Record of the COVID Treatments Advisory Group Meeting held on 12 December 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.

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Attendance

Present
Chair – Dr Jane Thomas
Dr Ajay Makal
Professor Brian Anderson
Eamon Duffy
Dr Gillian Hood
Dr Liza Lack (PTAC member - observer)
Associate Professor Marius Rademaker
Dr Nigel Raymond
Dr Robyn Manuel
Professor Stephen Munn

Apologies
Dr Graham Mills
Dr Justin Travers
Dr Kerry Benson-Cooper
Dr Tim Cutfield

1. Long COVID

Application

1.1. The Advisory Group reviewed further information presented by Pharmac staff relating to Long COVID.

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 **deferred** its recommendation on use of COVID-19 treatments for Long COVID.

1.4. The Advisory Group considered further evidence for the efficacy of treatments in this setting is required before making a recommendation for funding.

Discussion

Māori impact

1.5. The Advisory Group discussed the impact of funding antiviral treatments for the treatment of Long COVID on Pharmac's Hauora Arotahi (Māori health areas of focus) and Māori health outcomes. The Group noted its previous considerations of local data suggesting that Long COVID symptoms in New Zealand may occur at similar frequency in Māori and non-Māori. The Group acknowledged that Long COVID is a debilitating condition for those experiencing it, as well as their family and whānau.

Background

1.6. The Advisory Group noted its previous considerations of treatments of Long COVID from May 2023. The Group noted that at this meeting its recommendation was deferred for further evidence to become available for the use of antivirals for treating and preventing Long COVID. The Group noted its previous consideration that people with Long COVID experience a decreased health-related quality of life and increased risk of death, and that the variable definition of Long COVID and breadth of symptoms was similar to chronic fatigue syndrome. The Group noted that the evidence to support the use of pharmaceutical treatments at the time of COVID-19 infection may result in lower incidence of Long COVID, but this evidence is limited, and the evidence to support the use of currently available treatments to treat established Long COVID symptoms is not yet available.

Health need

1.7. The Advisory Group noted again that there are a range of names for Long COVID with differing definitions. The Group considered that Long COVID is an umbrella term commonly used by the public and patient groups, with post-COVID-19 syndrome or condition(s) or post-acute symptoms of COVID-19 or sequelae of SARS-CoV-2 infection having more strict definitions. The Group noted that the international definitions from National Institute of Clinical Excellence (NICE), World Health Organisation (WHO) and Centre for Disease Control (CDC) had different definitions with most defining a time period for extended (i.e., more than 1 month) symptoms that are otherwise unexplained by an alternative diagnosis. The Group noted that the definition varied between studies and a number of studies did not use any definition (Chaichana et al. JAMA Netw Open. 2023;6: e235856).

1.8. The Advisory Group noted a prospective observational longitudinal cohort study from the RECOVER adult cohort that developed a weighted score for

symptoms to aid with positive and indeterminate diagnosis of Long COVID (post-acute sequelae of SARS-COV-2 (PASC)) (Thaweethai et al; RECOVER Consortium. JAMA. 2023;329:1934-46). The Group noted that 10% of participants in the study were classified as PASC positive at six months when using the score. The Group noted that common symptoms were fatigue, post-exertional malaise, brain fog and dizziness, with over 60% of PASC-positive participants experiencing these symptoms.

1.9. The Advisory Group noted its previous consideration of chronic fatigue syndrome (CFS) and considered that there is overlap with symptoms in people experiencing Long COVID and those experiencing CFS. The Group considered that both conditions share similar symptoms and biological abnormalities and noted suggestions that this leads to metabolic re-programming and behavioural changes to reduce energy expenditure on non-essential physiological activities (Komaroff & Lipkin. Front Med (Lausanne). 2023:10:1187163). The Group considered evidence of elevated autoantibodies in people with Long COVID that may indicate that a response injury from infection, eg vascular injury that requires time to recover from after the acute phase of infection is over. The Group noted that participants with Long COVID have autoantibodies affecting the vascular system and autonomic nervous system (Seibert et al. Autoimmun Rev. 2023;22:103445).

Health benefit

1.10. The Advisory Group considered that meaningful endpoints for assessment of treatments for Long COVID include:

1.10.1. Major clinical features: eg fatigue, post-exertional malaise, brain fog. The Group considered that patient-centred qualitative measures of these symptoms are one form of likely useful study endpoint.

1.10.2. Disability: impact on work capacity or other functional dimensions. The Group considered these also related to quality of life of the person.

1.11. The Advisory Group considered that quantifiable objective measures including biomarkers or other physiological measures were not well identified or validated for Long COVID.

1.12. The Advisory Group noted that at this time, there is insufficient evidence currently available for therapeutics considered to be disease modifying or reduction in symptoms. The Group noted that this is similar to other indications with similarly disparate symptom profiles eg CFS or other post-infectious fatigue. The Group noted that there are controlled clinical trials in progress evaluating treatments for Long COVID but these have not yet been completed.

1.13. The Advisory Group noted a cohort study from the USA using data from Veteran's Affairs Administration (*N*=281,793) comparing people who had at least one risk factor for progression to severe COVID-19 illness compared with those that did not. The Group noted that it was reported that use of nirmatrelvir in the acute phase of COVID-19 infection was associated with reduced risk of post COVID-19 condition (PCC), sequelae in various organ systems, hospitalisation and death. The Group noted that this effect was reported regardless of COVID-19 vaccination status (unvaccinated, vaccinated or boosted) or whether it was a primary SARS-CoV-2 infection or reinfection (Xie et al. JAMA Intern Med. 2023;183:554-564).

1.14. The Advisory Group noted the STOP-PASC trial evaluating nirmatrelvir with ritonavir for 15 days compared to placebo in adults (>18 years) in the

community. The Group noted the primary outcome was a symptoms severity scale score at week 10. The Group noted that at the time of review this trial had not been published (ClinicalTrials.gov identifier: NCT05576662).

1.15. The Advisory Group noted the RECOVER project was evaluating Long COVID interventions in the US including the RECOVER-Vital randomised control trial using a longer duration of nirmatrelvir with ritonavir during the acute phase of COVID-19 infection and assessing the impact on Long COVID.

1.16. The Advisory Group noted a meta-analysis of observational studies evaluating COVID-19 vaccination efficacy in preventing Long COVID (Watanabe et al. Vaccine. 2023;41:1783-90). The Group noted that it was reported that having two doses of vaccine (compared to no doses or one dose) was protective against Long COVID. The Group noted that this analysis also reported that amongst those with ongoing long COVID symptoms, symptomatic improvement was observed in 20.3% of participants two to six months after COVID-19 vaccination, 20.5% experienced symptomatic worsening (often transient during two to seven days) and 54.4% did not report symptomatic change.

1.17. The Advisory Group again noted the RECOVER observational study from the US assessing the development of a definition of PASC had stratified the cohort by vaccination status (vaccinated versus unvaccinated), with a higher proportion of the unvaccinated cohort experiencing Long COVID (post-acute symptoms with pre-Omicron variant(s): 37% vaccinated vs 31% vaccinated; post-acute symptoms with Omicron variant: 22% vs 16%) (Thaweethai et al. 2023).

1.18. The Advisory Group noted a systematic review that included five studies assessing vaccination before and after COVID-19 infection or after Long COVID diagnosis. The Group noted the studies reported odds ratios ranging from 0.38 to 0.91 (Byambasuren et al. BMJ Med. 2023;2:e000385). The Group noted that the authors concluded that there was high heterogeneity between studies, precluding any meaningful meta-analysis, and the studies failed to adjust for potential confounders, such as other protective behaviours and missing data, thus increasing the risk of bias and decreasing the certainty of evidence to low.

1.19. The Advisory Group considered that interpretation of these studies is difficult given the heterogeneity and potential confounding. The Group considered that there may be a signal from the evidence that vaccination does reduce the risk of Long COVID. The Group considered that it is still important for people to get vaccinated against COVID-19 to protect against severe COVID-19.

1.20. The Advisory Group considered that in order to evaluate and make a recommendation for funding, further evidence would be required to support the use of therapeutics to prevent or treat Long COVID, as required with all standard funding applications assessed by Pharmac, including randomised control trials, meta-analyses and systematic reviews with additional observational evidence. The Group noted that internationally there are no funded or recommended pharmaceutical treatments for Long COVID.

1.21. The Advisory Group considered that treatment of people with Long COVID is currently best supportive care in the form of symptomatic pharmacological treatments eg sleep aids or pain relief as required or non-pharmacological therapies as decided by a clinician and person experiencing Long COVID, as outlined in the guideline from the Ministry of Health - Manatū Hauora. The Group acknowledged that Long COVID is a debilitating condition that is not well understood and with very few evidence-based helpful treatments.

2. COVID-19 antivirals cost-effectiveness discussion

Application

2.1. The Advisory Group reviewed the information provided by Pharmac staff relating to cost-effectiveness of COVID-19 antivirals.

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

Recommendation

2.3. The Advisory Group **recommended** the following changes be considered to the access criteria for COVID-19 treatments based on preliminary cost-effectiveness modelling of undertaken by Pharmac:

- Increase age of access in criterion 4.1 from 65 years or over to people aged 70 years or over
- Increase age of access in criterion 4.2 from 50 years or over for People of Māori or Pacific ethnicity to aged 55 years or over; or
- Increase age of access in criterion 4.3 from 50 years or over to aged 55 years or over,

2.4. The Advisory Group considered the following in making these recommendations:

- The risk of severe outcomes (hospitalisation and death) of each group
- The Omicron variant of SARS-CoV-2 has a reduced risk of severe outcomes in all people compared to earlier variants
- The list of groups discussed is not exhaustive and not all groups included in the current access criteria were able to be discussed.

2.5. The Advisory Group **considered** additional changes that could be made to the access criteria could include 1) increasing the number of high risk factors for severe illness required to access COVID-19 antivirals and 2) using age restrictions in other clinical criteria.

2.6. The Advisory Group **considered** that cost effectiveness analysis would need to be undertaken by Pharmac on any further changes considered to the access criteria.

2.7. The Group **noted** that additional changes may need to be made to the access criteria to reflect the budget available and the price of COVID-19 treatments from 1 July 2024.

Discussion

Māori impacts

2.8. The Advisory Group discussed the impact of funding COVID-19 antivirals for treatment of COVID-19 on Māori health areas of focus and Māori health outcomes. The Group considered that an increased risk of severe COVID-19 outcomes (hospitalisation or death) is well supported by local data for Māori. The Group considered that it was appropriate to maintain a difference in age to reflect the difference in risk between Māori and non-Māori, non-Pacific peoples. The Group considered that the eligibility age for Māori by age alone be increased by five years to 55 years and over, which is the same sized increase as for the recommended 70 years and over for any ethnic group including non-Māori, non-Pacific peoples.

Impact on Pacific peoples, disabled people, tāngata whaikaha Māori, and other people who have been underserved by the health system

2.9. The Advisory Group discussed the impact of funding of COVID-19 antivirals for treatment of COVID-19 on Pacific, disabled, and underserved populations. The Group considered that an increased risk of severe COVID-19 outcomes (hospitalisation or death) is supported by local data for Pacific peoples and DSS recipients.

2.10. The Group considered that it was appropriate to maintain a difference in age to reflect the difference in risk between Pacific peoples and non-Māori, non-Pacific peoples. The Group considered that the eligibility age for Pacific peoples by age alone be increased by five years to 55 years and over, which is the same sized increase as for the recommended 70 years and over for any ethnic group including non-Māori, non-Pacific peoples.

Background

2.11. The Advisory Group noted that the current access criteria for funded COVID-19 antivirals includes the following groups:

- People aged 65 years or over; or
- People of Māori or Pacific ethnicity AND aged 50 years or over; or
- People aged 50 years or over AND has not completed a primary course (two vaccinations) of COVID-19 vaccination; or
- People who are immunocompromised (as defined here) and not expected to reliably mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection, regardless of vaccination status; or
- People who have had a previous admission to Critical Care or High Dependency care directly as a result of COVID-19; or
- People with Down syndrome; or
- People with sickle cell disease; or
- People who receive Disability Support Services funded by Whaikaha - Ministry of Disabled People (previously Ministry of Health); or
- People who have pre-existing high risk due to a health condition and needs direct family, whānau or external disability care most days; or
- People who have pre-existing severe frailty and/or vulnerability due to one or more severe health conditions ie severe or very advanced disease including, but not limited to, severe neurological, cardiovascular, renal and respiratory conditions; or
- People who have any combination of three or more high-risk factors for severe illness from COVID-19 (as defined here).

2.12. The Advisory Group noted an estimate from the World Health Organization (WHO), which suggested that a cost per quality adjusted life year (QALY) of less than a country's per capita GDP was considered very cost-effective. Members noted that this would correspond to a cost-per-QALY of approximately $76,000 (or 13 QALYs per $1 million). Members considered this was useful to gauge groups who may benefit more from COVID antivirals. Members noted that Pharmac does not use a cost-effectiveness threshold, and that other estimates of what is considered good value in the wider health system can differ markedly from this particular method and metric.

2.13. The Advisory Group noted previous feedback on the complexity of the access criteria and prescribers' difficulty using them. The Committee considered that it was preferred that the criteria be simpler with high-risk groups with consistent age restrictions where possible.

Health need

2.14. The Advisory Group considered that the absolute risk of hospitalisation for COVID-19 has been around 0.8% in the known infected population of New Zealand. The Group considered that those with a known infection were people with COVID-19 confirmed by a rapid antigen test (RAT) or highly likely due to household or other close contact to a confirmed case. The Group considered that the number-needed-to-treat (NNT) if all infected people were given COVID-19 antivirals would be 125 people to prevent one COVID-19 hospitalisation.

Age

2.15. The Advisory Group considered that there was a marked age gradient for COVID-19 severity, with people over 70 years of age at particularly high risk of severe outcomes from COVID-19 infection (ie COVID-19 attributed hospitalisation or death). The Group noted that most dispensing of COVID-19 antiviral courses occur in people aged 65 years and older. The Group noted that for anyone aged 70 years and older, the odd ratio of COVID-19 hospitalisation was 13.5 (95% confidence interval (CI) 10.3, 17.6), as estimated from early Omicron-era case and hospitalisation data from Northern region hospitals (which the group had considered in May 2022). The Group considered that the risk of severe COVID-19 outcomes is strongly associated with age and that in general, the risk of severe outcomes increases with increasing age. The Group considered that people younger than 70 years who are vaccinated are at substantially lower risk of severe COVID-19 outcomes.

Māori and Pacific peoples

2.16. The Advisory Group considered that compared to non-Māori, non-Pacific peoples, Māori and Pacific peoples have a higher risk of hospitalisation or death at the same age. The Group considered that it was appropriate to maintain a difference in the age of eligibility to reflect the difference in risk between Māori and Pacific peoples and non-Māori, non-Pacific peoples. Members considered it was appropriate to retain the same 15-year age difference between Māori and Pacific and non-Māori, non-Pacific, to retain consistency with previous criteria, and that the age be therefore increased by five years to 55 years and over. Members noted that Māori and Pacific people ages 55 and over had a lower level of risk than some other groups, such as people aged 70 and over, but that it was appropriate to retain a significantly lower age for Māori and Pacific peoples to promote equitable access.

People not fully vaccinated

2.17. The Advisory Group considered people who were not fully vaccinated to be people who had not received two primary doses of COVID-19 vaccine (three primary doses for immunocompromised people). The Group considered that people who have received no vaccinations are at greatest risk of severe outcomes compared to people who are fully vaccinated. The Group considered that this is a small group of people that have not had a vaccination or COVID-19 infection that would have no immunity. The Group noted the analysis from the Northern region hospitals presented in May 2022 reported that there was a 3.5-fold increase in the risk of hospitalisation in unvaccinated people and a threefold increase in partially vaccinated people. The Group considered that people who had not received a booster (≥4 doses for non-

immunocompromised people) were likely not at material greater risk than people who had. The Group considered that the initial vaccination course of two doses and a booster conferred more protection than additional boosters. The Group considered that the under-vaccinated group would be small but still at risk of severe outcomes. The Group considered that eligibility for COVID-19 antivirals should not be determined based on time since vaccination or time since booster dose, given the significant complexity this could entail. The Group considered this would also encompass people outside of the higher-risk patient groups.

People with solid organ transplants, immunocompromise or cancer

2.18. The Advisory Group was made aware of a French retrospective cohort study comprising 60,456 solid organ transplant recipients receiving immunosuppressive drugs, which reported that 11.4% of people were hospitalised for COVID-19 of the 2.4 years measured (Kolla et al. JAMA Netw Open. 2023;6:e2342006). The Group noted that when istratified by age, COVID-19 hospitalisation risk increased modestly with older age, but the age gradient for hospitalisation risk was less marked than the general population. There was no reporting in the study on the incidence of COVID-19 infection and differences between groups, nor adjustment for differences in COVID-19 attack rates and timing.

2.19. The Group considered that among people who have received solid organ transplants, there was unlikely to be a material age gradient for severe outcomes, as older people are less likely to be treated with high dose immunosuppressives compared to younger people, particularly children. The Group considered that all solid organ transplant recipients would be at high risk of severe outcomes, and that therefore access in this group should not be restricted according to age.

2.20. The Advisory Group was made aware of a US population-based retrospective cross-sectional study of 34,350 people with cancer and 628,156 people without cancer who died from COVID-19 during when wild type (ancestral), Delta and early Omicron variants were circulating (Potter et al. JAMA Oncol. 2023;9:1417-22). The Group noted that there was no adjustment in the study for different COVID-19 attack rates across age groups and prevalent variant time periods.

2.21. The Advisory Group considered that while people with cancer are commonly immunocompromised, particularly during treatment, that as people with cancer increase in age, the risk of death from COVID-19 also increases. The Group considered that this differs from people who have solid organ transplants or are immunocompromised as a result of other conditions or treatments.

2.22. The Advisory Group considered that for people using most monoclonal antibodies or ciclosporin, or with solid tumours, the risk is lower compared to those using B-cell depleting therapies eg rituximab or mycophenolate. The Group considered that people using ciclosporin or monoclonal antibodies do not need the same access as people using B-cell depleting therapies. The Group considered that it was difficult to estimate the risk for people with HIV as most are well managed on anti-retroviral medications. The Group considered that these individuals should not be considered significantly immunocompromised from the perspective of access to COVID-19 antivirals. The Group considered that those who have not had cancer treatment for 10 years or longer were likely not at materially increased risk, and should not have access to funded antivirals as a part of this group.

2.23. The Advisory Group noted that Pharmac's current list of severely immunocompromised conditions for access to COVID-19 antiviral treatments includes *'is considered otherwise severely immunocompromised and had been given or would have been given a third dose in their primary course of COVID-19 vaccine'.* The Advisory Group considered that this aspect of the criteria was no longer required as people within this group at high risk of poor outcomes from COVID-19 would be included in other aspects of the criteria.

2.24. The Advisory Group considered that people who have complex medications that are not able to be stopped during COVID-19 antiviral treatment, are often hospitalised for remdesivir treatment. The Group noted that this applies particularly to those with solid organ transplants.

People with Down syndrome

2.25. The Advisory Group noted an international survey for clinicians and caregivers of people with Down syndrome that reported that mortality risk rapidly increased after age 40 even after adjusting for known risk factors for COVID-19 mortality (Huls et al. EClinicalMedicine. 2021:33:100769). The Group considered that people with Down syndrome may have increases in risk associated with age at rates similar to the general population, though those with Down syndrome would have significantly increased risk of severe outcomes at a younger age than those in the general population.

2.26. The Advisory Group considered that people with Down syndrome have a significantly lower life expectancy compared to people without Down syndrome, and that including age restrictions above the age of 40 to 50 years could result in a large proportion of people with Down syndrome not having access to COVID-19 antivirals. The Group therefore considered that the other age limits in the criteria specified for other groups would not be appropriate for people with Down syndrome. The Group however considered that an age restriction of 40 years would be appropriate for people with Down syndrome, but more work is required to validate if any age restriction is required.

2.27. The Advisory Group noted a UK population-based cohort study had identified people with Down syndrome are at a much higher risk of death and hospitalisation related to COVID-19 than people without Down syndrome. The Group noted that the authors considered that this increased risk reflected a genetic predisposition and increased susceptibility to infection (Hippisley-Cox et al. BMJ 2021;374:n2244).

2.28. The Advisory Group noted that people with Down syndrome would be supported by Disability Support Services (DSS) from Whaikaha – Ministry of Disabled People. The Group noted an analysis from Whaikaha – Ministry of Disabled People reported a higher risk of hospitalisation and death from COVID-19 for DSS recipients (Whaikaha. COVID19 Outcomes for People Receiving Disability Support Services (DSS). 2023). The Group considered that any restrictions for people with Down syndrome should also apply for DSS recipients.

People with sickle cell disease

2.29. The Advisory Group considered that it was unclear whether there was a risk of severe outcomes associated with COVID-19. The Group considered that people with sickle cell disease are a small group comprising mostly young people or children, and that there was limited information to assess how risk of severe COVID-19 differed by age. The Group considered that people with sickle cell disease and COVID-19 infection are at risk of sickling and thrombotic events that increase the risk of hospitalisation or death from COVID-19, compared to those without sickle cell disease. The Group

considered that it would pragmatic, given the limited evidence for those with sickle cell disease, to not have age restrictions for these people, so that anyone with sickle cell disease could access antiviral treatments.

People with disabilities

2.30. The Advisory Group noted a retrospective cohort study from Canada reported an increased risk of any-cause hospitalisation for people with various disabilities who had COVID-19. The Group noted that among 1279 people admitted to hospital with (not necessarily for) COVID-19, 22.3% had a disability. The Group noted that reported relative risks of death or admission to ICU were not statistically significant when adjusted for age, sex and residence in a long-term care facility, medical comorbidities, predicted risk of death upon presentation to hospital, neighbourhood income, and people who identified as an ethnic minority. The Group noted that disabled people who were admitted with COVID-19 had longer all-cause hospital stays (median 13.9 v. 7.8 days) and for those 64 years and under more readmissions (17.6% v 7.9%) compared to people who were not disabled, and this effect persisted after adjusting as described above. (Brown et al. CMAJ. 2022; 194(4): E112–21). The Group considered that overall people who are disabled have risk likely similar to that of the general population. The Group noted that this study was conducted in a pre-Omicron variant era.

2.31. The Advisory Group noted the Whaikaha - Ministry of Disabled People analysis for DSS recipients as reviewed at its May 2023 meeting. The Group again considered that DSS recipients had an increased risk of hospitalisation and death from COVID-19 disease.

People who are frail and/or have high risk medical conditions

2.32. The Advisory Group noted a systematic review and meta-analysis on the predictive value of frailty in case fatalities of people hospitalised with COVID-19 reported pooled estimates of frailty in people hospitalised with COVID-19 of 51.4% (95% CI 39.9–62.9%) (Zou et al. Ann Transl Med. 2022;10:166). The Group noted that the 21 studies included in the systemic review were heterogenous in the measurement of outcomes.

2.33. The Advisory Group considered that definitions of frailty are broad and can be challenging to understand in clinical practice. The Group noted that there are many medical conditions that could result in someone being considered frail and scoring systems to identify these people. The Group considered that this criterion was intended to target the population that is similar to older people in terms of physical frailty. The Group considered that it was appropriate to restrict COVID-19 antiviral access to people who are considered frail to those aged 50 years old and over, and where frailty is due to medical conditions as determined by their medical practitioner.

2.34. The Advisory Group considered there would be value in retaining a criterion for those people with multiple high-risk conditions for severe COVID-19. However, it was not certain how many conditions should be included, or if there should be an age restriction for access. The Group recommended that further modelling be done to gauge the cost-effectiveness of COVID-19 antivirals for this subgroup.

Health benefit

2.35. The Advisory Group noted that the treatment effects of COVID-19 antivirals were based on randomised controlled trials conducted in earlier variant eras eg ancestral SARS-CoV-2 or the Delta variant, in unvaccinated populations. The Group considered that the reported benefits of COVID-19 antivirals may

not reflect the actual benefit in the current New Zealand context, given that many people have received at least a primary course of COVID-19 vaccination and a booster and/or had acquired COVID-19 infection, alongside the reduction in virulence of the circulating Omicron variants.

2.36. The Advisory Group considered that it was important that the benefit of treatment with COVID-19 antivirals is balanced against the risk of harm, and that for groups with low risk of COVID-19 attributed hospitalisation or death the potential harm of treatment may outweigh the benefit of reduction in risk of hospitalisation or death.