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:

Patients considered high risk for severe outcomes include:

Age 18 or older plus one immunocompromising condition

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)
- 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 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.

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 COVID19. It is not approved for use as prophylaxis.

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

[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_InfosotrovimabPaxlovid.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.**