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 its 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 at-home treatment for the SARS-CoV-2, the cause of 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.

What are the eligibility criteria for Alberta patients?
Paxlovid™ 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, 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. (Age of eligibility may be lowered as supply increases.) This includes:

- People who are unvaccinated or have only received one dose of a COVID-19 vaccine and are:
  - 55 years of age and older, regardless of other health conditions
  - Pregnant (if potential benefits outweigh the potential risks to the fetus.)
  - 18 years of age and older with a co-morbidity
    - 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
  - 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
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- High dose steroids (≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days)
- Rituximab, ocrelizumab
- JAKs inhibitors: Tofacitinib, Upadacitinib, Baricitinib
- Immunosuppressive/immune-modulator treatments: mycophenolate, cyclophosphamide, azathioprine, cyclosporine, tacrolimus, IVIG, Methotrexate, leflunomide, sulfasalazine, apremilast

Is a positive rapid/at-home test sufficient to start treatment?  
Eligible patients are required to have an AHS-confirmed COVID-19 test (confirmed by a text message from AHS) before receiving Paxlovid™. Patients should book a test to confirm they are positive for COVID-19 before receiving a prescription. If there is a delay in either booking a test, or receiving test results, options for repeat rapid testing in the presence of a healthcare provider may be considered. Anyone who tests negative will not be eligible to receive Paxlovid™. Eligible patients who are symptomatic for COVID-19 should be encouraged to book a test as soon as possible and to call Health Link at 1-844-343-0971 if the test is positive.

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 eligibility for either Paxlovid™ or the monoclonal antibody treatment, Sotrovimab.

Why are immunocompromised patients who have been vaccinated eligible for Paxlovid™?  
Paxlovid™ 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 an outpatient treatment may offer additional protection.

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 Sotrovimab treatment. More information is available in the Sotrovimab FAQs.

How were the health conditions for unvaccinated individuals selected?  
Aside from pregnancy, eligibility criteria are based on the evidence from the EPIC-HR study used to approve Paxlovid™, and adjusted slightly to ensure consistency with criteria for the monoclonal antibody treatment, Sotrovimab.

How come pregnancy is included if pregnant patients were not included in the study?  
Even though pregnant patients were not included in the clinical trials leading to the approval of Paxlovid™ or Sotrovimab, Health Canada has not listed pregnancy as a contraindication. Pregnant individuals are offered therapeutic COVID-19 treatments based on the increased risk of progression to severe disease including admission to hospital and ICU. After consultation with specialists in
Alberta, therapy with either Paxlovid™ or Sotrovimab can both be offered to pregnant individuals. This approach is supported by international societies such as the American College of Obstetricians and Gynecologists which consider treatment with Paxlovid™ or Sotrovimab to be safe (COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics). Because treatment needs to begin within five days of symptom onset, please consult with a specialist if there are questions about the suitability of either Sotrovimab or Paxlovid™ for individual patients.

**How will eligible patients be identified and informed?**
People in the eligible age brackets will receive information about the available treatments in a text from Alberta Health Services that notifies them of a positive COVID-19 test result. If they are interested in receiving treatment or want more information, they will be asked to visit ahs.ca/covidopt 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 Monoclonal Antibody Program (MAP) team where a healthcare professional will determine eligibility and obtain consent. The MAP physician will either recommend Paxlovid™ or Sotrovimab. A prescription will be issued and the patient will be directed to the nearest community pharmacy stocking Paxlovid™ or, they will have an appointment booked for a Sotrovimab infusion.

**Physicians should advise transplant patients to call the Health Link at 1-844-343-0971 directly if they believe they are eligible to receive either Paxlovid™ or Sotrovimab.**

Patients should notify their specialized healthcare team (e.g. Transplant Coordinators) if they test positive for COVID-19 and then call and leave a message with Health Link at 1-844-343-0971. This dedicated line will call back to collect patient demographics, create a chart and send a referral to the MAP physicians. A physician will call the patient to collect relevant information, including a comprehensive drug list, will outline options, benefits and risks, obtain consent, and will issue a prescription for Paxlovid™, or complete a medication order and referral to the infusion team to receive Sotrovimab.

If the patient is a resident of a Long-Term Care facility, a primary care physician, nurse practitioner, or family member can call the dedicated number at 1-844-343-0971 on the patient’s behalf, if is believed they meet the eligibility criteria to receive Paxlovid™ or Sotrovimab.

**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. Patients with a reduced kidney function (eGFR of 30 to 59 mL/min) have the dose reduced to one nirmatrelvir (pink) tablet and one ritonavir (white) tablet, taken twice a day for five days.

**Where will the Paxlovid™ be available?**
Patients will be able to fill their prescriptions for free at a select number of pharmacies around the province. The physician with the AHS COVID-19 Outpatient Treatment Program will direct them to their nearest pharmacy after they are assessed. The medication will not be available from Emergency Departments or hospital pharmacies as this treatment is not recommended for hospitalized patients.
What if there are no community pharmacies that carry Paxlovid™ near my patient?
Alberta Health is coordinating a network of pharmacies that will stock Paxlovid™ to ensure access throughout the province.

How will people be monitored after treatment?
Within the first two to three 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, they should 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 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, COVID-19 symptoms 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 there is 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.

I am a Primary Health physician. Can I prescribe Paxlovid™ to my patients?
AHS will be transitioning the administration of Paxlovid™ to Primary Care, but this will take up to two months after the initial rollout on Jan. 31, 2022. Until then, patients are required to call the dedicated Health Link line at 1-844-343-0971 for assessment.
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.

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 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 Paxlovid™, utilizing the same criteria and processes as Albertans.

Why hasn’t this drug been considered before now?
This is a new drug developed by Pfizer. Health Canada received the submission for Paxlovid™ from Pfizer on Dec. 1, 2021. The review process was expedited and Health Canada approved Paxlovid™ on January 17, 2022. The data Pfizer submitted to Health Canada included results from clinical trials for Paxlovid™ where patients had not been vaccinated and had not previously had COVID-19.

I have a patient I believe is eligible for Paxlovid™. How do I refer that patient on for further assessment?
Patients (or their family members) who believe they are eligible to receive Paxlovid™ should call Health Link directly at 1-844-343-0971.

I have a patient admitted to an AHS facility for care. Are they eligible for Paxlovid™?
No, Paxlovid™ is not available for inpatient use at this time. However, Sotrovimab may be considered. 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.

Patients admitted during a course of Paxlovid™
- For patients admitted for a reason other than COVID-19 should finish their supply. In this instance they would be required to bring their supply form home as AHS does not currently have supply of Paxlovid™ in hospitals to provide to patients.
- For patients admitted due to COVID-19, it is recommended that Paxlovid™ treatment stop, as the intent of treatment is to prevent hospitalization. Please consider other treatment options in this instance.

Date: February 15, 2022
I have additional questions about outpatient treatments like Paxlovid™ and Sotrovimab. Who can I speak to? 
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 physicians cannot enroll patients without the patient calling Health Link at 1-844-343-0971 to initiate the process. Health Link will help create a chart for this program, allowing physicians from anywhere in the province to assist patients to obtain the medication.

For more information on the AHS implementation of outpatient treatments, visit ahs.ca/covidopt.