FAQs for Healthcare Providers

Remdesivir (antiviral medication) Outpatient Treatment

What is Remdesivir?

Remdesivir is an antiviral medication that prevents the replication of the coronavirus that causes COVID-19.

Has Remdesivir been approved for use?

Health Canada provided authorization in October 2020 for use of Remdesivir in Canada to treat adults and adolescents (aged 12 years and older with body weight at least 40 kg) who have tested positive for COVID-19.

Remdesivir 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 Remdesivir?

Remdesivir 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 are able to receive treatment **within seven 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. The evidence around who is most at risk for severe outcomes is evolving. These criteria are guidelines, and clinicians can still assess patients on a case-by-case basis for appropriateness. These guidelines will continue to be reviewed as evidence evolves.

Patients considered high risk for severe outcomes:

1. Immunocompromised

- have received a transplant – solid organ or stem cell (Transplant patients should **NOT** receive Paxlovid™ due to the potential for life-threatening drug interactions but are eligible for other therapies, such as Remdesivir.) Transplant patients should be assessed and treated through the centralized Outpatient Treatment Program by calling 1-844-343-0971 or through their transplant specialist. All prescribers in the community including Primary Care physicians, Nurse

Practitioners and Pharmacists should refer transplant patients to the centralized team or the patient's specialist/team.

- is an oncology patient who has received a dose of any IV or oral chemotherapy or other immunosuppressive treatment since December 2020
- has an inflammatory condition (e.g., rheumatoid arthritis, lupus, inflammatory bowel disease) and has received a dose of any systemic immunosuppressive treatment since December 2020.
- has sickle cell anemia
- has had their spleen removed
- has pulmonary hypertension
- is receiving treatment for tuberculosis

2. Living in long-term care or designated supportive living

3. Age 18 or older with three or more high risk comorbidities*

4. Age 50 or older (40 or older for First Nations, Métis or Inuit) with two or more high risk comorbidities*

5. Age 60 or older (50 or older for First Nations, Métis or Inuit) with one or more high risk comorbidities*

* High risk comorbidities include:

- received fewer than three doses of COVID vaccine
- diabetes (taking medication for treatment)
- obesity (BMI >30)
- chronic kidney disease (estimated glomerular filtration rate, <60 ml per minute per 1.73 m^2 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
- pregnancy

*Please note that Remdesivir is also approved for patients admitted to hospital for COVID-19. 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 seven days of onset of symptoms?

Remdesivir 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-like symptoms, they are advised to get tested as early as possible to allow sufficient time to determine appropriateness for Remdesivir treatment.

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

For those aged 12 to 17, Remdesivir may be considered if the individual is considered high risk per the guidelines above, or the clinician deems its use appropriate. For those with COVID-19 in this age group who are immunocompromised and potentially eligible for Remdesivir, a consultation with a Pediatric Infectious Disease specialist needs to occur to determine whether Remdesivir is an appropriate treatment for the patient. Health Canada has not approved Remdesivir use for patients under the age of 12.

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

For pediatric patients, treatment should be directed initially through the EMS Mobile Integrated Health (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.

How were the guidelines developed?

Guidelines were partly based on evidence from the PINETREE study, 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.

Why is pregnancy included if pregnant patients were not included in the initial study?

While pregnancy was not included in the clinical trial leading to licensing of Remdesivir, Health Canada notes use can be considered when the benefits outweigh the risks to the mother and fetus. This is based on the increased risk of progression to severe COVID-19 in pregnant individuals and the overall safety profile. A systematic review of 113 individuals notes that safety and efficacy of Remdesivir in combination with other COVID-19 treatments in pregnancy remains inconclusive. Careful monitoring for adverse reactions including transaminase enzyme levels is required. A specialist consult is recommended.

My patient is a resident of a Long Term Care or DSL4/4D facility. How do they access treatment?

A primary care physician or nurse practitioner may prescribe Paxlovid™ directly for residents who they think may benefit from treatment. If the resident cannot take Paxlovid™, the primary care physician or nurse practitioner can call the dedicated number at 1-844-343-0971 to discuss potential treatment with Remdesivir.

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

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

Are there any laboratory tests required prior to treatment?

According to the Health Canada monograph, a baseline ALT, eGFR and PT INR are required. These are recommended prior to starting therapy, if not available in the last six months. However, therapy should not be held pending results, and should go ahead even if laboratory testing is not possible.

Are there any renal dose adjustments required?

Current guidance is that patients with a reduced renal function (i.e., eGFR <30mL/min) do not require dose adjustment due to the short course of therapy. This is supported by published articles including:

- Real-world risk evaluation of Remdesivir in patients with an estimated glomerular filtration rate of less than 30 mL/min - PMC (nih.gov)
- Safety of Remdesivir in Patients With Acute Kidney Injury or CKD - PMC (nih.gov)

Drug	eGFR > 60mL/min	eGFR ≤ 60mL/min and ≥ 30mL/min	eGFR < 30mL/min	Dialysis
Remdesivir				
Hospitalized patients predominant with vehicle metabolite GS-19 pneumonia[1] for OR duration of therapy Patients within 7 days be beneficial in COVID- No dosage progressing COVID-19[1] Dose after	200mg IV loading dose on day 1, then confirmed COVID-100mg IV once daily for 441524 and early onset indication) SBECD with short dialyzable thus, there is a of unlikely. Remdesivir may lower concern 19 injury in hemodialysis at increased risk to severe reduction recommended. dialysis.		Significant toxicity 4 days (or 2 days its vehicle SBECD are of renal symptom of –induced AKI.[2] No reduction	from Remdesivir's remdesivir and its ~50% onset who are dosage patients. recommended.

[1]For full eligibility criteria, see ahs.ca/covidopt

[2]Consider that patients with AKI and ESRD are at high risk of suffering excess morbidity and mortality from a COVID-19 infection.

NOTE: The above is meant as guidance only and does not replace clinical judgment.

AKI=acute kidney injury; ESRD=end stage renal disease; SBECD=sulfobutylether-beta-cyclodextrin

How will high risk patients be identified and informed?

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 and

obtain consent over the phone. The appointment for Remdesivir will then be booked to take place in a third-party infusion site, the patient's home, continuing care facility, or in an AHS site.

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.

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

If your patient is not eligible to receive Paxlovid, but may be eligible for Remdesivir, you or the patient will need to call 1-844-343-0971 . An appointment will be booked to take place at an AHS site, the patient's home, or continuing care facility.

How is Remdesivir administered?

Remdesivir is administered intravenously by a qualified health professional over three days: 200mg on the first day and 100mg on days two and three. The infusion is administered over 30 minutes and the patient is monitored for an additional 15 to 30 minutes after the infusion. The expected total administration time is about 1.5 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 AHS site in Calgary and Edmonton.
- Some patients will receive treatment by EMS MIH in their homes or in their continuing care facility, depending on availability.

How will patients be monitored after treatment?

Patients should 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?

Side effects reported in the clinical trial include

- nausea,
- headache,
- cough,
- diarrhea,
- shortness of breath.

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 15 to 30 minutes 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 Remdesivir 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 Remdesivir treatment?

While no interaction between Remdesivir and COVID-19 vaccine is anticipated, 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 if the patient tests positive for COVID-19 again? Can Remdesivir be offered more than once?

Remdesivir 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?

Remdesivir may help prevent mild to moderate COVID-19 from progressing. By providing access to Remdesivir, it is anticipated that the outcomes of patients most at risk will be improved.

Is Remdesivir being used elsewhere?

Yes. Outpatient antiviral treatments like Remdesivir are currently being used in many areas of the United States, as well as in Saskatchewan, Ontario, British Columbia. 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 Remdesivir?

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

I have a patient I believe is eligible for Remdesivir treatment. How do I refer that patient for further assessment?

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

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

Remdesivir is also approved for patients with severe COVID-19, however the eligibility criteria are different than the outpatient criteria. Please consult the AHS Provincial Drug Formulary for further information.

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. 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 Remdesivir or other outpatient treatments for COVID-19, visit **ahs.ca/covidopt**.