Record of the COVID Treatments Advisory Group Meeting held on 30 May 2023

The role of Advisory Groups and records of meetings

Note that this document is not necessarily a complete record of the COVID Treatments Advisory Group meeting; only the relevant portions of the meeting record relating to COVID Treatments Advisory Group discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

Conflicts of Interest are described and managed in accordance with section 7.2 of the PTAC Terms of Reference.

The COVID Treatments Advisory Group may:

(a). recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule; or

(b). defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c). recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule; or

(d). recommend that Pharmac discontinue funding of a pharmaceutical currently on the Pharmaceutical Schedule.

Advisory Groups give advice to Pharmac, including recommendations', based on the Groups' different, if complementary, roles, expertise, experience, and perspectives. Recommendations made by the COVID-19 Treatments Advisory Group are in the context of COVID-19 treatments only. Pharmac is not bound to follow the recommendations made below.

The record of this Advisory Group meeting will be reviewed by PTAC at an upcoming meeting.

Excerpt from Record of the COVID Treatments Advisory Group Meeting held on 30 May 2023

Attendance

Present

Chair – Dr Jane Thomas
Dr Ajay Makal
Professor Brian Anderson
Dr Gillian Hood
Dr Graham Mills
Dr Nigel Raymond
Dr Robyn Manuel
Professor Stephen Munn
Dr Tim Cutfield

Apologies

Eamon Duffy
Dr Justin Travers
Dr Kerry Benson-Cooper

Associate Professor Marius Rademaker

Disability Support Services (DSS) recipients and COVID-19 outcomes

Application

1.1. The Advisory Group reviewed information provided by Pharmac with regards to the disability support services (DSS) recipients and COVID-19 outcomes.

1.2. The Advisory Group took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

1.3. The Advisory Group **recommended** that disability support services recipients be included in the Access Criteria for funded COVID-19 antivirals.

1.4. The Advisory Group considered the following in making this recommendation:

- DSS recipients are at higher risk of hospitalisation and death from COVID-19 infection compared with the general population.
- Epidemiological data available is directly relevant to the group considered for funding, and risk ratios are replicable.
- The current COVID-19 antivirals Access Criteria allow access to people who may have lower risks of severe COVID-19 outcomes, including hospitalisation and death, than DSS recipients.
- The population being considered is very well-defined, making implementation practical.
- The absolute risk of hospitalisation or death attributable to COVID-19 will vary for DSS recipients, depending on their age, the nature of their disability, the number of other established risk factors and vaccination status. As such, clinical judgement is warranted as to whether antivirals are indicated on a case-by-case basis.

Discussion

Māori impact

1.5. The Advisory Group discussed the impact of funding COVID-19 antivirals for disabled people on Māori health areas of focus and Māori health outcomes. The Group noted that within the DSS recipient group, Māori DSS recipients comprised 19% compared with 16% in the general population (Ministry of Health. 2019. Demographic Report for Clients Allocated the Ministry of Health's Disability Support Services: 2018 update). The Group considered that the Māori were over-represented in the DSS recipients compared to the general population. The Group considered that inclusion of DSS recipients as a priority group within the criteria would improve health outcomes for whaikaha Māori.

Background

1.6. The Advisory Group noted its previous consideration of disabled people in February 2023. The Group had considered that at that time there were not sufficient data available to specifically add DSS into the community COVID-19 antiviral Access Criteria, but noted that information was expected from Manatū Hauora - Ministry of Health and Whaikaha - Ministry of Disabled People (February 2023 meeting record paragraphs 2.23 to 2.26).

1.7. The Advisory Group previously recommended the access criteria include people with pre-existing disability warranting direct family, whānau or external care most days as a specific named group (February 2023 meeting record paragraphs 2.3 and 2.44). The Group

considered that this group was likely to be highly vulnerable to COVID-19 severe outcomes due to their disability. Members considered most, but not necessarily all, disabled people needing either direct family, whānau or external care most days will be receiving DSS already.

Health need

1.8. For context, the Advisory Group noted that 10.7% of COVID-19 deaths in the general population had occurred in those under 70 years of age. Of these, 25% (ie 2.7% of total all-age deaths associated with COVID-19) were as a direct result of a current infection in this age group (Ministry of Health. COVID-19 Risk Among Disabled People. 2023). The Group considered the risk of hospitalisation and death from COVID-19 for the general population, < 70 years, is lower than that of the all-age population, as increasing age is an independent risk factor for hospitalisation and death.

1.9. The Advisory Group noted that there were 43,000 DSS recipients aged < 70 years with varying physical, sensory or intellectual disability or autism, likely identified before the age of 65, and not the result of an accident (Ministry of Health. 2023). The Advisory Group noted they had a median age of 26 years (Ministry of Health. 2019). The Group noted that in general, only people aged < 65 are eligible for DSS services, hence there will be lower numbers of people in the ≥ 65 age groups compared with the general population (Ministry of Health. 2019). The Group noted that some people had multiple disabilities, that are included in multiple subgroups, and that DSS recipients are likely to have more complex impairments and co-morbidities than the wider disabled community.

1.10. The Advisory Group noted DSS is often used to describe a range of support that may be available, including disability information and advisory services; environmental support, child development services, personal care, respite, individualised funding, supported living, behaviour support and residential support. The Group noted that DSS recipients are either living in residential care (residential), or living with a caregiver, usually family/whānau (non-residential). In 2018 17.7% of DSS users were living in DSS community residences, the median age was 49 years, and 86% had a principal disability type classified as 'intellectual' (Ministry of Health. 2019).

1.11. The Advisory Group noted that tāngata whaikaha Māori (Māori DSS recipients) made up 19% of the DSS recipient group, compared to 16% in the general population, with a median age of 21 years. The Group noted that Pacific peoples made up 6% of the DSS recipient group compared to 8.1% in the general population (Ministry of Health. 2019). The Group considered that the Māori were over-represented in DSS recipients, while Pacific peoples were under-represented compared to the general population.

1.12. The Advisory Group noted a Ministry of Health - Manatū Hauora report comparing DSS recipients aged < 70 years with non-DSS recipients (rest of the general New Zealand population) aged < 70 years. The report calculated the age-standardised relative risk (RR) of hospitalisation or crude RR death attributable to COVID-19 during 2022 (Ministry of Health. 2023).

1.12.1. The Group noted almost 14,000 (32%) DSS recipients aged < 70 years were reported as a COVID-19 case during the first 10.5 months of 2022. After age standardising, DSS recipients aged < 70 years' cumulative risk of being reported as a case was around 15% lower than the rest of the population aged < 70 years over that time. The Group noted age standardisation is used to make comparisons between populations that may have different age structures, which is particularly important if examining an outcome where the risk is strongly related to age, such as being hospitalised.

1.12.2. The Group considered that nearly all the differences in infection risk between all DSS recipients, and the rest of the population aged < 70 years (the 15% less cumulative risk above), appeared to have occurred early during the first half of the

March 2022 wave of Omicron variant COVID-19 cases (where cumulative likelihoods of acquiring then reporting COVID-19 were higher in the rest of the population than in DSS recipients). The Group noted that wave dominated all cases, but since then serial risk (case incidence) had appeared very similar.

1.12.3. The Group considered that the difference in infection risk in the early first half of the first wave may have been due to added shielding (isolation, mask-wearing or physical distancing by DSS residents and caregiver staff) for this group particularly during earlier waves.

1.12.4. The Group noted that 431 people receiving DSS support aged < 70 years were hospitalised with COVID-19 (1046 age-standardised hospitalised cases per 100,000 DSS recipients < 70 years), and 18 who died were COVID positive (65 crude COVID-19 associated deaths per 100,000 DSS recipients across all ages) (Ministry of Health. 2023). The Group noted that in this analysis the definition of attributable mortality was the same as the contributory mortality as reported by Ministry of Health - Manatū Hauora for the general New Zealand population (Ministry of Health. COVID-19: Case demographics. 2023).

1.12.5. The Group considered that the comparison of non-DSS recipients and DSS recipients in 2022 was reasonable, as this is when New Zealand experienced most of the COVID-19 cases, and the majority of these were an Omicron variant.

1.12.6. The Group considered that there were important differences between the first 6 months of 2022 and last 6 months, such that there was a large spike in cases initially and most cases were first infections. The Group considered this was different to most of the world, which experienced large waves of cases and many different variants throughout the last three years of the pandemic. The Group considered that late 2022 was more reflective of the state throughout the rest of the world, and the current state in New Zealand, where most of the population is fully vaccinated, and a large proportion have had at least one COVID-19 infection.

1.13. The Advisory Group noted that people living in DSS community residences (15-20% of all DSS users) are more likely to have particularly complex needs or co-morbidities, which may make them more susceptible to COVID-19 than DSS users who receive non-residential support.

1.14. The Advisory Group noted information on COVID-19 outcomes in DSS recipients that stratified by broad type of residential support (Whaikaha. COVID-19 Outcomes for People Receiving Disability Support Services (DSS). 2023). The Group noted this reported that within the overall DSS user population during most of 2022, outcomes differed substantially for people living in DSS community residences compared with those not receiving residential support.

1.14.1. The Advisory Group noted that in 2022 inclusive, across all ages, but not adjusting for age distributions, a non-residential DSS recipient was 16% less likely to test positive for COVID-19, while those in residential care were 19% more likely to test positive for COVID-19 compared to the rest of the New Zealand population. The Group noted that, without adjusting for age but including those aged >70 years, all DSS recipients were 9% less likely to test positive for COVID-19 than the rest of the general population (Whaikaha. 2023).

1.14.2. The Advisory Group noted the crude non-age standardised risk ratios (RR) across all ages, compared with the rest of the NZ population grouped by all DSS recipients, non-DSS residential, and DSS residential support (Whaikaha. 2023), were as follows:

- All DSS recipients' hospital admissions with COVID-19 RR, compared with the rest of NZ population was 4.2, comprising and weighted by:

- DSS recipients not in DSS residences' hospital admissions with COVID-19 RR: 3.5
- DSS recipients living in DSS residences' hospital admissions with COVID-19 RR: 8

- All DSS recipients' death from COVID-19 or with COVID-19 RR was 13, comprising and weighted by:
  - DSS recipients not in DSS residences' death from or with COVID-19 RR: 7
  - DSS recipients living in DSS residences' death from or with COVID-19 RR: 47

1.14.3. The Group considered that people living in DSS community residences experienced higher levels of COVID-19 support than those DSS users receiving non-residential support, and the rest of the New Zealand population. However, the Group noted the Whaikaha analysis reported only crude rates and did not adjust for the differences in age distributions between the groups (DSS community residence users, non-community resident DSS users, all DSS users and the rest of the population). The Advisory Group considered limitations with the above risk ratios included:

- The lack of age-standardised of incidence rates, where the age structures of DSS residence users and non-residence users differ (median ages 49 years vs. 26 years for DSS community residences and other DSS users respectively) (Ministry of Health. 2019), and both these DSS groups age structures differ from the general population (median age 37.4 years in 2018).
- No adjustment for multiple confounding by pre-existing health conditions and comorbidities, gender, ethnicity, vaccination status, or interactions with the health system affecting case reporting probabilities, etc.

1.15. The Advisory Group considered that the data presented by Ministry of Health - Manatū Hauora illustrated the higher risk of hospitalisation and death from COVID-19 infection for DSS recipients compared to the general population. The Group considered that although the risk is higher in those who are in DSS residential care, this does not diminish the relatively high risk in those DSS recipients not in residential care. The Group considered that this data was of high strength, and medium quality, as it is relevant to the group considered for funding, as well as being local New Zealand data and risk ratios were reproducible by Members.

1.16. The Advisory Group considered that the DSS population was very well-defined, and therefore the numbers of disabled people potentially accessing COVID-19 antivirals is well-defined.

1.16.1. The Group noted that people with Down syndrome already have priority access to COVID-19 antivirals. The Group noted that those who are both DSS recipients and have Down syndrome will not contribute to an increase in people eligible for COVID-19 antivirals. The Group considered that there are an estimated 3000 people with Down syndrome in New Zealand, but was not able to confirm that all were DSS recipients.

1.16.2. The Group noted that those DSS recipients with more than three identified high-risk medical conditions risking severe COVID-19 illness, DSS recipients aged 65-69 years and Māori/Pacific DSS recipients aged 50-69 also already have access to antivirals. The Group considered that total estimates of DSS recipients who are already eligible for COVID-19 antivirals under the current Access Criteria was not able to be confirmed.

1.17. The Advisory Group understood that the epidemiological literature presented RR that range from 1.69 to 5.3 for COVID-19 hospitalisation, when comparing disabled and non-disabled groups. The Group understood that in the epidemiological literature the COVID-19 mortality RR range from 1.0 to 8.2 when comparing disabled and non-disabled groups.

1.18. The Advisory Group understood that pre-pandemic there was an increased risk of death amongst those with disabilities compared to the general population (RR 2.5 to 3.23), and that this RR has increased with the pandemic to between 3.26 and 3.38. The Group noted that this risk varied based on the disability considered. The Group considered that people with Down syndrome were likely at the highest risk of hospitalisation and death, and are already a priority population for access to funded COVID-19 antivirals.

1.19. The Advisory Group noted information on the experiences of disabled people during the COVID-19 lockdowns (Health Quality & Safety Commission. The health care experience of disabled people during COVID-19: Summary of findings from the COVID-19 patient experience survey. 2021), with disabled people more likely to report that they found barriers to accessing care during the 2020 lockdown period.

1.20. The Advisory Group noted the following further international evidence of COVID-19 need in disabled people:

- Brown et al. CMAJ 2022;194:E112-21
- Yuan Y et al. MMWR Morb Mortal Wkly Rep. 2022;71:791-6
- Henderson et al. J Epidemiol Community Health. 2022;76:550-5
- Williamson et al. BMJ. 2021;374:n1592
- Bosworth et al. Lancet Public Health. 2021;6:e817-e825
- So et al. CDC COVID-19 Scientific Brief on Disabilities and Severe COVID-19 outcomes. 2021
- Cuypers et al. Lancet Public Health. 2023;8:e356-e363
- Landes, Finan & Turk. Disabil Health J. 2022;15:101376
- Deal et al. Disabil Health J. 2023;16:101441
- Lunsky et al. Disabil Health J. 2022;15:101174
- Hippisley-Cox et al. BMJ 2021;374:n2244

Health benefit

1.21. The Advisory Group considered that there was no reason to assume that relative reductions, in mortality or hospitalisation risk with antiviral treatment, would be any different in DSS recipients than for those without disability. The Group considered that there is no evidence that disabled people would have worse adverse event rates, or less benefit, than those included in efficacy trials. The Group considered that the relatively low hospitalisation rate in cases receiving DSS support may be confounded by that population having a younger age structure than the rest of the New Zealand population (Ministry of Health. 2019). The apparent lower case event rates may therefore reflect DSS recipients being younger.

1.22. The Advisory Group considered that there were other groups currently funded that have at least the same health need as DSS recipients, as presented and discussed at this meeting.

1.23. The Advisory Group considered that the inclusion of DSS recipients as a priority group in antiviral access criteria may improve health outcomes for Māori with disabilities.

1.24. The Advisory Group considered that there was large disutility for carers of people with disabilities. The Group considered that this disproportionately affected female carers (EQ-5D of 0.64) compared to male carers (EQ-5D of 0.79), as women were more likely to be carers overall (72.8% v 27.2%) (Rico-Blazquez et al. BMC Nursing. 2022;21:69). The Group considered that although there is no direct evidence of benefit for carers and/or family/whānau, benefit is likely to occur as the person they are caring for becomes less

likely to be hospitalised, or die from their COVID-19 infection.

Suitability

1.25. The Advisory Group considered that there may be people in the DSS recipient group who are unable to take tablets, and that these people could use intravenous remdesivir. The Group noted that both currently available oral COVID-19 antivirals are able to be crushed for those with difficulties swallowing tablets (Society of Hospital Pharmacists of Australia (SPHA). Don't Rush to Crush. 4th Edition. Nirmatrelvir with ritonavir. Update December 2022). The Group considered that crushing would not be a solution for everyone unable to take tablets, but could allow access to individuals able to take medicines in this way.

Funding criteria

1.26. The Advisory Group considered that those receiving DSS funding are a well-defined group that are easily identifiable by clinicians, and their hospitalisation and death rates from COVID-19 infection are appreciably higher than in the general population, and therefore they should be included in the criteria as such.

1.27. The Advisory Group reiterated that some DSS recipients (excluding those with Down syndrome) would already have access to antivirals via the current age, ethnicity, and comorbidity criteria. The Group considered the proportion of this group already accessing treatment was unknown but was informed of feedback received by Pharmac staff that disabled people were having difficultly accessing COVID-19 antiviral treatment. The Group considered that the addition of DSS recipients to the funding criteria would allow easier access to COVID-19 antivirals for this group.

1.28. The Advisory Group noted that the inclusion of DSS recipients in the Access Criteria was not a guideline for the treatment of the recommended groups, but would allow easier access for a group that has a clear health need. The Group considered that individual need for antiviral treatment would be the responsibility of prescribers, based on the relevant clinical circumstances of the person they are treating.

Summary for assessment

1.29. The Advisory Group considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for COVID -19 antivirals if they were to be funded in New Zealand for the treatment of mild to moderate COVID-19 for people receiving DSS support. This PICO captures key clinical aspects of the proposal and may be used to frame any future assessment by Pharmac staff. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Disabled people are registered with and receiving Disability Support Services (DSS). Of this group, people with Down syndrome, and/or who have underlying medical conditions (specifically 3+ identified high-risk medical conditions risking severe COVID-19 illness), and/or aged 65+ years and/or Māori or Pacific aged 50+ already have priority access to COVID-19 antivirals.
Intervention	Any funded COVID-19 antiviral: • nirmatrelvir 300 mg with ritonavir 100 mg PO BD for 5 days, • molnupiravir 800 mg PO BD for 5 days • remdesivir 200mg IV on day 1, then 100mg IV q24h for further 2 days for maximum 3 days total
Comparator(s)	Best standard care
Outcome(s)	Reduced hospitalisations for COVID-19 Reduced mortality attributed to COVID-19
Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.	

_____	_____
Chair	Date