Primary Care physician or visit ahs.ca/covidopt for more information. If the patient is considered appropriate for and interested in receiving treatment, but it isn't deemed appropriate for them to receive Paxlovid (as outlined at ahs.ca/covidopt), a message may be left on **the dedicated line at 1-844-343-0971**. Staff will call back and ask some initial screening questions and refer them to a physician with the Outpatient Treatment Program where a healthcare professional will determine appropriateness for other treatment options.

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 appropriateness.

Where is Paxlovid™ available?

While all pharmacies are able to order Paxlovid™, not all pharmacies may have supply on hand.

My patient tested positive with a Rapid Antigen Test at home. Is this sufficient for treatment?

Most patients with confirmed COVID-19 do not require specific treatment as they will not benefit from treatment. Patients with an increased risk for poor outcomes may benefit from Paxlovid™ or other outpatient medications. Patients who are symptomatic, with symptom onset within the last 5-7 days, and have tested positive with an home Rapid Antigen Test, should consult with a healthcare provider to determine the best course of treatment. To do this, they have two options:

1. They can contact the dedicated line at 1-844-343-0971 for screening and referral to a healthcare professional for assessment.

OR

2. They can contact their family physician.

AHS is in the process of transitioning the prescribing of Paxlovid™ to Primary Care, and some family physicians and pharmacists have started prescribing Paxlovid™ to their patients.

How will patients be monitored after treatment?

Patients prescribed Paxlovid™ will get an information sheet with their prescription.
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, they should call 911. All patients should follow up with their family physician or healthcare provider 10 days after onset of their COVID19 symptoms.

What are the potential adverse effects of Paxlovid™?

According to Health Canada, reported side effects include:

- altered sense of taste
- diarrhea
- muscle pain
- vomiting
- high blood pressure
- headache

Paxlovid™ is a new medication, so patients may experience unexpected side effects. 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 continue to worsen?

Even with Paxlovid™ treatment, symptoms of COVID-19 may continue or get worse. Patients are 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 taking Paxlovid™?

While no interaction between Paxlovid™ and COVID-19 vaccine is anticipated (as occurs with monoclonal antibodies), patients should wait until they are fully recovered from the infection before getting vaccinated to ensure they receive the maximum benefit from the vaccine.

What do we know about rebound symptoms after treatment with Paxlovid™?

A small percentage of patients may develop a relapse of COVID-19 symptoms within a few days of completing a course of treatment (eg. recurrence of sore throat, runny nose, etc.). This may be accompanied by a new positive test for COVID-19 (PCR or Rapid Antigen Test), after testing negative. (Of note, this has also occurred in a small number of patients who have not received treatment.)

At this time, it is NOT recommended that treatment be extended or repeated**.**

Does treatment of acute COVID-19 prevent Long COVID?

Some individuals experience prolonged symptoms after acute infection with SARS-CoV-2. There is no evidence at this time whether treatment will influence the total number of people who will experience these symptoms, or their severity. This is an important area for research. Treatment does

prevent progression of COVID-19 and prevents severe outcomes but should not be offered as a means of preventing Long COVID.

Should symptoms of Long COVID be treated with Paxlovid™?

Current therapies for COVID-19 (including Paxlovid™, Remdesivir and monoclonal antibodies) target actively replicating virus during acute infection. There is no reason to believe that there would be any benefit to offering such therapies weeks or months later for symptoms of Long COVID. At this time, Paxlovid™ should not be considered a treatment for individuals experiencing symptoms of Long COVID.

What if the patient has tested positive for COVID-19 again? Can Paxlovid™ be prescribed more than once?

Paxlovid™ can be prescribed again for a confirmed new COVID-19 infection, but patients are strongly encouraged to get vaccinated against COVID-19 after fully recovering from the infection. Occasionally, COVID-19 symptoms can recur within a few days of treatment with Paxlovid™. At this time, retreatment with Paxlovid™ is not recommended in this situation.

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

Paxlovid™ may help prevent mild to moderate COVID-19 from progressing. By providing access to Paxlovid™, it is anticipated that the outcomes of patients most at risk will be improved and that we may avoid the need for hospitalization, ICU stays or deaths.

Is Paxlovid™ being used elsewhere?

Yes. Other provinces are also launching programs to provide Paxlovid™ to individuals at greatest risk for severe COVID-19 infection. AHS is working with other health authorities in Canada.

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

For information on Saskatchewan's program, visit www.saskatchewan.ca/monoclonal. For Information on the British Columbia program, visit the Health_Care_Provider_InfoPaxlovidremdesivir-sotrovimab.pdf (bccdc.ca)
Residents from other provinces who are visiting or working in Alberta will be eligible to receive Paxlovid™, utilizing the same criteria and processes as Albertans.

I have a patient I believe may benefit from Paxlovid™. How do I refer that patient on for further assessment?

Any physician or nurse practitioner, and some pharmacists, in Alberta may prescribe Paxlovid™ to patients. Patients should be assessed for treatment appropriateness.

If the physician, nurse practitioner, or prescribing pharmacist is not comfortable assessing patients, they can refer to another clinician or direct patients or their family members to call the dedicated line at **1-844-343-0971**.

I have a patient that cannot use/access Paxlovid™ or remdesivir. Are Sotrovimab or Evusheld™ still available?

Sotrovimab and Evusheld™ are no longer recommended as treatments for COVID-19 due to recent evidence that they are unable to adequately neutralize the dominant circulating variants in Alberta.

I have additional questions about outpatient treatments like Paxlovid™ and Remdesivir. Who can I speak to?

The Infectious Diseases team is available to answer questions about treatments. They 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 outpatient treatments, visit **ahs.ca/covidopt.**