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NSW TAG 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 ≥18 years, or aged 12 to 17 years 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) 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

- O Male
- O Female
- O Other

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

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

7. *Patient location

- O ICU
- O NICU
- O PICU
- O 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

- O Not sure
- O Yes
- O No
- O 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	◯	◯	◯
COVID-19 symptoms onset has occurred within the last 10 days	◯	◯	◯
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:

- 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.
- 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