



NSW  
Therapeutic  
Advisory  
Group Inc.

Advancing  
quality use  
of medicines  
in NSW

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ONLINE FORM COMPLETION ENCOURAGED WHENEVER POSSIBLE

# Remdesivir Prescribing Declaration Form or Remdesivir IPU Application Form, if proposed use is outside Restricted Formulary Criteria\*\*

## \*\*Restricted Formulary Criteria

- Patients with confirmed SARS-CoV2 or known contact of a confirmed case awaiting confirmation by diagnostic testing; AND,
- Aged  $\geq 18$  years, or aged 12 to 17 years weighing  $\geq 40$  kg; AND,
- With oxygen saturation (SpO<sub>2</sub>)  $\leq 92\%$  on room air and requiring supplemental oxygen. (N.B. remdesivir is not recommended in patients receiving non-invasive or invasive mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO) although it may be continued if it was started prior to requiring ventilation)
- with  $< 10$  days since symptom onset

Prescribing considerations and precautions may apply to your patient including: 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.

Patients with **evidence of multiorgan failure**, including but not limited to coagulopathy (significant thrombocytopenia), hepatic failure, renal failure or significant cardiomyopathy (low cardiac output) are not eligible to access remdesivir from the National Medicines Stockpile.

For those outside the above criteria: complete this form for consideration as an IPU and provide any supporting evidence.

## Please read before you begin:

- The [Remdesivir Drug Guideline](#) provides guidance for remdesivir use in hospitalised patients.
- Some sites may require peer review / multidisciplinary team consultation for approval to access remdesivir. If this is required, please undertake prior to completing this form.
- Provide a response to each starred\* question. Failure to provide responses may delay the processing of this form and subsequent supply of remdesivir

1. \*Enter a 'code' unique for this patient

Suggest follow this template Remdesivir\_LHD\_MRN\_DATEofADMISSION

e.g. Remdesivir\_NSLHD\_0123456\_30092021

## Section A. Patient Demographics

2. \*Patient's initials

3. \*Patient's MRN

4. \*Patient's Gender

- Male
- Female
- Other

5. \*Patient's Date of Birth (preferred) or Age

6. Patient's weight (in kg) (if child or adolescent)

7. \*Patient location

- ICU
- NICU
- PICU
- Non-ICU

## Section B. Consent, COVID-19 Infection Status and Criteria for Remdesivir Use

8. \*Has informed patient consent been obtained and documented in the medical record?

For patient information leaflets and consent forms, visit the NSW TAG COVID-19 Resources [webpage](#)

- Not sure
- Yes
- No
- Pending

9. \*I confirm that:

	Yes ("Yes" responses meet the Restricted Formulary Criteria)	No ("No" responses mean that this submission will be evaluated as an IPU application)	Other ("Other" responses mean that this submission will be evaluated as an IPU application)
the patient has confirmed SARS-CoV2 or is a known contact of a confirmed case awaiting confirmation by diagnostic testing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
COVID-19 symptoms onset has occurred within the last 10 days	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient has NO KNOWN hypersensitivity including anaphylaxis to remdesivir, its metabolites, or formulation excipients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient's ALT is less than or equal to 5 x ULN and, if ALT is greater than or equal to 3 x ULN, then bilirubin is less than 2 x ULN	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient's eGFR >30 mL/min/1.73m <sup>2</sup> and they are NOT on dialysis or continuous veno-venous haemofiltration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient's oxygen saturation (SpO <sub>2</sub> ) is less than or equal to 92% on room air and they require supplemental oxygen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient is NOT receiving ventilation (non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO))	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the patient does NOT have evidence of multiorgan failure including but not limited to: •coagulopathy (significant thrombocytopenia); • hepatic failure (elevated bilirubin); • renal failure (low urine output or estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m <sup>2</sup> ); or •significant cardiomyopathy (low cardiac output)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. \*I confirm that the patient is receiving supplemental oxygen via:

- A Low Flow Oxygen device
- A High Flow Nasal Oxygen (HFNO) or other high flow oxygen device

## Section C. Prescribing considerations

11. \*A check for drug interactions is required prior to prescribing remdesivir.

Note: Potential drug interactions have not been investigated in patients with COVID-19.

- In vitro, remdesivir is a substrate and inhibitor of [CYP3A4](#) as well as several other drug metabolising enzymes.
  - Inhibition of CYP3A4 by remdesivir may be clinically relevant for medicines that are [CYP3A4](#) substrates. Consider whether medication doses require adjustment during hospitalisation.
  - Strong inducers of [CYP3A4](#) (e.g. carbamazepine, phenytoin, rifampicin) may affect remdesivir efficacy.
- It is prudent to minimise the concurrent use of any nonessential medications.
- Further information can be found in the [remdesivir drug guideline](#).

Please select if the patient is prescribed/is likely to be prescribed any of the medicines which may potentially interact with remdesivir (more than one answer may be selected)

- No known drug interactions present
- Antiepileptics e.g. carbamazepine, phenytoin
- Other (please provide details in next question)

12. If other drug interaction(s), provide details

## Section D. Remdesivir Dosing Information

13. \*Duration of remdesivir treatment and the corresponding supply required

- 5 day duration of treatment; 6 vials of remdesivir 100 mg required (200 mg IV on day 1, then 100 mg IV daily for a further 4 days)
- Other (please provide details in next question)

14. If other, please specify proposed dose, frequency, duration and reason

15. Formulation of remdesivir required

Please note: lyophilized powder is required for treatment of paediatric patients weighing less than 40 kg.

- either formulation
- concentrate solution
- lyophilized powder

## Section E. Prescriber's Details

16. \*Prescriber's full name

17. \*Prescriber's email address

18. \*Prescriber's contact number (Pager and/or extension and/or mobile number)

19. \*Prescriber's specialty
- Infectious Diseases Physician (jump to question 21)
  - Intensivist (jump to question 21)
  - Respiratory Physician (jump to question 21)
  - Emergency Medicine Physician (jump to question 21)
  - Other, please specify (jump to question 20)

20. If other specialty, please specify including specialist qualifications

21. Some sites may require peer review / multidisciplinary team consultation for approval to access remdesivir. If your site requires this, has this occurred?

- No, not applicable at this site (jump to question 23)
- Yes (jump to question 22)
- No, undertake consultation and communicate this to the DTC after submission of this form (jump to question 23)

22. Please provide the name and specialty of the clinician(s) who have been consulted

23. \*Hospital name

## Section F. Additional Information

24. (If required by your site) Please provide the AMS / ID approval number

25. If this application is for an IPU, you may provide further information or evidence to support use if not captured elsewhere in this form. e.g. lung infiltrates on imaging.

## Pharmacovigilance:

- You may be contacted at a later time for information about clinical outcomes of the patient who received this medicine
- Adverse events related to medicines should be reported to the TGA and via the hospital ims+ or Riskman system

## Submission

1. Before clicking 'Submit' please ensure you have responded to all the questions marked with an asterisk\*
2. You must email the DTC/Pharmacy Dept. to notify them of your submission so that they can review and arrange supply of remdesivir. **See quick email hyperlink and email template below.** Click on the relevant hyperlinked email below to open an email window to write a submission email.

DTC/Pharmacy Dept. email: [ ] DTC/Pharmacy Dept. phone number: [ ]

Include in the email the following details at a minimum (suggest copy & paste and then complete the template below):

Dear DTC/Pharmacy Dept.,

A prescribing declaration/IPU (delete whichever is not applicable) for remdesivir has been submitted for [patient name, MRN] for DTC review.

Unique code: Insert the unique code\* Remdesivir\_[LHD]\_[MRN]\_[DATE] \*(code entered at beginning of the form).

Kind regards,

Prescriber Name

**Your local DTC or pharmacist will contact you with the outcome of your submission and arrange supply of remdesivir, if appropriate/approved. Thank you**