Te Pou Hauora Tūmatanui
Public Health Agency

MANATŪ HAUORA
MINISTRY OF HEALTH

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14 June 2024

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2024042455

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 24 May. This request was partially transferred from Health New Zealand (Te Whatu Ora) on 23 May 2024. You requested:

> *"1) all guidelines for the use of remdesiver in NZ that applied at any NZ hospital from 2021 and and changes to any such guidance and the dates of any such changes and reasons.*

The following is a timeline of clinical guidance with regards to the use of remdesivir to treat COVID-19, including updates and, where stated, reasons for any change. Reasons were often included in the guideline itself. The Therapeutics Technical Advisory Group (TAG) monitored the clinical literature constantly for any evidence about remdesivir that would change existing guidance and planned updates regularly to the guidance. Where clinical guidelines were updated, this is outlined in the timeline below and these have been released to you in full.

- August 2021
  The first Therapeutics Technical Advisory Group (TAG) meeting was held on the Friday 27th August 2021. The TAG considered whether the "Middlemore Guidelines Management of COVID-19 in Adults" were suitable as interim national guidelines. A recommendation regarding the use of Remdesivir is included in the 'Anti-viral Therapy' section. Attached as document #15 is an email dated Friday 20th August 2021 (labelled "RE: 'Middlemore guidelines' Clinical Guidelines"). The guidelines are attached as document #1.

- 7th September 2021
  The "Interim Guidance – Clinical Management of COVID-19 in Adults" was released. With regards to remdesivir, an addition was made to the recommendations regarding adults with significant immunocompromise. See document #2.

- 24th September 2021
  The updated guideline contains a modified recommendation for use of remdesivir. The new content is highlighted in red. See document #3.

- 5th November 2021
  The updated guideline contains some changes to the recommendations regarding adverse effects for remdesivir. See document #4.

- December 3rd 2021
  The updated guideline contains a change to the recommendations for the use of remdesivir during pregnancy. See document #5.

- March 4th 2022
  The updated guideline contains changes to the recommendations for remdesivir with an addition of recommendation to consider use of remdesivir in hospitalised adults not requiring oxygen and at high risk of developing severe disease and the removal of conditional recommendation to consider remdesivir for moderate hospitalised patients requiring oxygen within the first week of illness. The reasons for these changes are provided in the guideline on page 7. See document #6.

- March 23rd 2022
  The Therapeutics TAG published "Guidance for temporary prioritisation of remdesivir for early COVID-19 in people not requiring oxygen" dated 23rd March 2022 (document #7). The reasons for these changes are detailed in the document and include a mismatch between the availability of remdesivir courses and the infected eligible population, and to offer remdesivir to people with early COVID-19 in the community who are at very high risk of progression to requiring in-hospital treatment. Note that the guideline for the management of people with COVID-19 in hospital was still relevant at this time. See document #7.

- April 1st 2022
  The updated guideline contains amended advice for the use of remdesivir; a new recommendation to consider the individual balance of risks and benefits when prescribing remdesivir to people with estimated glomerular filtration rate (eGFR) <30 ml/min and an addition of an optional two-dose prescription in this group. See document #8.

- May 6th 2022:
  This updated guideline contains updated eligibility criteria for antivirals with addition of Down Syndrome and sickle cell disease; the addition of advice to assess eligibility criteria for antivirals on hospital discharge, and a new figure added that provides a 'Heatmap' of eligibility for antivirals based on risk. See document #9.

- July 1st 2022
  The updated guideline contains a new recommendation to consider remdesivir for patients with moderate COVID-19 within 7 days of symptom onset. See document #10.

- July 15th 2022
  The updated guideline include expanded access criteria included for antiviral treatments in early COVID-19, and a new recommendation to consider remdesivir for patients with moderate COVID-19 within 7 days of symptom onset (document #11).

- August 26th 2022
  This updated guideline includes a recommendation not to prescribe remdesivir for 'rebound' COVID-19. See document #12.

- October 5th 2022
  The Therapeutics TAG published a paper about antiviral options in chronic kidney disease. This was updated March 20th 2023. See document #13. This document is also publicly available here: https://www.tewhatuora.govt.nz/assets/For-the-health-

sector/Health-sector-guidance/Diseases-and-conditions/Antiviral-Options-for-COVID-19-Infection-in-Patients-with-Chronic-Kidney-Disease.pdf

3) any advice or analysis or guidance on the safety and/ or effectiveness of the use of remdesiver, and any consideration of alternatives to remdesiver including off label use of approved medicines. Please provide all such advice whether generated within HealthNZ or externally.

5) any communications between the Ministry/DG of Health, Medsafe, DPMC, Unite against COVID' and / or Pharmacy about legal status, safety, effectiveness, prescribing guidance, research and/or review of outcomes, alternatives and/ or funding in relation to the use of Remdesiver, and any representative of Health NZ."

The May 2021 document "REMDESIVIR: Clinical Criteria and Distribution" (document #14) contains a literature review providing information from four randomised controlled trials of the efficacy of remdesivir in hospitalised patients with COVID-19. This also contains information regarding side effects. Please note there are some redactions under section 9(2)(b)(ii) of the Act, as its release would likely unreasonably prejudice the commercial position of the person who supplied the information. I have considered the countervailing public interest in releasing information and consider that it does not outweigh the need to withhold at this time.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Kristie Carter
Group Manager, **Intelligence, Surveillance and Knowledge**
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Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	August 2021	'Middlemore Guidelines' Management of COVID-19 in Adults	Released in full.
2	September 2021	Interim Guidance - Clinical Management of COVID-19 in Adults	
3	September 2021	Interim Guidance - Clinical Management of COVID-19 in Adults	
4	November 2021	Clinical Management of COVID-19 in Adults	
5	December 2021	Clinical Management of COVID-19 in Adults	
6	March 2022	Clinical Management of COVID-19 in Adults	
7	March 2022	Guidance for temporary prioritisation of remdesivir for early COVID-19 in people not requiring oxygen	
8	April 2022	Clinical Management of COVID-19 in Adults	
9	May 2022	Clinical Management of COVID-19 in Adults	
10	July 2022	Clinical Management of COVID-19 in Adults	
11	July 2022	Clinical Management of COVID-19 in Adults	
12	July 2022	Clinical Management of COVID-19 in Adults	
13	March 2023	Antiviral Options for COVID-19 Infection in Chronic Kidney Disease – Therapeutics TAG position statement	
14	May 2021	REMDESIVIR: Clinical Criteria and Distribution	Some information withheld under section 9(2)(b)(ii) of the Act, as withholding of the information is necessary to protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the

#	Date	Document details	Decision on release
			person who supplied or who is the subject of the information.
15	August 2021	Email chain: RE: 'Middlemore guidelines' Clinical Guidelines	Some information withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons.