NSW TAG NSW Therapeutic Advisory Group Inc. | Advancing quality use of medicines in NSW

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The information on page 1 of this form do not apply to the manual completion of this PDF form.

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

**Restricted Formulary Criteria

- With confirmed SARS-CoV2 or known contact of a confirmed case awaiting confirmation by diagnostic testing; AND,
- Aged ≥ 18 years, or aged ≥ 12 and < 18 years of age weighing ≥ 40 kg; AND,
- With oxygen saturation (SpO2) ≤ 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))

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; Preterm birth; Known or suspected pregnancy; Breastfeeding; Other

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

Please read before you begin:

- **Familiarise yourself with the questions and the information required in this online form BEFORE proceeding. (Scroll down to view all questions).**
- **The form can only be completed in one session**
  You cannot save, close and return to this form at a later time (if you are called away, the form will remain open unless your browser is closed).
- **Completion of the form takes approximately 5 minutes**
- **The Remdesivir Drug Guideline provides guidance for remdesivir use in hospitalised patients.**
- **Some sites will require peer review / multidisciplinary team consultation for approval to access remdesivir, please undertake prior to completing this form.**
- **Provide a response to each applicable question. Failure to provide responses may delay the processing of this form and subsequent supply of remdesivir.**
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1. *Enter a 'code' unique for this patient

Suggest follow this template Remdesivir_LHD_MRN_DATEofADMISSION
e.g. Remdesivir_NSLHD_0123456_03122020 [Question ID: 38368]

Section A. Patient Demographics

2. *Patient's initials [Question ID: 33301]

3. *Patient's MRN [Question ID: 33302]

4. *Patient's Gender [Question ID: 33303]

- O Male
- O Female
- O Other

5. *Patient's Date of Birth (preferred) or Age [Question ID: 35700]

6. *Patient's weight (in kg) [Question ID: 35701]

7. *Patient location [Question ID: 39435]

- O ICU
- O NICU
- O PICU
- O Non-ICU

Section B. 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 [Question ID: 38376]

O Yes

O No

O Pending

9. *I confirm that: [Question ID: 39447]

	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	◯	◯	◯
the patient has NO KNOWN hypersensitivity including anaphylaxis to remdesivir, its metabolites, or formulation excipients	◯	◯	◯
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	◯	◯	◯
the patient's eGFR > 30 mL/min/1.73m2 and they are NOT on dialysis or continuous veno-venous haemofiltration	◯	◯	◯
the patient's oxygen saturation (SpO2) is less than or equal to 92% on room air and they require supplemental oxygen	◯	◯	◯
the patient is NOT receiving ventilation (non-invasive or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO))	◯	◯	◯
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/1.73m2); or •significant cardiomyopathy (low cardiac output)	◯	◯	◯

10. *I confirm that the patient is receiving supplemental oxygen via: [Question ID: 35849]

- O A Low Flow Oxygen device
- O 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 whenever possible. Further information can be found in the remdesivir drug guideline and the University of Liverpool interactions checker.

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) [Question ID: 38373]

- ☐ 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 [Question ID: 33331]

Section D. Remdesivir Dosing Information

13. *Duration of remdesivir treatment and the corresponding supply required [Question ID: 35715]

- O 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)
- O Other (please provide details in next question)

14. If other, please specify proposed dose, frequency, duration and reason [Question ID: 33335]

15. *Formulation of remdesivir required

Please note: lyophilized powder is required for treatment of paediatric patients weighing less than 40kg. [Question ID: 38245]

- O concentrate solution
- O lyophilized powder
- O either formulation

Section E. Prescriber's Details

16. *Prescriber's full name [Question ID: 33341]

17. *Prescriber's email address [Question ID: 33345]

18. *Prescriber's contact number (Pager and/or extension and/or mobile number) [Question ID: 38736]

19. *Prescriber's specialty [Question ID: 39537]

- O Infectious Diseases Physician (if **Infectious Diseases Physician**, jump to question **21)**
- O Intensivist (if **Intensivist**, jump to question **21)**
- O Respiratory Physician (if **Respiratory Physician**, jump to question **21)**
- O Emergency Medicine Physician (if **Emergency Medicine Physician** jump to question **21)**
- O Other, please specify (if **Other, please specify**, jump to question **20)**

20. If other specialty, please specify including specialist qualifications [Question ID: 33348]

21. Some sites will require peer review / multidisciplinary team consultation for approval to access remdesivir. If your site requires this, has this occurred? ; [Question ID: 39409]

- O No, not applicable at this site (jump to question **23**)
- O Yes (jump to question **22**)
- O 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 [Question ID: 39410]

23. *Hospital name [Question ID: 33352]

Section F. Outcome reporting

24. *I agree to report any suspected adverse events and other clinical outcomes of the use of remdesivir in this patient

[The DTC will provide you with a hyperlink to the 'Remdesivir Adverse Events and Clinical Outcomes Report Form' for completion within 2 weeks of remdesivir cessation, discharge or death.]

[Question ID: 38964]

- O Yes
- O No

Section G. Additional Information

25. (If required by your site) Please provide the AMS / ID approval number [Question ID: 33355]

26. If this application is an IPU, you may provide further information or evidence to support use if not captured elsewhere in this form. [Question ID: 38738]

Submission

1. Before clicking 'Submit and Close' please ensure you have responded to all the questions marked with an asterisk*
2. You must email the DTC to notify them of your submission so that they can review and arrange supply of remdesivir. **See email template below.**

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

   Dear DTC,

   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 approved.

The DTC will provide you with a hyperlink to the 'Remdesivir Adverse Events and Clinical Outcomes Report Form' for completion within 2 weeks of remdesivir cessation, discharge or death.

Thank you