PHARMAC
TE PĀTAKA WHAIORANGA

Eligibility Criteria for access to remdesivir

A limited amount of remdesivir is available for use in New Zealand. Please note that it is an unapproved medicine, and this means its quality, safety and efficacy have not been evaluated by Medsafe. For more information on prescribing of unapproved medicines under Section 25 of the Medicines Act 1981, please refer to the information on the Medsafe website.

The prescribing physician is required to review the below inclusion and exclusion criteria, which have been adopted and adapted from the current Australian Government's criteria for access (as of 14 October 2020). To secure supplies of remdesivir this form must be signed by the prescribing physician, who must declare that all of the inclusion criteria and none of the exclusion criteria have been met.

Inclusion Criteria:

- Patient
    - age ≥ 18 years, or aged ≥ 12 and < 18 years of age weighing ≥ 40 kg.
    - is hospitalised with confirmed SARS-CoV2 or known contact of confirmed case with syndrome consistent with coronavirus disease (COVID-19) awaiting confirmation by diagnostic testing.
    - has oxygen saturation (SpO2) ≤ 92% on room air and requiring supplemental oxygen
    - has alanine aminotransferase (ALT) < 5 x upper limit of normal (ULN) by local laboratory measure and/or ALT < 3 x ULN and bilirubin < 2 x ULN
- Informed consent has been provided by the patient or the patient's legal representative, according to local practices.

Exclusion Criteria:

- Patient
    - has evidence of multiorgan failure including but not limited to coagulopathy (significant thrombocytopenia), hepatic failure (elevated bilirubin) or renal failure (low urine output or estimated glomerular filtration rate (eGFR) < 30 mL/min), or significant cardiomyopathy (low cardiac output)
    - has renal failure (eGFR < 30 mL/min or dialysis or continuous venovenous haemofiltration
    - has been on mechanical ventilation for longer than 48 hours at time of application
    - is receiving ECMO
    - has known hypersensitivity to remdesivir, the metabolites, or formulation excipient

Special Considerations

The clinical benefit of remdesivir is uncertain in the following scenarios. The prescribing physician should give strong consideration to whether remdesivir is likely to benefit the patient in the following scenarios:

- Mechanical ventilation for less than 48 hours at time of commencing treatment with remdesivir
- Presence of an intercurrent illness which is likely to lead to the patient's death within one year
- Advanced age with limitations on activities of daily living
- Need for more than a 5 day treatment course

Accessing supply of remdesivir

The maximum quantity permitted is sufficient for a treatment course of 5 days.

To request stock from Auckland Hospital, please call the following number(s) and forward the completed and signed form to the following emails:

- 8am-4:30pm (Monday-Friday)
  - Ph: 09 307 4949 ext:29129
    pharmacyprocurement@adhb.govt.nz
- After hours, including public holiday
  - Ph: 09 307 4949, request for on-call pharmacist
    pharmacyoncall@adhb.govt.nz

Please also copy waivers@pharmac.govt.nz to the requesting email.

For more information, such as dosage and method of administration, please refer to the Factsheet provided by Gilead Sciences (New Zealand).

Please be advised that the requesting DHB will be responsible for organising transportation of the stock from Auckland Hospital.

Name of the medical practitioner (NZMC) and DHB requesting the supply
Name of the patient (NHI) the medicine is required for
Quantity requested

I, …….. , declare the following:

- I understand that remdesivir is being requested for a patient under my care.
- I understand that remdesivir is an unapproved medicine.
- The patient meets all of the inclusion criteria.
- The patient does not meet any of the exclusion criteria.
- I have not requested more than the maximum quantity permitted (5 days treatment).

<SIGNED>……