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

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Remdesivir
Adverse Events and Clinical Outcomes Report
for prescriber (or delegate) completion

Please read before you begin:

- **It is recommended that the respondent familiarises themselves 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 come back to the report at a later time (if you are called away, the form will remain open unless your browser is closed).**
- **Completion of this report may take approximately 15 - 20 minutes.**

A response to each applicable question should be provided.

1. *Enter a 'code' unique to this patient **(suggested template Remdesivir_LHD_MRN_DATE)**

(if applicable, use the same code that was selected in the IPU application / remdesivir initiation notification submission with the same suggested template *Remdesivir_LHD_MRN_DATE*)
[Question ID: 26938]

Click or tap here to enter text.

2. *What is today's date? (date format: dd/mm/yyyy) [Question ID: 26939]

Click or tap here to enter text.

Section A. Clinician's details

3. Full name of clinician providing report [Question ID: 26943]

4. *Are you the same clinician who made the original remdesivir IPU application / initiated remdesivir? (if **Yes**, jump to question **9** ; if **No**, jump to question **5**) [Question ID: 26942]

- ☐ Yes
- ☐ No

5. Clinician's email address [Question ID: 26944]

6. Clinician's contact phone number (extension and/or mobile number) [Question ID: 26945]

7. Clinician's specialty (if **Infectious Diseases Physician**, jump to question **9** ; if **Intensivist**, jump to question **9** ; if **Respiratory Physician**, jump to question **9** ; if **Other, please specify**, jump to question **8**) [Question ID: 26946]

- ☐ Infectious Diseases Physician
- ☐ Intensivist

☐ Respiratory Physician

☐ Other, please specify

8. If other specialty, please specify [Question ID: 26947]

Section B. Patient Demographics

9. *Patient's initials [Question ID: 26950]

10. *Patient's MRN [Question ID: 26951]

11. *Patient's Date of Birth (date format: dd/mm/yyyy) [Question ID: 26952]

12. *What date was the patient admitted? (date format: dd/mm/yyyy) [Question ID: 26953]

13. *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected) [Question ID: 28671]

☐ Age = or > 65 years

☐ Current smoker

☐ BMI equal to or greater than 30 kg/m2 and less than 40 kg/m2

☐ BMI equal to or greater than 40 kg/m2

☐ Hypertension

☐ Hyperlipidaemia

☐ Other cardiovascular disease (please specify in next question)

☐ Cerebrovascular disease

☐ Diabetes

☐ Chronic respiratory disease (please specify in next question)

☐ Chronic kidney disease (eGFR < 60 mL/min/1.73 m2)

☐ Hepatic impairment

☐ Cancer

☐ Other (please provide details in next question)

☐ No poor prognostic factors for COVID-19 identified

14. Please provide more specific details of other cardiovascular disease, chronic respiratory disease, cancer or other factors, if relevant. [Question ID: 28834]

Section C. Remdesivir Details

15. *What date was remdesivir commenced? (date format: dd/mm/yyyy) [Question ID: 26954]

16. *Actual dosing (i.e. dose, frequency and duration administered) (if **200 mg IV on day 1, then 100 mg IV daily for a further 4 days (total 5 days; 6 vials of remdesivir 100 mg)**, jump to question **18** ; if **200 mg IV on day 1, then 100 mg IV daily for a further 9 days (total 10 days; 11 vials of remdesivir 100 mg)**, jump to question **18** ; if **Other (please provide details in next question)**, jump to question **17**) [Question ID: 26955]

◯ 200 mg IV on day 1, then 100 mg IV daily for a further 4 days (total 5 days; 6 vials of remdesivir 100 mg)

◯ 200 mg IV on day 1, then 100 mg IV daily for a further 9 days (total 10 days; 11 vials of remdesivir 100 mg)

◯ Other (please provide details in next question)

17. If other, please specify dosing (dose, frequency, duration) and reason [Question ID: 26956]

18. *If the actual dosing was different to that initially proposed, provide details (use N/A if dosing not different)

Also include information if:

- **infusion incomplete/ceased early**
- **consent to treatment withdrawn**
- **still ongoing/additional doses planned**
- **contraindication identified**
- **adverse drug effect experienced (identify here and provide details in section E)**
- **death occurred**

[Question ID: 26957]

Section D. Concomitant Therapy

19. *Select if the patient was acutely commenced on any of the listed therapies below during hospitalisation with COVID-19 (more than one answer may be selected) [Question ID: 26958]

☐ Other antiviral therapy

☐ Corticosteroid (not topical)

☐ Immunomodulator

☐ Antibacterial therapy

☐ Antithrombotic therapy

☐ Convalescent plasma

☐ Hyperimmune immunoglobulin

☐ ACE inhibitor

☐ Sartan

☐ Statin

☐ Other therapy (specify in next question)

☐ The patient was not commenced on any of the listed medicines above

20. Provide details of relevant therapies identified in question 19, including if it was part of a clinical trial [Question ID: 26959]

21. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient? (e.g. required change in choice of therapies / dose changes) (if **No relevant drug interactions identified**, jump to question **23** ; if **Yes, interaction(s) involving remdesivir**, jump to question **22** ; if **Yes, interaction(s) involving other relevant COVID-19 therapies**, jump to question **22** ; if **Yes, interaction(s) involving remdesivir AND other COVID-19 therapies**, jump to question **22**) [Question ID: 26962]

- ◯ No relevant drug interactions identified
- ◯ Yes, interaction(s) involving remdesivir
- ◯ Yes, interaction(s) involving other relevant COVID-19 therapies
- ◯ Yes, interaction(s) involving remdesivir AND other COVID-19 therapies

22. Provide details of drug interaction(s) [Question ID: 26963]

Section E. Possible or Likely Adverse Effects Due to Remdesivir

23. *Did the patient experience any adverse effects (possible or likely) due to remdesivir use? (if **Yes**, jump to question **24** ; if **No**, jump to question **47**) [Question ID: 26964]

- O Yes
- O No

24. Select the adverse effects, which were possible or likely due to remdesivir use (more than one answer may be selected) [Question ID: 26965]

- ☐ Increase in LFTs < 5 times upper limit of normal
- ☐ Increase in LFTs = or > 5 times upper limit of normal
- ☐ Possible allergic reaction, including anaphylactic reactions and angioedema
- ☐ Infusion-related reactions (within 24 hours of IV infusion; including but not limited to hypotension, nausea, vomiting, diaphoresis and shivering)
- ☐ Gastrointestinal symptoms not related to infusion reaction (e.g. nausea, vomiting, diarrhoea)
- ☐ Headache
- ☐ Rash
- ☐ Death
- ☐ Other (please provide details in next section)

You are required to provide details for each adverse effect identified. If there are more than TWO adverse effects, a free text field to provide details of additional adverse effects follows.

Section E continued.
Details of Possible/Likely Adverse Effects Due to Remdesivir

First adverse effect

25. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 26966]

26. What was the likelihood that this adverse effect was due to remdesivir use? [Question ID: 26968]

- O Possibly
- O Likely
- O Don't know

27. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)? [Question ID: 26967]

28. What was the severity of the adverse effect? (if **Mild, no treatment required**, jump to question **30** ; if **Moderate to Severe, treatment required**, jump to question **29** ; if **Life-threatening**, jump to question **29** ; if **Don't know, no treatment required**, jump to question **30**) [Question ID: 26969]

- O Mild, no treatment required
- O Moderate to Severe, treatment required
- O Life-threatening
- O Don't know, no treatment required

29. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 26970]

30. Has the patient recovered from the adverse effect? (if **Yes**, jump to question **31** ; if **No**, jump to question **32** ; if **Don't know**, jump to question **32**) [Question ID: 26971]

- Yes
- No
- Don't know

31. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 26972]

32. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 26973]

- Yes
- No
- Don't know

33. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.) [Question ID: 26974]

34. Do you have a second adverse effect to provide information about? (if **Yes**, jump to question **35** ; if **No**, jump to question **46**) [Question ID: 26975]

- Yes
- No

Section E continued.
Details of Possible/Likely Adverse Effects Due to Remdesivir

Second adverse effect

35. What was the adverse effect?
(Name the adverse effect only, further details to be provided below) [Question ID: 26976]

36. What was the likelihood that this adverse effect was due to remdesivir use? [Question ID: 26977]

- O Possibly
- O Likely
- O Don't know

37. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)? [Question ID: 26978]

38. What was the severity of the adverse effect? (if **Mild, no treatment required**, jump to question **40** ; if **Moderate to Severe, treatment required**, jump to question **39** ; if **Life-threatening**, jump to question **39** ; if **Don't know, no treatment required**, jump to question **40**) [Question ID: 26979]

- O Mild, no treatment required
- O Moderate to Severe, treatment required
- O Life-threatening
- O Don't know, no treatment required

39. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures [Question ID: 26980]

40. Has the patient recovered from the adverse effect? (if **Yes**, jump to question **41** ; if **No**, jump to question **42** ; if **Don't know**, jump to question **42**) [Question ID: 26981]

- ◯ Yes
- ◯ No

◯ Don't know

41. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)? [Question ID: 26982]

42. Did the adverse effect prolong the hospitalisation or cause death? [Question ID: 26983]

- O Yes
- O No
- O Don't know

43. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.) [Question ID: 26984]

44. Were any other adverse effects due to Remdesivir (possible or likely) experienced by the patient? (if **Yes**, jump to question **45** ; if **No**, jump to question **46**) [Question ID: 26985]

- O Yes
- O No

Section E continued.
Details of Possible/Likely Adverse Effects Due to Remdesivir

Additional adverse drug effects (three or more)

45. Please provide a free text description of all additional adverse effects identified. Include the following information:
(If helpful, copy and paste the dot points below in your response)

- Name the adverse effect
- Likelihood that this adverse was due to remdesivir: [possibly/ likely/ don't know]
- Timing of onset of the adverse effect after initial remdesivir administration: [hours/minutes, as applicable]
- Severity of the adverse effect: [mild, no treatment required; moderate to severe, treatment required; life-threatening; don't know, no treatment required]
- Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures: [provide details or N/A]
- Recovery from the adverse effect? [yes/ no/ don't know]
- Time to recovery from the adverse effect: [minutes/hours/days]
- Prolongation of hospitalisation or caused death by adverse effect: [yes/ no/ don't know]
- Any other relevant details of the adverse effect (include results of relevant laboratory data and other investigations, monitoring required etc.)

[Question ID: 26986]

Section E continued. Possible/Likely Adverse Effects Due to Remdesivir

46. *Were adverse effect(s) reported elsewhere? [Question ID: 26987]

- O No
- O Yes, reported to both the TGA/Gilead and the hospital's adverse events reporting system
- O Yes, reported within the hospital's adverse events reporting system
- O Yes, reported to the TGA/Gilead
- O Not sure

Section F. Clinical Outcomes

47. *Select the current clinical status of the patient
Refer to National COVID-19 Clinical Evidence Taskforce Living Guidelines https://covid19evidence.net.au/ for definitions of respiratory support requirements. (if **Not hospitalised, no limitations on activities**, jump to question **51** ; if **Not hospitalised, limitations on activities, home oxygen requirement, or both**, jump to question **51** ; if **Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons)**, jump to question **52** ; if **Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions)**, jump to question **52** ; if **Hospitalised, requiring supplemental oxygen via low flow oxygen devices**, jump to question **52** ; if **Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices**, jump to question **52** ; if **Hospitalised, on non-invasive ventilation (NIV)**, jump to question **52** ; if **Hospitalised, on invasive mechanical ventilation**, jump to question **53** ; if **Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO)**, jump to question **53** ; if **Death**, jump to question **48**) [Question ID: 26988]

- O Not hospitalised, no limitations on activities
- O Not hospitalised, limitations on activities, home oxygen requirement, or both
- O Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons)
- O Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions)
- O Hospitalised, requiring supplemental oxygen via low flow oxygen devices
- O Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices
- O Hospitalised, on non-invasive ventilation (NIV)
- O Hospitalised, on invasive mechanical ventilation
- O Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO)
- O Death

48. Date of death (date format: dd/mm/yyyy) [Question ID: 26990]

49. Cause of death (as documented on death certificate) (if **COVID-19**, jump to question **51** ; if **Other**, jump to question **50**) [Question ID: 26991]

- O COVID-19
- O Other

50. If other, specify cause of death as per death certificate [Question ID: 26992]

51. *Specify the total hospital length of stay (LOS) in days (numeric field) [Question ID: 26993]

52. *Did the patient require intensive care? (if **Yes**, jump to question **53** ; if **No**, jump to question **54**) [Question ID: 26994]

O Yes

O No

53. Specify the ICU LOS in days (numeric field) [Question ID: 26995]

54. *Select if the patient experienced any of the following during the course of the COVID-19 disease (more than one answer may be selected) [Question ID: 26996]

☐ Respiratory failure

☐ Multiorgan failure

Section G. Additional Information

55. Optional: please include any other information relevant to this report if not captured elsewhere (E.g. consider including requirements and duration of intubation or ECMO, scores on admission to and discharge from ICU such as SOFA or APACHE 2 etc.) [Question ID: 26997]

Submission

- You are now ready to submit the Remdesivir Adverse Events and Clinical Outcomes Report data.
- Please ensure you have completed all the questions marked with an asterisk*.
- Your local DTC will contact you if any further information is required.

Thank you for your contribution.