PHARMAC
TE PĀTAKA WHAIORANGA

Specialist Advisory Committees
Objective advice to Pharmac
www.pharmac.govt.nz

Record of the Immunisation Advisory Committee Meeting held on 6 November 2025

Immunisation Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

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

The Immunisation Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(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.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

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

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

Table of Contents

1. Attendance

Present
Stephen Munn
Christine Pihema
Edwin Reynolds
Elizabeth Wilson
Erasmus Smit
Helen Evans
James Ussher
Karen Hoare
Lance Jennings
Nikki Turner
Osman Mansoor
Tony Walls
Stuart Dalziel

Apologies
David Murdoch
Sean Hanna

Respiratory Advisory Committee members for part of the meeting
Betty Poot
Neil Whittaker

Tim Christmas
David McNamara
Stuart Dalziel

Apologies
Greg Frazer
Justin Travers
Matthew Dawes
Matthew Strother

Observers
Faith Woodcock
Janet Hayward
Richard Jaine

2. Summary of recommendations

#	Pharmaceutical and Indication	Recommendation
8.3	Pneumococcal 20-valent conjugate vaccine for the prevention of invasive pneumococcal disease (IPD) for all children up to 59 months of age, within the context of vaccines and immunisation subject to criteria	High Priority
8.5	Pneumococcal 20-valent conjugate vaccine for the prevention of invasive pneumococcal disease (IPD) for people under the age of 18 years with eligible conditions, within the context of vaccines and immunisation subject to criteria	High Priority
8.7	Pneumococcal 20-valent conjugate vaccine for the prevention of invasive pneumococcal disease (IPD) for people 18 years and older with eligible conditions, within the context of vaccines and immunisation subject to criteria	High Priority
8.9	Pneumococcal 20-valent conjugate vaccine for the prevention of invasive pneumococcal disease for all adults aged 65 years and older, within the context of vaccines and immunisation	High Priority
11.3	Nirsevimab for all infants at birth or in their first RSV season, and for high-risk infants entering their second RSV season, within the context of vaccines and immunisation subject to criteria	High Priority
12.3	RSVPreF3 Vaccine (Arexvy) for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older, within the context of vaccines and immunisation subject to criteria	Medium Priority
12.4	RSVPreF3 Vaccine (Arexvy) for for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in high-risk adults aged 60 to 74 years with eligible comorbidities and all adults 75	High Priority

	years of age and older, within the context of vaccines and immunisation subject to criteria	

3. The role of Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Immunisation Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

3.3. The Immunisation Advisory Committee is a Specialist Advisory Committee of Pharmac. The Immunisation Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Immunisation Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for Immunisation that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for Immunisation that differ from the Immunisation Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

3.4. Pharmac considers the recommendations provided by both the Immunisation Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for Immunisation.

4. Welcome and introduction

4.1. The chair welcomed the Committee with a karakia followed by whakawhanaungatanga.

5. Pharmac update

5.1. The Committee noted the Pharmac update.

5.2. Pharmac staff provided an update on funding applications received over the last quarter and the July 2025 decisions regarding ongoing supply of COVID-19 vaccines and COVID-19 antivirals.
Pharmac staff also provided an update on measles and vaccine supply.

5.3. Pharmac staff provided an update on the proposal to decline inactive funding applications.

5.4. The Committee acknowledged the recent changes in Pharmac kaimahi and ongoing leadership and strategic changes, including the new Chief Executive who started at Pharmac in mid-September and the recent release of the 2025/2026 Letter of Expectations.

5.5. The Committee noted an update about the organisation reset programme and acknowledged that more information can be found on the Pharmac Website.

5.6. The Committee noted the following updates to the record processes:

5.6.1. 30-day provisional recommendation trial update.

5.6.2. The Committee noted the removal of second committee reviews, with targeted reviews to be used as required, and supported the use of direct engagement with Discussion Leads to resolve outstanding issues.

5.6.3. The Committee noted the proposed publishing of agenda summaries for all Advisory Committee meetings.

6. Record of previous Immunisation Advisory Committee meeting held Thursday, June 26, 2025

6.1. The Committee reviewed and accepted the record of the Immunisation Advisory Committee meeting held on 26 June 2025.

7. Matters Arising: Fluad influenza vaccine for people at least 65 years of age and Flucelvax influenza vaccine for people at high risk aged 6 months to under 65 years of age

Discussion

7.1. The Committee noted that PTAC and the Immunisation Advisory Committee have considered applications for several different influenza vaccines on multiple occasions. At the April 2025 meeting the Committee reviewed a resubmission application (data update) from Seqirus for the listing of Fluad - trivalent adjuvanted inactivated influenza vaccine (aTIV) in the Pharmaceutical Schedule as the seasonal vaccination for people aged 65 years and over. The Committee recommended the listing of Fluad aTIV with high priority. The Committee also reviewed a resubmission application from Seqirus at the same meeting for the listing of Flucelvax inactivated trivalent influenza vaccine prepared in cell cultures (TIVc), as the seasonal influenza vaccination for eligible people aged 6 months to under 65 years. The Committee recommended listing Flucelvax TIVc with high priority.

7.2. The Committee noted its previous view (April 2025 meeting) around the limited evidence for a reduction in mortality benefit from influenza complications. The Committee considered that vaccine efficacy against influenza mortality is difficult to assess due to deaths in elderly people often being related to complex health events and underlying conditions, and not easily attributable to a single cause. For both influenza vaccines, the Committee had previously considered that no data had been provided to support claims that the vaccines would reduce mortality further than standard influenza vaccines, and that Pharmac should exclude mortality from all modelled scenarios in its economic assessment where standard influenza vaccine is the comparator.

7.3. The Committee noted correspondence and further evidence from Seqirus that has requested reconsideration of the exclusion of mortality benefit in the economic modelling for these vaccines.

7.4. The Committee noted that a number of international National Immunisation Technology Advisory Groups (NITAGs) included a reduction in mortality benefit in their economic modelling of enhanced influenza vaccines, including Germany, Netherlands, Canada, Ireland, and Australia. The Committee noted that some of the analyses were on adjuvanted vaccines, and some were on high-dose vaccines, but none were on cell-based vaccines.

7.5. The Committee noted the following retrospective cohort studies (all from Italy):

- Bellino et al., Human Vaccines & Immunotherapeutics, 2019; 16(2), 301–312.

- Fabiani et al., Expert Review of Vaccines, 2020; 19(5), 479–489.
- Acuti Martellucci et al., Vaccines. 2025; 13(3):309.

7.6. The Committee noted. Bellino et al. assessed the effectiveness of an influenza vaccine in preventing deaths and hospital admissions compared with no vaccination in over 83,000 people aged from 65 years over three influenza seasons (2014-2017). The Committee noted that the MF59-adjuvanted trivalent-inactivated influenza vaccine was the primary vaccine administered, with approximately 50% coverage. The study reported a reduction of risk of death compared with no vaccination by 33%, 37%, and 39% ($p < 0.001$) during influenza seasons of 2014/15, 2015/16, and 2016/17. In the pooled analysis, adjusted incidence rate ratio of death and of influenza-related hospitalisations for vaccinated compared to unvaccinated was 0.63 [95% CI: 0.58–0.69, $p < 0.001$] and 0.86 (95% CI: 0.81–0.91, $p < 0.001$), respectively. The Committee considered that this study demonstrated that influenza vaccination is effective compared with no vaccination in preventing death and hospitalisation.

7.7. The Committee noted Fabiani et al. estimated influenza vaccine effectiveness (VE) in preventing influenza-related deaths and hospitalisations in 1,249,424 people aged from 65 years during the 2016-2017 influenza season, with a vaccination rate of 50.9%. Estimated VE was 26% (95%CI: 19 to 33) for preventing influenza-related deaths and 13% (95%CI: 10 to 16) for preventing influenza-related hospitalisations, each compared with no vaccination. Among people aged from 75 years, MF59-adjuvanted vaccine was more effective in preventing influenza-related hospitalisations and deaths compared with the other types of vaccines (MF59-adjuvanted VE in preventing deaths or hospitalization of 22% (95% CI: 18-26); other vaccines combined VE of 18% (95% CI: 15-21), $p = 0.044$). The study did not observe significant differences in vaccine effectiveness according to vaccine type and there was no outcome measuring death alone. The Committee considered that this study demonstrated that MF59-adjuvanted influenza vaccine is more effective than standard non-adjuvanted influenza vaccines in preventing death and hospitalisation in people aged at least 75 years.

7.8. The Committee noted Acuti Martellucci et al. was designed to evaluate the VE of quadrivalent influenza vaccines, offered alone or in combination with other recommended vaccinations, in 105,527 people aged from 60 years during the 2023-2024 influenza season. The vaccination rate was 43.9%, and the majority (71.7%) received an adjuvanted influenza vaccine. The study reported that 3,188 (3.0%) died of any cause and 1,047 (1.0%) were hospitalised for influenza and/or pneumonia during follow-up. Multivariable analyses reported that compared with no vaccination, those who received an influenza vaccine showed almost half the likelihood of death (adjusted HR: 0.52; 95%CI: 0.49–0.56) and hospitalisation (adjusted HR: 0.55; 95%CI: 0.48–0.62), regardless of the gender and age group. Those who received a MF59-adjuvanted vaccine had a 52% lower risk of death compared with no vaccination (adjusted HR: 0.48; 95% CI: 0.45–0.52; $p < 0.001$). Among vaccinated individuals, MF59-adjuvanted vaccine showed significantly lower mortality than the high-dose, non-adjuvanted vaccine (adjusted HR: 1.34; 95% CI: 1.18–1.51) but similar to non-adjuvanted standard dose (likely due to underpowering of the study). Among vaccinated individuals, the cell-based vaccine was reported to have no statistically significant difference compared with adjuvanted vaccine (adjusted HR: 0.98 95% CI 0.76–1.26; $p=0.872$); however the Committee considered the study was underpowered to compare these two vaccines. The Committee considered that this study demonstrated that the MF59-adjuvanted influenza vaccine is likely to be more effective in preventing death than a high-dose influenza vaccine.

7.9. The Committee noted that there can be confounding factors with observational studies, including access to different types of vaccines. The Committee considered that the evidence was of lower quality.

7.10. The Committee noted Veroniki et al., BMJ Evid Based Med. 2024 Jul 23;29(4):239-254.was a meta-analysis of randomised controlled trials of influenza vaccines in people aged 60 or more. The Committee noted two studies comparing adjuvanted vaccines against standard dose vaccines, that reported a combined odds ratio that favoured standard doses but was not statistically significant (IIV3-Adj vs IIV3-SD: OR: 1.09 (0.73 to 1.62). The total participants across those two studies was 7,577 which the Committee considered was underpowered to detect a mortality difference between two vaccines.

7.11. The Committee noted a randomised controlled trial Frey et al. Vaccine 2014; 32(39):5027-34. of aTIV compared with TIV in 6961 people aged from 65 years who were monitored up to day 366. The study reported 98 deaths: 1.5% in aTIV and 1.3% in TIV (hazard ratio 1.13 (95% CI 0.76-1.68). Seven deaths were recorded as a consequence of influenza (3 in aTIV and 4 in TIV). The Committee considered that the study was underpowered to be able to draw conclusions on the results.

7.12. The Committee noted that the following studies on the efficacy of standard-dose (SD) compared with high-dose (HD) influenza vaccines:

- Christensen et al. Circ Cardiovasc Qual Outcomes. 2025;18(2):e011496
- Shay et al. The Journal of Infectious Diseases. 2017; 215(4): 510–517.
- Young-Xu et al. Euro Surveill. 2020; 25(19):1900401

7.13. The Committee noted Christensen et al. was an open-label randomised feasibility trial comparing a HD vaccine against a SD vaccine in 12,477 people aged 65-79 years, both with and without cardiovascular disease. The study reported a 48.9% reduction in all-cause mortality with the HD vaccine (hazard ratio 0.51 (0.30-0.86, p=0.49), regardless of chronic cardiovascular disease.

7.14. The Committee noted Shay et al. was a prospective study comparing HD vaccines to SD vaccines over two influenza seasons in US Medicare beneficiaries aged 65 years and over. Rates of post-influenza death were 0.028 and 0.038/10,000 person-weeks in HD and SD recipients, respectively. The comparative effectiveness of HD in preventing post-influenza death was 24.0% (95% CI: 0.6%–42%). The Committee noted that there was seasonal variation. In 2012-2013, HD vaccines were 36.4% (95% CI, 9.0%–56%) more effective in reducing mortality. In 2013–2014, HD vaccines were 2.5% (95% CI, –47% to 35%) more effective in reducing mortality.

7.15. The Committee noted Young-Xu et al. was a prospective study on the effectiveness of HD influenza vaccines compared with SD vaccines in preventing influenza/pneumonia-associated and cardiorespiratory mortality. The study reported a statistically significant decrease in influenza/pneumonia-associated mortality with HD over SD vaccines. The pooled adjusted VE estimate of HD compared with SD during the high influenza periods was 42% (95%CI: 24-59) against influenza/pneumonia-associated mortality and 27% (95% CI: 23-32) against cardiorespiratory mortality.

7.16. The Committee considered that these studies demonstrated a reduction in all-cause and influenza-related mortality with HD influenza vaccine compared with SD influenza vaccine. The Committee considered that, based on Acuti Martellucci et al. study, adjuvanted influenza vaccines are likely to be at least as effective as HD vaccines.

7.17. The Committee considered that there is sufficient evidence to indicate that there is likely to be a mortality benefit with adjuvanted influenza vaccines compared with non-adjuvanted vaccines in people aged 65 years and over. The Committee

recommended that, despite it being difficult to assess the magnitude of the benefit, a mortality benefit be included in the economic modelling of adjuvanted influenza vaccines.

7.18. The Committee considered it is reasonable to assume that there would also be a mortality benefit with TIVc compared with SD influenza vaccine based on the principle that cell-based vaccines, as a new-generation vaccine product, would have similar advantages as other new-generation vaccine products like adjuvanted vaccines and HD vaccines. Cell-based vaccines have also demonstrated higher relative vaccine effectiveness compared to egg-based SD vaccines.

7.19. The Committee considered that, based on available evidence, the mortality reduction of aTIV and TIVc compared with SD influenza vaccine is likely to be the magnitude of 10-50%, based on the results of the HD studies. The Committee considered that a 10% mortality reduction would be a reasonable estimate to include in the base case of the economic analysis. The Committee considered the mortality reduction could be as high as 50% based on Christensen et al. study, and that it is reasonable to assume that adjuvanted vaccines provide similar mortality reductions as HD vaccines.

8. Pneumococcal polysaccharide conjugate vaccine, 20-valent for the prevention of invasive pneumococcal disease

Application

8.1. The Committee reviewed the application for Pneumococcal 20-valent conjugate vaccine (Prevenar 20; PCV20) for the prevention of invasive pneumococcal disease (IPD) in paediatric populations and adults at high-risk (ie groups currently eligible for Prevenar 13 [PCV13] and Pneumovax 23 [PPV23]), and in adults aged 65 years and over.

8.1.1. The Committee acknowledged the application proposed to: replace the current schedule of PCV13 and PPV23 in high-risk adults with a single dose of PCV20; replace PCV13 on the National Immunisation Schedule for children; and provide access for adults aged 65 years and over (currently unfunded).

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

Recommendation

8.3. The Committee **recommended** that PCV20 be listed with a **high priority**, within the context of vaccines and immunisation, for all children up to 59 months of age, subject to the following criteria:

1. A course of up to three doses for children up to the age of 59 months inclusive who are either previously unvaccinated with PCV13 or have not yet completed a primary vaccination course.

8.4. In making this recommendation, the Committee:

8.4.1. Noted the signals of changing serotype distribution affecting older adults and emphasised the importance of proactive protection in children in response to early signals of serotype distribution change, including the key role of timely, strategic, vaccine decision-making for the National Immunisation Schedule

8.4.2. Noted that PCV13 and PCV15 would not be clinically appropriate options for childhood vaccination in upcoming years due to inadequate serotype coverage (based on current data of an increasing number of IPD cases caused by serotypes not included in either of these vaccines), and given the importance of a proactive vaccine strategy

8.4.3. Noted that there is a lack of recent evidence to inform the impact of non-IPD pneumococcal disease in this age group (eg otitis media, community acquired pneumonia)

8.4.4. Considered the high impact of IPD on Māori and other groups experiencing health inequity, and a very high impact on Pacific peoples

8.4.5. Considered that simplification of the current pneumococcal vaccine schedule to one pneumococcal vaccine for all ages including high risk groups would offer additional, albeit secondary, suitability for the health sector

8.4.6. Considered it appropriate to complete the primary course with PCV20 for those who received a partial course of either PCV10 or PCV13 vaccine up to the age of 59 months inclusive.

8.5. The Committee **recommended** that PCV20 be listed with a **high priority**, within the context of vaccines and immunisation, <u>for people under the age of 18 years with eligible conditions</u>, subject to the following criteria (which are adapted from the current PCV13 and PPV23 eligibility criteria with addition proposed in **<u>bold</u>**):

All of the following:

1. Any of the following:
   - 1.1. Up to four doses (3+1 schedule) for [re]immunisation of high risk children aged under five years; or
   - 1.2. A single dose for high risk individuals over the age of 12 months and under 18 years who have not yet started or completed a primary pneumococcal vaccination course; or
   - 1.3. Both:
     - 1.3.1. A booster dose every five years for the [re]immunisation of high-risk individuals aged between five and 18 years (inclusive); and
     - 1.3.2. Either:
       - **1.3.2.1.** Person has not received a pneumococcal vaccination within the past five years**; or**
2. **Person has had a haematopoietic stem cell transplantation and requires revaccination within five years of previous pneumococcal vaccination; and**Person is or has or is receiving any of the following:
   - 2.1. Immunosuppressive therapy or radiation therapy; or
   - 2.2. Primary immune deficiencies; or
   - 2.3. HIV infection; or
   - 2.4. Renal failure or on renal dialysis,
   - 2.5. Nephrotic syndrome; or
   - 2.6. Pre- or post- organ transplantation (including haematopoietic stem cell transplantation), or chemotherapy; or
   - 2.7. Cochlear implants or intracranial shunts; or
   - 2.8. Cerebrospinal fluid leaks; or
   - 2.9. Receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   - 2.10. Chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   - 2.11. Pre term infants, born before 28 weeks gestation; or
   - 2.12. Cardiac disease, with cyanosis or failure; or
   - 2.13. Diabetes; or
   - 2.14. Down syndrome; or
   - 2.15. Pre- or post-splenectomy, or with functional asplenia; or
   - 2.16. Complement deficiency (acquired or inherited).

8.5.1. The Committee **recommended** amended wording of the proposed eligibility criteria for access to PCV20 for people under the age of 18 years with eligible conditions to include the inclusion of the following group definitions and clarifications to the eligibility criteria (adapted from the current PCV13 and PPV23 eligibility criteria), and revised the sequencing of criteria (additions to the current eligibility criteria beyond differences in dosing schedules in **bold,** rewording/clarifications <u>underlined</u> and deletions in ~~strikethrough~~):

All of the following:

1. Any of the following:
   - 1.1. Up to four doses (3+1 schedule) for [re]immunisation of high risk children aged under five years; or
   - 1.2. A single dose for high risk individuals over the age of 12 months and under 18 years who have not yet completed a primary vaccination course with PCV13; or
   - 1.3. Both:
     - 1.3.1. A booster dose every five years for high-risk individuals under the age of 18 years; and
     - 1.3.2. Either:
       - **1.3.2.1. Person has not received a pneumococcal vaccination within the past five years; or**
       - **1.3.2.2. Person has had a haematopoietic stem cell transplantation and requires revaccination within five years of previous pneumococcal vaccination; and**
2. Person is or has or is receiving any of the following:
   - 2.1. Pre term infants, born before 28 weeks gestation; or
   - **2.2. Previously documented episode of invasive pneumococcal disease; or**
   - **2.3.** ~~On immunosuppressive therapy or radiation therapy; or~~ **Immunodeficiency or immunosuppression including any of the following:**
     - 2.3.1. Primary ~~immune deficiencies~~ immunodeficiency; or
     - 2.3.2. Down syndrome; or
     - 2.3.3. Complement deficiency (acquired or inherited); or
     - 2.3.4. **Haematological malignancies; or**
     - 2.3.5. Pre- or post-~~organ transplantation (including~~ haematopoietic stem cell transplantation~~)~~**; or**
     - 2.3.6. Pre-, **current,** or post- chemotherapy or ~~on~~ radiation therapy; or
     - 2.3.7. Pre- or post-splenectomy~~, or with functional asplenia~~**; or**
     - 2.3.8. Asplenia or dysfunction of the spleen including individuals with coeliac disease who are diagnosed with splenic dysfunction and all haemoglobinopathies including homozygous sickle cell disease; or
     - 2.3.9. Pre- or post- solid organ transplant; or
     - 2.3.10. **Pre-,** current, **or post-**immunosuppressive therapy**,** including receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
     - 2.3.11. HIV; or
     - 2.3.12. **Within five years of confirmed measles infection; or**
   - 2.4. Chronic pulmonary disease (including ~~asthma treated with high dose corticosteroid therapy~~ bronchiectasis or cystic fibrosis); or
   - **2.5.** Severe or poorly controlled asthma; **or**
   - 2.6. Congenital or acquired (eg rheumatic heart disease) cardiac disease, with cyanosis or failure; or
   - 2.7. ~~Renal failure or nephrotic syndrome~~**,** Chronic kidney disease stage 4 or 5, including ~~on~~ renal dialysis; or
   - 2.8. Nephrotic syndrome; or
   - 2.9. **Pre- or post-**cochlear implants**;** or
   - 2.10. Intracranial shunts; or
   - 2.11. Cerebrospinal fluid leaks; or
   - **2.12. Neuromuscular disorders with restricted activity (eg impaired clearance of oral secretions, weakened musculature leading to reduced lung function, ineffective cough reflex, dysphagia or risk of aspiration); or**
   - 2.13. Diabetes; or
   - 2.14. **Neonatal cholestatic liver disease.**

8.6. In making this recommendation, the Committee:

8.6.1. Noted that PCV13 and PCV15 would not be clinically appropriate options for vaccination of people under the age of 18 years with eligible conditions in upcoming years due to inadequate serotype coverage (based on current data of an increasing number of IPD cases caused by serotypes not included in either of these vaccines), noting the upcoming discontinuation of PPV23

8.6.2. Noted the signals of changing serotype distribution affecting older adults and emphasised the importance of proactive protection in children and adolescents

in response to early signals of serotype distribution change, including the key role of timely, strategic, vaccine decision-making for the National Immunisation Schedule

8.6.3. Discussed unpublished evidence that current targeting of vaccines to people with high-risk conditions or status is not reaching these groups (Howe et al. 2022 [unpublished]) and considered the definitions of the eligible conditions should be reviewed further by the Committee

8.6.4. Considered the high impact on Māori and other groups experiencing health inequity, and a very high impact on Pacific people

8.6.5. Considered that simplification of the current vaccine schedule to one pneumococcal vaccine for all ages would offer additional, albeit secondary, suitability for the health sector. However, the Committee considered it feasible to manage a different schedule with multiple vaccines if necessary.

8.7. The Committee **recommended** that PCV20 be listed with a **high priority**, within the context of vaccines and immunisation, for people 18 years and older with eligible conditions, subject to the following criteria (which are adapted from the current PCV13 and PPV23 eligibility criteria and noting the criteria recommended for PCV21 in June 2025 for individuals 18 years and over, with addition proposed in **bold**):

All of the following
1. A single dose and a booster dose every five years for high-risk individuals aged 18 years and over; and
2. Person is or has or is with any of the following:
    2.1. HIV requiring (re-)immunisation; or
    2.2. pre- or post-haematopoietic stem cell transplantation; or
    2.3. chemotherapy; or
    2.4. pre- or post-splenectomy; or
    2.5. functional asplenia; or
    2.6. pre- or post-solid organ transplant; or
    2.7. renal dialysis; or
    2.8. complement deficiency (acquired or inherited); or
    2.9. cochlear implants; or
    2.10. intracranial shunts; or
    2.11. cerebrospinal fluid leaks; or
    2.12. primary immunodeficiency; and
3. **Either:**
    3.1. Person has not been vaccinated with both PCV13 AND PPV23 within the past five years**; or**
    3.2. **Person has had a haematopoietic stem cell transplantation and requires revaccination within five years of previous pneumococcal vaccination**.

8.7.1. The Committee **recommended** amended wording of the proposed eligibility criteria for access to PCV20 for people 18 years and older with eligible conditions with the inclusion of the following group definitions and clarifications to the eligibility criteria (adapted from the current PCV13 and PPV23 eligibility criteria, noting the criteria recommended for PCV21 in June 2025 for individuals 18 years and over), and revised the sequencing of criteria (additions to the current eligibility criteria beyond differences in dosing schedules in **bold,** rewording/clarifications underlined and deletions in ~~strikethrough~~):

All of the following:
1. A single dose and a booster dose every five years for high-risk individuals aged 18 years and over; and
2. Person is or has or is with any of the following:
    2.1. Previously documented episode of invasive pneumococcal disease; or
    2.2. ~~On immunosuppressive therapy or radiation therapy; or~~ **Immunodeficiency or immunosuppression including any of the following:**
        2.1.1. Primary ~~immune deficiencies~~ immunodeficiency; or
        2.2.1. Down syndrome; or

2.2.2. Complement deficiency (acquired or inherited); or
2.2.3. Haematological malignancies; or
2.2.4. Pre- or post~~- organ transplantation (including~~ haematopoietic stem cell transplantation~~)~~**; or**
2.2.5. **Pre-, current,** or **post-** chemotherapy **or** ~~on~~ **radiation therapy**; or
2.2.6. Pre- or post-splenectomy~~, or with functional asplenia~~**; or**
2.2.7. Asplenia or dysfunction of the spleen including individuals with coeliac disease who are diagnosed with splenic dysfunction and all haemoglobinopathies including homozygous sickle cell disease; or
2.2.8. **Pre- or post- solid organ transplant; or**
2.2.9. **Pre-,** current**, or post-immunosuppressive therapy,** including receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
2.2.10. HIV; or
2.2.11. **Within five years of confirmed measles infection; or**

2.3. Chronic pulmonary disease (including ~~asthma treated with high-dose corticosteroid therapy~~ bronchiectasis or cystic fibrosis); or
2.4. Severe or poorly controlled asthma; or
2.5. Congenital or acquired (eg rheumatic heart disease or ischaemic heart disease) cardiac disease, with cyanosis or failure; or
2.6. ~~Renal failure or nephrotic syndrome,~~ Chronic kidney disease stage 4 or 5**, including** ~~on~~ renal dialysis; or
2.7. Nephrotic syndrome; or
2.8. **Pre- or post-**cochlear implants**;** or
2.9. Intracranial shunts; or
2.10. Cerebrospinal fluid leaks; or
2.11. **Neuromuscular disorders with restricted activity (eg impaired clearance of oral secretions, weakened musculature leading to reduced lung function, ineffective cough reflex, dysphagia or risk of aspiration); or**
2.12. **Alcohol dependency**; or
2.13. **End-stage liver disease, including chronic hepatitis, cirrhosis; and**

3. Either:
3.1. Person has not received a pneumococcal vaccination within the past five years; **or**
3.2. **Person has had a haematopoietic stem cell transplantation and requires revaccination within five years of previous pneumococcal vaccination**.

8.8. In making this recommendation, the Committee:

8.8.1. Noted that PCV13 and PCV15 would not be clinically appropriate options for people 18 years and older with eligible conditions in upcoming years due to inadequate serotype coverage (based on current data of an increasing number of IPD cases caused by serotypes not included in either of these vaccines), noting the upcoming discontinuation of PPV23

8.8.2. Considered that funding PCV20 for adults with high-risk conditions or status would simplify the current adult high-risk regimen (PCV13 followed by up to three PPV23 doses) with expected improvements in suitability and uptake

8.8.3. Considered the high impact on Māori and other groups experiencing health inequity, and a very high impact on Pacific people

8.8.4. Considered that current targeting of vaccines to people with high-risk conditions or status is not reaching these groups sufficiently (although not included in the data reported by Howe et al. 2022 [unpublished]) and considered the definitions of the eligible conditions should be reviewed further by the Committee.

8.9. The Committee **recommended** that PCV20 be listed with a **high priority**, within the context of vaccines and immunisation, for all adults aged 65 years and older:

A single dose for individuals aged 65 years or older.

8.10. In making this recommendation, the Committee:

8.10.1. Noted that the highest burden of IPD is observed in older adults, however, this group can only access currently funded pneumococcal vaccine if they have a high-risk condition or status

8.10.2. Noted that there is no evidence to inform the magnitude of other known pneumococcal disease in this age group (eg community-acquired pneumonia and disease not serotyped)

8.10.3. Noted the signals of changing serotype distribution affecting older adults

8.10.4. Discussed unpublished evidence that current targeting of vaccines to people with high-risk conditions or status is not reaching these groups sufficiently (Howe et al. 2022 [unpublished] and considered substantial benefits would be gained by funding the vaccine universally for older adults rather than targeting a high-risk subset.

Discussion

Māori impact

8.11. The Committee discussed the impact of funding PCV20 for currently eligible groups and adults aged 65 years and older on Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee noted its comments of June 2025 during consideration of the PCV21 vaccine for high-risk adults.

8.11.1. The Committee noted the evidence of higher incidence (incidence rate ratio 2.3; 95% CI 1.4 to 3.7) of invasive pneumococcal disease (IPD) in Māori children under five years of age compared with European/Other children, and the authors comments that childhood immunisation coverage has been declining particularly in this population group (Burton, et al. Pediatr Infect Dis J. 2025;44:90-6).

8.11.2. The Committee noted recent local data indicating improvements in outcomes from IPD for some groups between 2023 and 2024, yet persistent inequities remain and a significant burden is experienced by Māori (PHF Science IPD Annual Report 2024). In particular, Māori children under two years of age experienced 4.2 times the incidence of IPD compared with European/Other children under two years of age.

Populations with high health needs

8.12. The Committee discussed the impact of IPD among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee noted its comments of June 2025 during consideration of the PCV21 vaccine for high-risk adults.

8.12.1. The Committee noted that recent local data indicated that the largest burden of IPD is experienced by Pacific people (PHF Science IPD Annual Report 2024). Pacific children under two years of age experienced 7.3 times the incidence of IPD compared with European/Other children under two years of age.

8.12.2. The Committee noted a clear deprivation gradient in IPD, with the highest rates observed in the most deprived areas (quintiles four and five) (PHF Science IPD Annual Report 2024).

8.12.3. The Committee discussed evidence that targeted vaccination approaches (eg targeting eligibility to adults with high-risk conditions) achieve markedly lower coverage than universal approaches (Howe et al. 2022 [unpublished]) and considered that broader eligibility (eg targeting all adults 65 years and older)

would better reach high-need populations.

Background

8.13. The Committee noted the current funding of PCV13 for childhood immunisations (primary course and booster for all children under five years of age) and for high-risk children under five years of age and between five and 18 years of age, and the current funding of PCV13 with PPV23 for adults with eligible conditions. The Committee noted that other adults 65 years of age and older are not currently eligible for funded pneumococcal vaccines.

8.14. The Committee noted that the Immunisation Advisory Committee (formerly the Immunisation Subcommittee) has provided advice pertaining to pneumococcal vaccines on multiple occasions, most recently in June 2025. For further details and the current status of these recommendations, please refer to the application tracker.

8.14.1. In September 2024, the Immunisation Advisory Committee made a recommendation that the eligibility criteria for PCV13 and PPV23 vaccines be widened with a high priority, in the context of immunisation and vaccines, to include people of any age who have bronchiectasis and adults who have had a previous episode of IPD (links to Application Tracker for PCV13 and PPV23 proposals).

8.14.2. In June 2025, the Immunisation Advisory Committee considered the pneumococcal 21-valent conjugate vaccine (PCV21) for prevention of IPD in high-risk adults. At that time, the Committee had recommended that PCV21 be included in the upcoming vaccines procurement process; be listed with a high priority for all adults aged 65 years and over; and be listed with a high priority for high-risk adult groups aged under 65 years.

8.15. The Committee noted that Pneumovax 23 (PPV23) is expected to be discontinued globally by the end of 2027. Members considered that the uptake of this vaccine in the New Zealand high-risk population was limited by factors including the complexity of the current schedule.

Health need

8.16. The Committee noted its comments of June 2025 during consideration of the PCV21 vaccine for high-risk adults and considered that the same health inequities regarding ethnicity and socio-economic status remained highly applicable.

8.17. The Committee noted that the highest incidence of IPD was in those aged 65 years and older (34.2 per 100,000 in the population), followed by those aged less than two years old (21.6 per 100,000) (PHF Science IPD Annual Report 2024). The Committee considered that whilst the burden of disease was decreasing in infants, it remained an issue for elderly.

8.17.1. Members noted that an age of 65 years or greater was a risk factor for pneumococcal disease even in healthy individuals. The Committee noted there was limited data for the greater risk of IPD in the very elderly and those with multiple comorbidities. Members considered that comorbidities ‘stack’, resulting in an unknown but potentially exponentially increased magnitude of risk for IPD.

8.18. The Committee noted that the incidence of serotype 19A-related IPD decreased across all age groups in 2024 (PHF Science IPD Annual Report 2024). The Committee noted preliminary 2025 data (January to September) indicate serotype 8 accounted for the highest number of cases (132; approximately 40% increase from 2024), followed by 19A (89) and 22F (72) in New Zealand (PHF Science IPD Dashboard).

8.18.1. The Committee noted the slight difference in serotype distribution between children and older adults including a signal of increasing disease from serotype 8 in older adults, acknowledging low case numbers for IPD in young children. The Committee considered this was an important serotype signal to monitor closely, with significance for those 65 years and older, with implications for vaccination of infants and children in upcoming years.

8.18.2. The Committee noted that cases of serotype 8 and 22F IPD predominantly affected adults and there were low numbers in children at time of the report. The Committee noted that other serotypes causing IPD were only reported in very small numbers in children and all relevant serotypes (eg 19A, 8, 3, 22F and 33F) would be covered by PCV20 except 15B, although there were only two 15B cases in children under five, of which one was under two years of age. The Committee considered based on this data that PCV20's serotype coverage would be appropriate for use as a childhood vaccine.

8.18.3. The Committee considered that review of serotype distribution of IPD cases (including serotype 8) according to more defined age bands for the younger and older ages (ie under five years, five to 18 years, 18 to 65 years, 65 to 75 years, and 75 years and older) and including information about comorbidities would be highly valuable and encouraged Pharmac staff to request this data.

8.19. The Committee emphasised that there is a burden of pneumococcal disease beyond that of IPD, though testing for *Streptococcus pneumoniae* among these non-IPD cases was uncommon and there was a lack of evidence to inform the impact of these manifestations of infection in New Zealand. The Committee noted that the CAPITA study (Bonten et al. N Engl J Med. 2015;372:1114-25) reported improved control of serotype-specific pneumococcal disease (not just IPD) using a conjugate pneumococcal vaccine and that this extended to community-acquired pneumonia. Members considered that pneumonia and meningitis are the most common presentations in those aged under two years of age, bacteraemia without focus is the second most common presentation for those aged between two and four years old, and pneumonia is most common in other ages.

8.19.1. The Committee considered that in the absence of data to inform serotypes in community acquired pneumonia, it was uncertain whether the serotype distribution is the same as for IPD. However, members considered it was reasonable to include a reduction on all pneumococcal disease (not just IPD) into an assessment of PCV20.

8.20. The Committee discussed evidence that targeted vaccination approaches (eg targeting eligibility to adults with high-risk conditions) achieve markedly lower coverage than universal approaches (Howe et al. 2022 [unpublished]). The Committee considered that a substantial proportion of those aged 65 years and older have high risk conditions and broader eligibility (eg targeting all adults 65 years and older) would reach these high-need populations better than targeting access based on risk.

8.21. The Committee considered it highly important to ensure broader pneumococcal serotype coverage in the childhood immunisation schedule and act proactively to manage emergent signals. The Committee considered it critical to act on such signals quickly given the expected lag in effect from implementation of an updated vaccine covering different serotypes and the potential for serotypes increasing in the adult population requiring coverage to prevent cases also increasing in children.

8.21.1. Members were made aware of evidence from a modelling study presented as a conference abstract (subsequently published by de Boer et al. BMC Med. 2024;22:69), which examined the impact of higher-valency pneumococcal

vaccines in children on the cost-effectiveness of pneumococcal vaccination strategies in older adults. Members noted that broader serotype coverage in paediatric programmes was associated with reduced cost-effectiveness of higher-valency conjugate vaccines for older adults, reflecting indirect protection effects. The Committee considered that the most cost-effective adult vaccination strategy could vary depending on the degree of serotype overlap between paediatric and adult vaccines, and that this supported an optimal approach in which broader serotype coverage in children contributes to cost-effective population-level coverage.

8.21.2. Members considered that it would be optimal to have a universal pneumococcal vaccination program (ie all currently eligible groups plus adults 65 years and older) for pneumococcal disease including a high valency vaccine in children.

Health benefit

8.22. The Committee noted that an application has been lodged for PCV20 (Prevenar 20) through Medsafe in March 2025 for the active immunisation for the prevention of pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals from 6 weeks of age and older.

8.23. The Committee considered that while PCV20 was likely designed as a childhood vaccine, it also offers good serotype coverage for adults and appears to be an effective vaccine that induces T-cell dependent immune response, enhanced B-cell responses and the generation of long-lasting immunological memory. The Committee noted that PCV20 uses the same CRM-197 conjugate as PCV13 and considered that it was reasonable to assume a similar expected duration of protection for PCV20 as that reported for PCV13 in the CAPITA study, ie at least four years (Bonten et al. N Engl J Med. 2015;372:1114-25).

8.23.1. The Committee noted that PCV13 does not provide coverage for serotypes 8, 21 and 22F, and that PCV15 does not provide coverage for serotype 8. The Committee noted that PCV13 and PCV15 would not be clinically appropriate options for vaccination of currently eligible groups in upcoming years due to inadequate serotype coverage (based on current data of an increasing number of IPD cases caused by serotypes not included in either of these vaccines), given the importance of a proactive childhood vaccine strategy and noting the upcoming discontinuation of PPV23 affecting coverage for people with eligible conditions (high risk).

8.23.2. The Committee noted that PCV21 provides coverage of serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B. Of these, serotypes 9N, 23A, 23B and 16F, are not covered by PCV20. The Committee considered that this difference in serotype coverage would cumulatively account for approximately 14% of cases of IPD across the population. However, given the incidence data is based on small numbers across all ages, this difference could be greater for the elderly. The Committee had no specific comments or concerns about coverage of serotypes 1, 4, 5, 6B, 9V, 14, 15B, 18C, 19F and 23F which are covered by PCV20 but not by PCV21.

8.24. The Committee noted it had reviewed international recommendations for pneumococcal vaccines in June 2025 during consideration of the PCV21 vaccine for high-risk adults. The Committee noted that many jurisdictions had moved to using a single PCV dose for those 65 years and older; there were various recommendations and approaches for children (eg targeting broader coverage to high-risk children or

targeting all children) and some countries used either PCV20 or PCV21 while others had both available. The Committee considered there was clear international support for changing to either PCV20 or PCV21 and considered which had been implemented might depend on funding arrangements.

8.25. The Committee noted that the evidence for PCV20 reports immunogenicity benefits and vaccine effectiveness data is not available (similar to PCV21).

Evidence for PCV20 in children

8.26. The Committee noted that the main data of relevance in children came from B7471012; a phase III, randomised (1:1), double-blind study in 1,204 healthy infants (Korbal, et al. Paediatr Infect Dis J. 2024;43(6):587-95). Participants received three doses of either PCV20 or PCV13: one given at enrolment, a second about eight weeks later and a third dose at about 12 months of age. Immunoglobulin G geometric mean concentrations (IgG GMCs) were measured one month after the third dose.

8.26.1. The Committee noted that 19 of 20 serotypes met noninferiority by IgG GMCs and PCV20 met non-inferiority for 12 of 13 shared serotypes versus PCV13, with serotype 6B narrowly missing non-inferiority (GMR 0.57; 95%CI 0.48–0.67; threshold >0.5). The Committee consider these results were good in terms of a paediatric vaccine and serotype coverage.

8.26.2. The Committee considered that there was no clear difference in reactogenicity for PCV20 compared with PCV13, including no difference in the risk of fever (occurring in about 3.6% of each group) or according to dose. The Committee noted that mild and moderate serious adverse events (SAEs) were rare.

8.27. The Committee noted supporting evidence from B7471011; a phase III, randomised (1:1), double-blind study in 1,991 healthy infants (Senders, et al. Paediatr Infect Dis J. 2024;43(6):596-603). Participants received four doses of either PCV20 or PCV13: doses were given at approximately two, four, six and 12-15 months of age. IgG GMCs were measured one month after the fourth dose.

8.27.1. The Committee noted that non-inferiority by IgG GMCs was met for all 13 shared serotypes and for all seven additional serotypes relative to PCV13's lowest IgG.

8.27.2. The Committee considered that the reactogenicity profile was similar and the vaccine would be suitable for use in a paediatric population.

8.28. The Committee noted evidence from a phase III, single-arm trial which evaluated safety and immunogenicity of PCV20 in healthy children 15 months through to 18 years of age (N=839). The Committee considered that supported the same conclusion regarding similar immunogenicity with PCV20 (Meyer, et al. Pediatr Infect Dis J. 2024;43(6):574-581)

8.29. The Committee noted that evidence from the Clinical Study Report (CSR) of the phase II, multi-centre, randomised, active-controlled double-blind B7471003 study of 460 infants randomised (1:1) to receive either PCV20 or PCV13 at two, four and six months of age, with a booster at 12 months also reported noninferior immunogenicity.

8.30. The Committee noted that evidence from the phase III, randomised, partially double-blind study investigating the safety, tolerability and immunogenicity of PCV20 in healthy toddlers who had previously received two doses of PCV13 also reported good immunogenicity and no issues with subsequent dosing using PCV20 (Martinon-Torres, et al. Vaccine. 2025;126931).

Evidence for PCV20 in adults

8.31. The Committee noted that the main data of relevance in adults came from the B7471007 Phase III, randomised, active-controlled, double-blind, multi-centre study in pneumococcal vaccine-naïve adults. The study included three cohorts based on age at enrolment: 60 years and over (n=3009), 50 to 59 years (n=445) and 18–49 years (n=448) (Essink, et al. Clin Infect Dis. 2021;75(3)390-98). Participants received either one dose of PCV20 or PCV13, and one dose of saline or PPV23 after one month in participants aged 60 years and older.

8.31.1. The Committee considered that the study included a good number of participants, although there were smaller numbers of very elderly (aged 80 and over) and some comorbidities were covered.

8.31.2. The Committee noted that noninferiority was met for all 13 common serotypes with PCV13. Serotype 8 did not meet noninferiority, with an OPA GMR of 0.55 (95% CI, 0.49 to 0.62). However, the Committee considered this result indicated PCV20 was effective from a T-cell perspective and clinical effectiveness would be expected against serotype 8 disease. The Committee again considered that this serotype requires careful monitoring given its increased signal in New Zealand.

8.31.3. The Committee noted that there was no clear difference in reactogenicity of PCV20 compared with PCV13, and that all reported SAEs were considered not related.

8.32. The Committee noted evidence from B7471006; a phase III, randomised, open-label, multi-centre study of 875 pneumococcal vaccine-experienced adults aged 65 and older who received PCV20 co-administered with the quadrivalent influenza vaccine (QIV) (Cannon, et al. Vaccine. 2021;39(51):7494-502). Participants were enrolled into three cohorts based on their prior pneumococcal vaccination history (history of PPV23 but not PCV13; history of PCV13 but no prior PPV23; recent history of PCV13 and PPV23. The Committee noted that the authors reported there was a similar reactogenicity profile when co-administered with QIV.

8.33. The Committee noted B7471009; a phase III, randomised, double-blind study investigating the safety and immunogenicity of PCV20 vs PCV13 + PPV23 in 1,421 participants aged over 60 years in East Asia (Haranaka, et al. Vaccine. 2024;42(5):1071-77). The Committee noted that serotype 8 did not meet non inferiority for immunogenicity but the OPA GMR was met.

8.34. The Committee also noted the following supportive evidence:

8.34.1. A phase III, randomised, multi-centre, double-blind (lot consistency) study of 1,710 pneumococcal vaccine-naïve adults 18-49 years (Klein, et al. Vaccine. 2021;39(38):5428-35). Participants were randomised (2:2:2:1) to receive one of three lots of PCV20 or PCV13. Noninferiority was fully met.

8.34.2. A phase III, randomised, double-blind, multicentre coadministration study, including 1,796 adults over 65 years of age (Cannon, et al. Vaccine. 2023;41(13):2137-46). PCV20 noninferiority was met with coadministration of QIV.

8.34.3. A phase III, randomised, double-blind multicentre study (coad covid BNT162b2) in 570 adults aged over 65 years (Fitz-Patrick, et al. Vaccine. 2023;41(28):4190-98). The Committee considered this provided good evidence to support coadministration of PCV20 with the COVID vaccine in adults.

8.34.4. Evidence comparing PCV20 with PCV21 from the P003 (Stride-3) study, which was considered in June 2025. The Committee noted its past consideration concluded both were good and comparable, with some serotype differences.

General

8.35. The Committee noted that the evidence was bridging immunogenicity data only, and no vaccine effectiveness studies were available for PCV20. The Committee considered this evidence was complex with multiple serotypes and no ability to have comparative data on immunogenicity against certain newer serotypes to date. The Committee considered the evidence was additionally limited by the ability to measure serotypes in IPD but that this is much more difficult for other pneumococcal outcomes (eg otitis media, community acquired pneumonia). The Committee considered it was not appropriate to compare outcomes against PPV23, given its limited efficacy and very low uptake in the New Zealand high-risk population.

8.36. The Committee considered that there was good quality evidence of greater immunogenicity with PCV20 compared with PPV23 for serotypes unique to PCV20; non-inferior immunogenicity compared with PCV13 for common serotypes; and a similar, acceptable safety profile compared with PCV13 including in paediatric populations.

8.37. The Committee considered that the evidence supported a primary PCV13 course being completed with PCV20 (2+1), and a high-risk course (3+1) with PCV13 or PPV23 being completed with PCV20. The Committee considered that when transitioning from PCV13 to PCV20 for high-risk children five to 18 years of age (who are currently funded for a single dose of PCV13 followed by up to four doses of PPV23), the dosing schedule would be a single PCV20 dose potentially with a booster every five years. The Committee considered it important to implement a simple and likely effective schedule, noting that current targeting is not achieving optimal vaccination uptake among those with high-risk conditions. The Committee considered that dosing for those over 18 years of age would be a single dose with a booster administered every five years for those with high risk.

8.38. Overall, the Committee considered that clinically appropriate pneumococcal vaccine funding for the coming years would be either funding PCV20 for all eligible groups (and all adults aged 65 years and over, if access were widened) or funding both PCV20 and PCV21. The Committee considered that limitations of current data regarding pneumococcal disease meant it is unclear whether PCV20 or PCV21 would be a better serotype match for high-risk adults, however, considered that taking a broader approach would be optimal.

Suitability

8.39. The Committee noted that PCV20 is a single-dose pre-filled syringe with standard cold chain requirements and had no concerns about its shelf life or implementation.

8.40. The Committee considered that a single PCV vaccine in vaccinator fridges would simplify logistics, including cold chain management, and reduce administration errors. However, the Committee considered that decision-making related to which vaccine(s) were to be funded to control pneumococcal disease should primarily be based on clinical effectiveness and serotype coverage, and considered it feasible to manage a different schedule with multiple vaccines if necessary

8.41. The Committee considered that other advantages of PCV20 would include simplifying the vaccination schedule with a single injection event which may make it easier to manage booster doses and help address health inequities (as a single vaccine would be more likely to reach high risk groups eg Pacific people).

8.42. The Committee considered that PCV20 is a conjugate vaccine which cannot be used to assess polysaccharide responses for primary immunodeficiency testing (unlike PPV23). However, the Committee considered there are ongoing challenges already affecting the demand for testing, and ability to test with, PPV23. The Committee

therefore considered that the impact of not having a funded vaccine for this purpose post-discontinuation of PPV23 was minimal.

Cost and savings

8.43. The Committee noted there was no price for PCV20 included in the supplier's application. The Committee noted that Pharmac's August 2025 Request for Proposals (RFP) for supply of various vaccines and influenza vaccine is underway.

8.44. The Committee noted that simplification of the dosing schedule for the currently funded adult population to a single dose of PCV20 would result in a reduction of vaccination administration costs, as noted in June 2025 regarding PCV21, and may have other benefits (eg improving inequities and benefits to the health sector related to a simpler schedule).

Funding criteria

8.45. The Committee was made aware of evidence that current targeting of vaccines to people with high-risk conditions or status is not reaching these groups, likely due to the complexity of the schedule and difficulty identifying high risk (Howe et al. 2022 [unpublished]). The Committee considered the definitions of the eligible high-risk conditions should be reviewed further by the Committee to simplify and align targeted groups.

8.46. The Committee considered that there were a range of additional high risk conditions which would be reasonable to add to the list of eligible high risk conditions, if the proposed eligibility criteria were to be amended, as indicated in bold on the relevant eligibility criteria. Members considered that while some additional groups had an increased risk for IPD (eg residents in long term care facilities, smokers, and those exposed to occupational fumes), the magnitude of risk for these groups was not as high as that of the groups currently targeted and those proposed for widened access at this time.

8.47. The Committee further considered that substantial benefits would be gained by funding the vaccine universally and including older adults rather than targeting a high-risk subset.

8.48. The Committee considered it appropriate to fund dose(s) of PCV20 for those who received a partial course of current PCV13 vaccine, to complete childhood dose milestones up to the age of 59 months inclusive. The Committee considered that, subject to the serotype distribution at the time, there was no need to fund additional doses for children who have already completed a full (2+1) primary course of PCV13.

Summary for assessment

8.49. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for PCV20 if it were to be funded in New Zealand for the prevention of invasive pneumococcal disease. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Children ≤59 months of age – unvaccinated or partially vaccinated (with PCV10 or PCV13)	Children and individuals <18 years of age at high-risk* – unvaccinated or partially vaccinated (with PCV10 or PCV13) Currently funded group	Individuals ≥18 years with certain high risk* medical conditions (currently covered by the existing PCV13 +/- PPV23 eligibility criteria) Currently funded group	All adults ≥65 years Not a currently funded group

	Currently funded group	*Refer to proposed eligibility criteria for definitions of high risk. *May also include those with previously documented episode of invasive pneumococcal disease or bronchiectasis (recommended but currently unfunded)	*Refer to proposed eligibility criteria for definitions of high risk. *May also include those with previously documented episode of invasive pneumococcal disease or bronchiectasis (any age), or those 18 years and older with ischaemic heart disease (recommended but currently unfunded)	
Intervention	Up to three doses of PCV20 for infants	Up to four doses of PCV20 (eg 3+1 schedule if unvaccinated/partially vaccinated with PCV13, or a single dose if 5-18 years old)	PCV20 single dose	PCV20 single dose
Comparator(s) (NZ context)	Prevenar 13 (PCV13), three dose primary course	Prevenar 13 (PCV13) three dose primary course + additional dose for high-risk	Single dose of Prevenar 13 (PCV13) and up to 3 doses of Pneumovax23 (PPV23)	No immunisation
Outcome(s)	• Greater immunogenicity vs PPV23 for serotypes unique to PCV20 • Non-inferior immunogenicity vs PCV13 for common serotypes • Potential reduction in community-acquired pneumonia (ref CAPITA study)			

Table definitions:
Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)
Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).
Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).
Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.

9. Matters arising: [redacted]

Background

9.1. The Advisory Committee considered a paper from Pharmac staff regarding the 2025 Various Vaccines and Influenza Vaccine RFP, outlining a number of possible changes to funded vaccines the could occur from July 2027 as a result of the RFP and seeking clinical advice about the suitability of the bids received through the RFP.

9.2. Members noted the confidential nature of this discussion related to the RFP.

Discussion

Meningococcal ACWY vaccine

9.3. The Committee noted that MenQuadfi and Nimenrix are the currently funded brands of meningococcal ACWY vaccine. MenQuadfi has Principal Supply Status and is the currently funded brand of meningococcal ACWY vaccine for eligible people 12 months of age and over. Nimenrix is an Alternative Brand Allowance vaccine and is the currently funded brand for eligible infants from 6 weeks to under 12 months of age.

9.4. The Committee noted that Nimenrix is approved for use from 6 weeks of age and MenQuadfi is approved for use in children from 12 months of age. The Committee noted that the supplier of MenQuadfi has applied to Medsafe for approval for use from 6 weeks of age.

9.5. The Committee considered that Nimenrix would be suitable to be funded for all eligible people 6 weeks of age and older if there was a change to the Nimenrix brand as the only funded meningococcal ACWY vaccine

9.6. The Committee considered that no changes would be required to the specified dosing schedule or the eligibility criteria if Nimenrix was the only funded meningococcal ACWY brand

9.7. The Committee considered that if MenQuadfi continued to be the funded meningococcal ACWY vaccine for people 12 months of age and older, there would not be a need to continue funding the Nimenrix brand for people under 12 months of age if MenQuadfi gained regulatory approval for use from 6 weeks of age.

Pneumococcal conjugate vaccine

9.8. The Committee noted it had considered pneumococcal conjugate vaccines at its August 2021, April 2022 and September 2022 meetings. In August 2021 the Committee considered a report from the Institute of Environmental Science and Research on the changing epidemiology of IPD in New Zealand. Trends in this report showed a recent increase in serotype 19A notifications. Based on their review of this report, and a further review in April 2022 of additional surveillance data from early 2022, the recommended access to funded PCV13 to provide additional protection against pneumococcal disease, including serotype 19A, with a high priority. The Committee noted that Pharmac widened access to PCV13 vaccine from 1 December 2022 and listed it in the Pharmaceutical Schedule with a 2+1 dosing schedule for children under 5 years of age.

9.9. The Committee noted and agreed with its September 2022 considerations that PCV15 and PCV13 vaccines likely provide comparable benefit at a population level and would therefore be considered interchangeable, based on the immunogenicity data reviewed at that meeting.

9.10. The Committee noted that the supplier of PPV23 (Pneumovax 23) has made Pharmac aware of its decision to discontinue manufacturing, distribution and supply of PPV23 by the end of 2027.

9.11. The Committee noted it has considered an application from MSD for PCV21 vaccine at its June 2025 meeting. The Committee noted its previous recommendation that PCV21 be listed for high-risk adult groups with a high priority. The Committee noted that PCV21 targets serotypes that are more relevant to adult disease burden and that PCV21 would address a gap in pneumococcal disease prevention. The Committee noted that PCV21 is approved for use in people 18 years of age and older. The Committee therefore considered that if PCV21 were funded for high-risk adult groups, a suitable childhood vaccine would also be needed to provide pneumococcal disease prevention for all currently eligible population groups (ie childhood immunisation and high-risk individuals five to 18 years of age).

9.12. The Committee noted preliminary 2025 epidemiology data (January to September) indicate serotype 8 accounted for the highest number of cases (132; approximately 40% increase from 2024), followed by 19A (89) and 22F (72) in New Zealand (PHF Science IPD Dashboard). The Committee noted that both PCV20 and PCV21 provide coverage of serotypes 8, 19A and 22F. However, the Committee considered that it would be clinically inappropriate to fund PCV13 (for groups under 18 years of age) alongside PCV21 (for high-risk adults), or PCV15 (for groups under 18 years of age) alongside PCV21 (for high-risk adults) for the coming years, as these vaccine combinations would provide insufficient serotype coverage to proactively and broadly manage current serotype signals across all currently eligible child and adult groups (including especially the increase of serotype 8), which cumulatively account for approximately 20% of cases in adults and have the potential to impact children.

9.13. The Committee considered that PCV20 would provide suitable, broad and proactive serotype coverage for currently eligible child and adult groups (including for high risk children five to 18 years old), either funded alone or alongside PCV21.

9.14. The Committee noted the current eligibility criteria that were included as part of the RFP process. During its review of the PCV20 application, the Committee also considered an expanded eligibility criteria for PCV20 to cover some additional high-risk groups. The eligibility criteria are detailed in Committee's review of the PCV20 application.

Influenza vaccine

9.15. The Committee noted that Influvac Tetra quadrivalent inactivated vaccine (QIV) is the currently funded influenza vaccine on the Pharmaceutical Schedule, for all eligible people from 6 months of age and over.

9.16. The Committee noted that the RFP sought proposals for the following different types of influenza vaccine: quadrivalent inactivated egg based (QIV), trivalent inactivated egg based (TIVe), trivalent inactivated cell based (TIVc) and adjuvanted trivalent (aTIV). The Committee noted that Pharmac expressed a strong preference for a trivalent influenza vaccine in the RFP supporting the position to move to a trivalent influenza vaccine by the World Health Organisation and subsequent advice by Medsafe for influenza vaccine composition. Suppliers were asked to submit proposals for principal supply status (PSS) to cover the entire funded population. Proposals were also sought for widened access to groups that have previously been recommended for funding and are ranked on the Options for Investment list, as follows:

- Children under 5 years of age
- Children from 6 months up to 18 years of age
- All people 50 years of age and over
- Open listing (no restrictions)

9.17. The Committee noted that proposals were received for a range of different influenza vaccine technologies. The Committee considered that all vaccines included in bids were suitable for listing in the Pharmaceutical Schedule.

9.18. The Committee considered a possible change from quadrivalent Influvac Tetra to trivalent Influvac would be in line with the WHO recommendations to move to a trivalent influenza vaccine.

9.19. The Committee considered all influenza vaccine proposals were viable options however there would be a strong preference for the cell-based and adjuvanted influenza vaccine combination due to the reduction in hospitalisation and mortality in the over 65 age group and those at risk of severe illness. During its review of the cell-based and adjuvanted vaccines the Committee discussed the relative magnitude of the mortality benefit to be included.

9.20. The Committee considered all proposals for widened access were suitable and would meet the needs of the widened access groups.

[redacted]

9.22. The Committee considered the clinical health need of the pneumococcal polysaccharide vaccine (PPV23) could be met by other pneumococcal vaccines or combinations.

9.23. The Committee considered that alternative options existed for testing primary immunodeficiency when the pneumococcal polysaccharide vaccine (PPV23) is discontinued.

10. Welcome and introduction to Respiratory Advisory Committee members

10.1. The Chair welcomed members of the Respiratory Advisory Committee who joined the meeting for discussions for:

- Nirsivemab for protection of infants vulnerable to RSV infection.
- RSVPreF3 Vaccine (Arexvy) for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older – resubmission

10.2. For the purpose of the items 13 and 14, references to the Committee include members of the Immunisation and Respiratory Advisory Committees.

11. Nirsivemab for protection of infants vulnerable to RSV infection

Application

11.1. The Committee reviewed a supplier and clinician application for nirsevimab (Beyfortus) for preventing RSV lower respiratory tract disease in the following groups:

11.1.1. Neonates and infants during their first RSV season, and

11.1.2. Children up to 24 months entering a second RSV season, who remain at high risk.

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

Recommendation

11.3. The Committee **recommended** that nirsevimab be listed with a **high priority** for all infants at birth or in their first RSV season, and for high-risk infants entering their second RSV season, within the context of vaccines and immunisation, subject to the following eligibility criteria.

For administration to infants who are in, or are entering, their first RSV season (March-July):

1. Either:
    1.1. Both:
        1.1.1. Infant was born in the last 12 months; and
        1.1.2. One dose during or approaching their first RSV season August); or
    1.2. All of the following:
        1.2.1. Child was born within the last 24 months; and
        1.2.2. One dose within their second RSV season (Autumn–Spring); **and**
        1.2.3. Any of the following:
            1.2.3.1. Severe combined immune deficiency (not transplanted) or inborn error of immunity increasing susceptibility to life-threatening respiratory viral infection (including IFNAR deficiencies), confirmed by a paediatrician or immunologist**; or**
            1.2.3.2. Severe lung, airway, neurological or neuromuscular disease that requires ongoing, life-sustaining ventilatory/respiratory support (including home oxygen within the last 12 months) in the community; or
            1.2.3.3. Both:
                1.2.3.3.1. Haemodynamically significant heart disease; and
                1.2.3.3.2. Any of the following:

1.2.3.3.2.1. Unoperated simple congenital heart disease with significant left to right shunt that requires heart failure medication, and/or has significant pulmonary hypertension); or
1.2.3.3.2.2. Unoperated or surgically palliated complex congenital heart disease; or
1.2.3.3.2.3. Severe pulmonary hypertension; or
1.2.3.3.2.4. Left ventricular (LV) failure.

11.4. In making this recommendation, the Committee noted the significant health need among infants, as RSV is the leading cause of hospital admission for infants and young children in New Zealand.

11.4.1. The Committee further noted that the incidence of RSV in New Zealand is the highest globally and emphasised the inequities observed within the population.

11.4.2. The Committee noted the considerable annual RSV burden on general practice (GP), emergency departments (EDs), hospitals and intensive care units (ICUs).

11.4.3. In addition, the Committee observed that nirsevimab is a once in a generation medicine associated with a substantial reduction in medically attended RSV and bronchiolitis.

Discussion

Māori impact

11.5. The Committee discussed the potential impact of funding nirsevimab for the prevention of RSV in children on Māori health areas of focus | Hauora Arotahi and Māori health outcomes.

11.6. The Committee noted major inequity exists for Māori, as well as Pacific peoples and those living in areas of highest deprivation (NZDep 9–10). The Committee considered that, if funded, the delivery of nirsevimab should be designed to ensure equitable access for all infants.

Populations with high health needs

11.7. The Committee discussed the health need(s) of RSV among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs. The Committee discussed the impact of funding nirsevimab and noted that the ethnic and socioeconomic inequalities are considerable.

11.7.1. The Committee noted that Māori, Pacific peoples and children living in areas of highest deprivation (NZDep 9–10) independently increased the risk of RSV-associated hospitalisation among young children in New Zealand (Prasad, et al. Epidemiol Infect. 2019;147:e246). The Committee further noted that these factors are additive.

Background

11.8. The Committee noted that nirsevimab is a recombinant human IgG1 kappa monoclonal antibody that binds the F1 and F2 subunits of the RSV fusion (F) protein at a highly conserved epitope, stabilising the protein in its prefusion conformation thereby preventing viral entry into host cells.

11.8.1. The Committee noted nirsevimab employs weight-based dosing for children entering their first RSV season; 50mg in children weighing less than 5kg and 100mg in those 5kg and over. The Committee further noted nirsevimab

employs a fixed standard dose of 200mg for high-risk children entering their second RSV season.

Health need

11.9. The Committee noted that, for the general infant population in New Zealand, RSV-related disease is predominantly managed with supportive care, and the unmet health need remains substantial. The Committee further noted that bronchiolitis, approximately two thirds of which is attributable to RSV, is the most common reasons for hospital admission in young children in their first year of life in New Zealand. The Committee further noted that palivizumab prophylaxis is available for a small cohort of very high-risk infants

11.10. The Committee was made aware of the Respiratory Virus Hospitalization Surveillance Network (RESP-NET) dashboard from the Centers for Disease Control and Prevention (CDC, 2025) and noted the weekly rates of RSV-associated hospitalisations for children ≤12 months and adults aged ≥65 years (2023-2024), compared to hospitalisations related to COVID-19, influenza, and combined.

11.10.1. The Committee noted RSV hospitalisations in infants was four times greater than the rest of the population, highlighting the significant burden in children under 12 months of age.

11.11. The Committee was made aware of (Guo, et al. Nat Commun. 2025;16(1):6109), a study which developed a Bayesian model and web-based prediction tool to estimate RSV hospitalisation risk by infant age and birth month.

11.11.1. The Committee noted this study demonstrated that most RSV-related hospitalisations occurred under six months of age (peaking at two months), with a long tail extending up to and beyond 12 months of age.

11.12. The Committee noted (Prasad, et al. Epidemiol Infect. 2019;147:e246), a prospective, observational study, which used active surveillance of hospitalised children (< 5 years of age) in Auckland, New Zealand, with acute respiratory infection (ARI) during winter seasons (2012–2015), to estimate the incidence of laboratory-confirmed RSV hospitalisations, stratified by age, ethnicity, and socio-economic status (SES).

11.12.1. The Committee noted over the study period 5,309 ARI hospitalisations among children <5 years, of which 3,923 tested, 1,597 (40.7%) tested RSV-positive.

11.12.2. The Committee noted the highest incidence of RSV hospitalisation was among infants <3 months old (35.1 per 1,000 children), with risk decreasing with age. Infants <3 months were almost 30 times more likely to be hospitalised with RSV than children aged 2 to <5 years; even in the second year of life, the risk remained about 5 times higher than in older children.

11.12.3. The Committee noted children of Māori or Pacific ethnicity, and those living in the most deprived SES areas, had significantly higher rates of RSV hospitalisation. After adjustment, Māori children had a rate ratio (RR) of 4.0 (95% CI 3.4–4.7), Pacific children RR 2.9 (95% CI 1.0–1.6), compared with European/other ethnicities and least deprived areas.

11.13. The Committee noted findings from Prasad et al. (Prasad, et al. Epidemiol Infect. 2018;146:1861-69) which analysed hospitalisation for acute lower respiratory infection in children under the age of 2 years in Auckland, from 2012–2015.

11.13.1. The Committee noted that RSV was detected in 48% of cases and was associated with an increased risk of ICU admission (adjusted RR 1.55, 95% CI 1.00–2.39), particularly in infants under 5 months, while the risk decreased with age.

11.14. The Committee noted that, at Wellington Hospital between 2012 and 2014, 49% of viral bronchiolitis admissions in children under 2 years were RSV-positive, with 84% of admitted cases tested for RSV (Foley, et al. J Paediatr Child Health. 2019;55(5):528-32).

11.15. The Committee noted that New Zealand does not routinely test for RSV, and therefore robust epidemiological data is lacking outside of (Southern Hemisphere Influenza, Vaccine Effectiveness, Research & Surveillance) SHIVERS.

11.15.1. The Committee considered it appropriate to assume a mortality risk associated with infants who contract RSV. The Committee noted that Australian and New Zealand data suggest approximately 0.4% of ICU admissions result in mortality, while acknowledging that this figure is likely to be an underestimate.

11.16. The Committee considered that, in the absence of routine RSV testing, bronchiolitis (inflammation of the small passages of the lungs) hospitalisations can be used as a proxy for estimating the burden of RSV-related hospitalisations in infants and young children.

11.16.1. The Committee noted that bronchiolitis is the leading cause of hospital admission for infants in their first year of life, and is also a major reason for hospitalisation among children overall (Dalziel, et al. Lancet. 2022;400(10349):392-406). The Committee considered that at least two thirds of bronchiolitis is due to RSV.

11.16.2. Members considered that approximately 1 in 11 to 1 in 12 New Zealand children are admitted to hospital with bronchiolitis during their first year of life, each year. The Committee noted this figure likely underestimates the true burden, as it does not include infants assessed and discharged from emergency departments within three hours.

11.16.3. The Committee noted that management for bronchiolitis is supportive, focusing on hydration and respiratory support such as oxygen therapy when needed (Dalziel, et al. Lancet. 2022;400(10349):392-406), (Loveys, et al. J Paediatr Child Health. 2025;61(10)1549-65).

11.17. The Committee noted that each winter, bronchiolitis places significant strain on paediatric services across New Zealand, including increased bed occupancy pressures in EDs, cancellation of elective surgeries, and paediatric ICUs operating over capacity. Members noted similar pressures are experienced in primary care.

11.17.1. The Committee considered whether the assumed proportions of patients treated in each setting were reasonable (50% treated as inpatients, 10.1% of whom are treated in ICU, 27.5% in primary care, and the remainder in ED). The Committee noted that patient pathways are not a simple model of GP, ED or hospital care, but rather involve combinations such as GP with or without ED and hospital, or ED with or without hospital. The Committee further noted that the estimates, based on Prasad, et al. 2019 and Moore, et al. 2020 were not unreasonable (Prasad, et al. Epidemiol Infect. 2019;147:e246); (Moore, et al. J Infect Dis. 2020;222(1):92-101).

11.17.2. General practice has significant burden every winter, referring moderate to severe cases to secondary care.

11.18. The Committee was made aware of the Australasian Bronchiolitis Guideline: 2025 Update (Borland, et al. J Paediatr Child Health. 2025;61(8):1197-1215) and acknowledged that both international and local guidelines advise against viral testing for bronchiolitis, as it offers no benefit for individual clinical care and adds unnecessary cost.

11.19. The Committee was made aware of the Cure Kids State of Child Health Report (Tustin & Fleming. State of Child Health in Aotearoa New Zealand 2023) and noted that the rates of hospitalisation for bronchiolitis were highest for children under one year, accounting for 41% of admissions in this age group.

11.19.1. The Committee noted that New Zealand has some of the highest rates of hospitalisations for bronchiolitis internationally.

11.19.2. The Committee further noted in this report, that hospitalisation rates for bronchiolitis are highest among children under 12 months, at approximately 70–90 per 1,000 (7–9%). For those aged 12–23 months, rates drop substantially to around 8–15 per 1,000 (0.8–1.5%), and for 24–35 months, rates are very low at 1–3 per 1,000 (0.1–0.3%).

11.19.3. The Committee noted that hospitalisation rates for respiratory conditions among 0–19-year-olds increased with socioeconomic deprivation, with the highest rates observed in Quintile 5 (most deprived). Pacific children consistently had the highest hospitalisation rates across all quintiles, peaking at around 45 per 1,000 in Quintile 5, followed by Māori at approximately 35 per 1,000. Asian/Indian and European/Other groups had substantially lower rates (around 10–18 per 1,000), with only modest increases across deprivation levels. These findings highlight significant inequities by ethnicity and deprivation.

11.19.4. While mortality rates from this infection/illness are low the huge burden of morbidity is clearly the major issue for RSV. A vaccine that manages this burden would be expected to be very cost effective – example of post covid as the borders open with Australia we had a massive winter surge of RSV.

11.20. The Committee was made aware of (Schlapbach, et al. Eur Respir J. 2017;49(6):1601648), an observational, retrospective cohort study analysing ICU and PICU data from Australian and New Zealand between 2002–2014.

11.20.1. The Committee noted that bronchiolitis accounted for 27.6% (9,628/34,829) of all non-elective paediatric admissions during this period.

11.20.2. The Committee noted that RSV status was not routinely collected; however, among those tested, more than two-thirds were RSV positive, and RSV positivity was associated with a significantly increased likelihood of intubation (OR 1.56; 95% CI 1.39–1.78).

11.20.3. The Committee noted the study reported a mean ICU length of stay of approximately 3.5 days, a mean hospital stay of around 11 days, and a mortality rate of 0.4%.

11.20.4. The Committee noted known clinical risk factors such as prematurity, chronic lung disease (CLD), congenital heart disease (CHD), chronic respiratory disease, and chronic neurological conditions were present in only 28.9–36.5% of ICU admitted cases, indicating that severe bronchiolitis requiring ICU admission often occurs in otherwise healthy infants and that a strategy of only targeting those most at risk would fail the majority of children with severe disease.

11.21. The Committee was made aware of (Tang, et al. Crit Care Resusc. 2025;27(2):100113), an observational study using data from the short period incidence study of severe acute respiratory infection (SPRINT SARI) in 38 Australian ICUs from 2022–2024. The Committee noted RSV was present in 62% of all paediatric SARI cases.

Health benefit

11.22. The Committee noted that the evidence presented was of moderate to high quality. The Committee further noted that randomised controlled trials (RCTs), including pragmatic RCTs were of high quality, but only included a small number of New Zealand participants. The Committee noted real-world effectiveness studies were of moderate quality, with results that were consistent across studies.

11.23. The Committee noted that the available evidence was generalisable and relevant to the New Zealand context. The Committee further noted that, although only a small number of New Zealand-based participants were included in pivotal trials, these studies involved a wide range of countries with consistent effects observed across settings.

11.24. The Committee noted the MELODY phase 3 clinical trial (Hammit, et al. N Engl J Med. 2022;386:837-846), a randomised, double-blind, placebo-controlled study evaluating the efficacy and safety of nirsevimab for the prevention of RSV-associated lower respiratory tract infection (LRTI) in healthy infants.

11.24.1. The Committee noted the trial design, which included 1,490 infants randomised in a 2:1 ratio to receive either a single intramuscular injection of nirsevimab (50 mg if <5 kg, or 100 mg if ≥5 kg; n=994) or placebo (n=496).

11.24.2. The Committee noted the primary efficacy outcome was the incidence of medically attended RSV-associated LRTI (MA-RSV-LRTI) through 150 days post-injection. The Committee noted nirsevimab recipients had a lower incidence (1.2%) compared to placebo (5.0%), demonstrating an overall efficacy of 74.5% (95% CI: 49.6–87.1; P<0.001). The Committee noted rates of RSV in New Zealand would be significantly higher than 5.0%.

11.24.3. The Committee noted that although the hospitalisation efficacy estimate was 62.1% (95% CI: -8.6–86.8; P<0.07), this did not reach statistical significance (p<0.07).

11.24.4. The Committee noted efficacy was demonstrated across key subgroups including geographic hemisphere, RSV sub-types and age categories.

11.24.5. The Committee noted no significant safety concerns were identified, with the overall incidence of adverse events and serious adverse events comparable between nirsevimab and placebo groups, and no serious adverse events considered related to the trial regimen.

11.24.6. The Committee noted the number needed to treat (NNT) to prevent one MA-RSV-LRTI was 12, and the NNT to prevent one hospitalisation was 53.

11.25. The Committee noted Griffin et al, an earlier phase trial (Phase 2b) within the MELODY programme (Griffin, et al. N Engl J Med. 2020;383:415-425). The Committee noted this study was a double-blind, placebo-controlled trial which included three New Zealand sites.

11.25.1. The Committee noted the trial design, which included 1,453 healthy pre-term infants (29–34 weeks gestation), who, according to local or national guidelines, were not recommended to receive palivizumab. Infants were randomised in a 2:1 ratio to receive either a single intramuscular injection of nirsevimab (50 mg; n=969) or placebo (n=484).

11.25.2. The Committee noted the primary efficacy outcomes was the incidence of MA-RSV-LRTI through 150 days post-injection. The Committee noted nirsevimab recipients had a lower incidence (2.6%) compared to placebo (9.5%), demonstrating an overall efficacy of 70.1% (95% CI: 52.3–81.2); P<0.001.

11.25.3. The Committee noted that nirsevimab reduced the incidence of hospitalisation due to RSV by 78.4% compared with placebo (95% CI: 51.9–90.3; p<0.001).

11.25.4. The Committee noted no significant safety concerns were identified, with the overall incidence of adverse events and serious adverse events comparable between nirsevimab and placebo groups, and no serious adverse events considered related to the trial regimen.

11.26. The Committee was made aware of (Dagan, et al. J Pediatric Infect Dis Soc. 2024;13(2):144-47), a follow-up of the MELODY trial in the second RSV season. The Committee noted a theoretical concern about antibody-dependent enhancement (ADE), where antibodies could worsen disease upon later exposure.

11.26.1. The Committee noted this study demonstrated no evidence of enhanced disease in the second RSV season, as the incidence and severity of RSV LRTI were similar between nirsevimab and placebo groups. Of note, during the closure of the boarders associated with COVID-19 there was a dramatic reduction in RSV cases. Following the opening of the boarders there was a large surge in RSV across the healthcare spectrum (GP, ED, inpatient wards, ICU) in infants previously not exposed. Thus there was the theoretical concern that protecting infants in the first year of life could result in increased infection in the second year of life; this has not been seen in any RCT or real-world data.

11.27. The Committee was made aware of the final results from the MELODY trial (Muller, et al. N Engl J Med. 2023;388(16):1533-34), which demonstrated that a single dose of nirsevimab provided consistent and substantial protection against medically attended and hospitalised RSV-associated LRTI, with efficacy maintained across different subgroups.

11.28. The Committee noted the MEDLEY trial, season 1 data (Domachowske, et al. N Engl J Med. 2022;386:892-894), a phase 2–3 trial, which evaluated the safety of nirsevimab in high-risk infants, including those with congenital heart disease (CHD), chronic lung disease (CLD), or born at ≤35 weeks gestation and eligible for palivizumab.

11.28.1. The Committee noted that 925 infants were enrolled and randomised to receive either nirsevimab plus monthly placebo or palivizumab monthly, with safety and pharmacokinetics monitored over 361 days. The Committee noted that the study was not designed for direct comparison of key clinical outcomes between groups.

11.28.2. The Committee noted that nirsevimab demonstrated a similar safety profile to palivizumab, with a low incidence of adverse events and antidrug antibodies, and no serious treatment-related events reported.

11.28.3. The Committee noted that pharmacokinetic levels of nirsevimab were consistent with efficacy.

11.29. The Committee noted the MEDLEY trial, season 2 data (Domachowske, et al. J Pediatric Infect Dis Soc. 2023;12:477), which evaluated the safety of re-dosing nirsevimab in infants with CHD or CLD entering their second year of life.

11.29.1. The Committee noted that 262 out of 310 eligible infants with CHD/CLD continued into the second year of the study, with palivizumab recipients re-randomised.

11.29.2. The Committee noted that the study compared a single 200 mg dose of nirsevimab plus four monthly placebo injections to five monthly doses of palivizumab, with safety and pharmacokinetics monitored over 361 days. The

Committee noted this study was also not designed for direct comparison of key clinical outcomes.

11.29.3. The Committee noted that nirsevimab demonstrated a similar safety profile to palivizumab, with a low incidence of antidrug antibodies and no serious treatment-related events.

11.29.4. The Committee noted that pharmacokinetic levels of nirsevimab were consistent with efficacy.

11.29.5. The Committee noted there were no major safety concerns identified in the second year of dosing, but noted that the palivizumab group was relatively small (n=42).

11.30. The Committee noted (Simões, et al. Lancet Child Adolesc health. 2023;7:180-89), a pooled analysis of the phase 2b and phase 3 MELODY trials, which evaluated the efficacy of nirsevimab for the prevention of RSV-LRTI in infants born at ≥29 weeks gestational age, and extrapolated efficacy to high-risk infants (with CHD, CLD or extreme prematurity) using pharmacokinetic data.

11.30.1. The Committee noted that infants received weight-banded dosing, and the primary endpoint was the incidence of MA-RSV-LRTI to 150 days post-dose.

11.30.2. The Committee noted that nirsevimab demonstrated high efficacy compared to placebo, with a relative risk reduction (RRR) of 79.5% (95% CI 65.9–87.7) for MA-RSV-LRTI, 77.3% (50.3–89.7) for hospital admission due to RSV LRTI, and 86.0% (62.5–94.8) for every severe RSV LRTI.

11.30.3. The Committee noted that nirsevimab also reduced MA-LRTI of any cause (RRR 35.4%) and hospital admission for respiratory illness of any cause (RRR 43.8%), as well as outpatient visits for LRTI and antibiotic prescriptions.

11.30.4. The Committee noted that efficacy was consistent across subgroups.

11.30.5. The Committee noted that pharmacokinetic data supported extrapolation of efficacy to high-risk infants, with >80% of infants with CLD, CHD or extreme prematurity achieving target serum exposures.

11.31. The Committee was made aware of (Mankad, et al. Pathogens. 2024;13(6):503), a pooled analysis of three randomised controlled trials. The Committee noted that a single dose per season of nirsevimab had a favourable safety profile, with adverse events being mild or moderate and similar across treatment groups.

11.32. The Committee noted the HARMONIE trial (Drysdale, et al. N Engl J Med. 2023;389:2425-35), a phase 3b, pragmatic randomised study, which included 8,058 infants across the UK, France and Germany, all born at ≥29 weeks gestation.

11.32.1. The Committee noted that the infants received a single intramuscular dose of nirsevimab or standard care, with analysis triggered by exceeding a predetermined number of events.

11.32.2. The Committee noted that the mean age of participants was 4.5 months (24% neonates), with 14% born preterm.

11.32.3. The Committee noted that RSV hospitalisation occurred in 0.3% of the nirsevimab group compared to 1.5% in the control group. The Committee noted that nirsevimab demonstrated an overall efficacy of 83.2% (95% CI 67.8–92.0) in preventing RSV hospitalisation and 75.7% (32.8–92.9) efficacy against RSV cases where oxygen saturation was less than 90%.

11.32.4. The Committee noted that efficacy was consistent across countries and subgroups.

11.32.5. The Committee noted that no new safety concerns were identified.

11.32.6. The Committee concluded that nirsevimab is effective in preventing RSV hospitalisations in real-world settings, with a favourable safety profile.

11.32.7. The Committee noted (Munro et al. Lancet Child Adolesc Health. 2025;9:404-412), the 6-month follow-up of the HARMONIE trial (180 days after randomisation), which had similar results to the initial analysis. The Committee noted that nirsevimab continued to demonstrate high efficacy in preventing RSV hospitalisations and severe RSV disease in infants, with sustained protection observed over the 6-month period.

11.33. The Committee noted the results of a systematic review and meta-analysis (Sumsuzzman, et al. Lancet Child Adolesc Health. 2025;9:393-403), which included 32 cohort and case-control studies from five countries, focusing on infants aged 12 months or younger.

11.33.1. The Committee noted that pooled analyses demonstrated nirsevimab was associated with a substantial reduction in RSV-related outcomes:

- RSV hospitalisation: OR 0.17 (95% CI 0.12–0.23)
- ICU admission: OR 0.19 (0.12–0.29)
- LRTI incidence: OR 0.25 (0.19–0.33)

11.33.2. The Committee noted that there was no significant difference in length of hospital stay between nirsevimab and control groups (weighted mean difference 0.01 days, 95% CI -0.63–0.65).

11.33.3. The Committee noted that while some heterogeneity was observed based on country, the effect of nirsevimab was consistent across studies.

11.33.4. The Committee noted that the real-world effectiveness of nirsevimab in preventing RSV hospitalisation, ICU admission, and LRTI aligns closely with clinical trial data, supporting its use in infant immunisation programmes.

11.34. The Committee noted the study by Wadia, et al. (Wadia, et al. J Infect. 2025;90:106466), an observational case-control study conducted in Western Australia during the 2024 RSV season, evaluating the effectiveness of nirsevimab in preventing RSV-associated hospitalisation in infants and high-risk children.

11.34.1. The Committee noted that the study enrolled 284 nirsevimab-eligible children (184 RSV-positive cases, 100 test-negative controls) from three major hospitals in Perth between April and October 2024.

11.34.2. The Committee noted that nirsevimab effectiveness was assessed using conditional logistic regression, adjusting for age, sex, ethnicity, prematurity, medical risk factors, and site/week of enrolment.

11.34.3. The Committee noted that the adjusted effectiveness of nirsevimab against RSV-associated acute respiratory infection (ARI) hospitalisation was 88.2% (95% CI: 73.5–94.7).

11.34.4. The Committee noted that effectiveness against RSV hospitalisation requiring oxygen or respiratory support was 61.8% (95% CI: 16.4–82.5).

11.34.5. The Committee noted that there was no significant difference in illness severity (PICU admission, ventilation, length of stay) between immunised and unimmunised RSV-positive cases.

11.34.6. The Committee noted that breakthrough RSV infections occurred in 22.8% of immunised RSV-positive cases, with no significant demographic or clinical differences compared to unimmunised cases.

11.34.7. The Committee noted that nirsevimab coverage was higher among controls (64%) than cases (22.8%), with the highest coverage in the newborn cohort (85%) and lower in children entering their second RSV season (30%).

11.34.8. The Committee noted that the effectiveness estimate aligns with data from Northern Hemisphere studies and recent meta-analyses, supporting the generalisability of findings.

11.34.9. The Committee noted that the study's observational design may introduce bias, but confounders were adjusted for; effectiveness estimates were limited to hospitalisation outcomes, and genomic analyses of breakthrough cases are ongoing.

11.35. The Committee was made aware of a Western Australian population-based analysis (Bloomfield, et al. Med J Aust. 2025;222(11):568-79), which compared RSV-associated hospitalisations in infants before and after nirsevimab rollout. The Committee noted that 71% of eligible infants received nirsevimab and the programme was associated with a 57% reduction in RSV hospitalisations in infants under 1 year of age (NNT = 43), with no change in hospitalisations observed in older children.

11.35.1. The Committee further noted that the universal infant nirsevimab programme was acceptable and supports the strategy of catch-up and at-birth RSV immunisation.

11.36. The Committee was made are of (Carcione, et al. PIDJ. 2025;44(5):174-76) an active post-marketing safety surveillance study conducted in Western Australia (April–July 2024), which used SMS-based surveys to assess adverse events following nirsevimab immunisation in children.

11.36.1. The Committee noted that 23.2% reported any reaction (higher with coadministration of other vaccines), most commonly fatigue, local reaction, fever or gastrointestinal symptoms; only 1.5% sought medical care and no serious adverse events were reported.

11.37. The Committee noted a retrospective observational study by Torres et al. (Torres, et al. Lancet Infect Dis. 2025:S1473-3099(25)00233-6) of Chile's 2024 national nirsevimab immunisation strategy, which used a birth plus catch-up approach during the RSV season and focused on infants aged 0–12 months (primary) and <24 months (secondary).

11.37.1. The Committee noted that 94% of eligible infants received nirsevimab, with effectiveness estimates of 76.4% (95% CI: 72.6–79.7) against RSV-related LRTI hospitalisation (NNT = 35), 84.9% (79.5–89.0) against RSV-related ICU admission and 47.9% (44.4–51.2) against all-cause hospitalisation.

11.37.2. The Committee further noted that real-world effectiveness aligned with clinical trial data and that the programme was highly acceptable.

11.38. The Committee further noted the following international real-world studies:

11.38.1. Perramon-Malavez, et al. Lancet Reg Health. 2025;55:101334

11.38.2. Touati, et al. Ann Intensive Care. 2025;15(1):56

11.38.3. Martínez, et al. Paediatrics. 2024;154(4):e2024066584

11.38.4. Vazquez-Lopez, et al. Pediatr Emerg Care. 2025;41(5):365-371

11.39. The Committee considered whether it was appropriate to assume that nirsevimab and palivizumab are of similar efficacy. The Committee noted that both agents have similar pharmacokinetic and safety profiles, as demonstrated in the MEDLEY study, although no adequately powered study has directly compared them for clinically important endpoints. The Committee further noted that real-world use in Spain, France, Japan, the USA, the UK and Australia has not indicated any differences in efficacy.

11.40. The Committee, when considering broader health benefits of nirsevimab for whānau and wider society, noted that reduced disease in elderly populations may become evident as further data matures.

11.40.1. The Committee also noted an interrupted time-series analysis from France (Fafi, et al. Clin Infect Dis. 2025:ciaf564), which found that RSV immunisation in infants led to a significant reduction in rates of acute otitis media (AOM). The Committee considered that more studies examining indirect and additional benefits of RSV immunisation are likely to become available over time.

11.40.2. The Committee considered it appropriate to assume that RSV requiring inpatient treatment is associated with an increased risk of asthma or long-term wheezing. The Committee noted that evidence supports this association, including studies reporting a relative risk of 2.5 for subsequent asthma following bronchiolitis and an odds ratio of 2.5 for asthma following RSV-LRTI (Wang, et al. BMJ Open. 2021;11:e043956); (Brunwasser, et al. Lancet Respir Med. 2020;8(8):795-806).

11.40.3. The Committee considered the applicant's estimate reasonable that 31% of infants with RSV would develop asthma or wheezing. The Committee further considered that the estimates were reasonable that 87% of those who wheeze would continue to do so in the following year, and that 55% would still be wheezing two years later.

11.40.4. The Committee considered that RSV infection was an indication towards COPD and cardiac or respiratory related mortality later in life.

Suitability

11.41. The Committee considered that universal access to nirsevimab would be far more efficient and equitable than targeted high-risk access, as it streamlines programme delivery and ensures all infants receive protection as standard care.

11.41.1. The Committee noted that nirsevimab could be administered to infants upon hospital discharge for their first RSV season, and for those at high-risk in their second RSV season could be delivered through general practice, Plunket, or mobile clinics.

11.41.2. The Committee noted that for the first RSV season, nirsevimab could be administered concomitantly with vitamin K at birth, which would maximise equity by ensuring all infants receive protection regardless of risk factors or access barriers.

11.41.3. The Committee acknowledged that approximately 6% of births in New Zealand occur at home and noted that midwifery-led clinics and home immunisation services would play an important role in ensuring access to nirsevimab for these infants.

11.42. The Committee noted that, to achieve maximum efficacy during the period of highest RSV risk, the timing of nirsevimab administration is important; for example, a healthy infant born in December would need to re-attend the general practitioner around March to receive nirsevimab and ensure adequate protection for the RSV season.

Cost and savings

11.43. The Committee noted that adopting a universal approach to nirsevimab administration for infants in their first year of life, when RSV risk is greatest, rather than limiting to a high-risk subgroup, would significantly reduce the resources required for programme delivery, as all eligible infants would receive treatment as part of standard care.

11.43.1. The Committee further noted that, for example, in the Waikato District, significant nursing resources are currently required to deliver palivizumab to a small number of eligible infants, with challenges including the need to follow-up families, make appointments, and manage medically fragile infants, many of whom live in regional or rural areas far from health services. The Committee considered that universal administration would simplify delivery and improve equity of access.

11.44. The Committee noted that, should nirsevimab be funded exclusively for high-risk infants, it is estimated that approximately 1,400 infants and toddlers would be eligible annually to receive treatment. The Committee noted this estimate is based on the assumption that the definition of 'high-risk' aligns with those currently eligible for palivizumab. The Committee expressed a strong preference for universal funding rather than a targeted approach.

11.45. The Committee considered that if nirsevimab were funded for all infants in year one, regardless of risk factors, uptake among infants born during the RSV season (who would receive the vaccine in hospital) would likely be comparable to vitamin K administration, which is approximately 95% in New Zealand. The Committee noted that uptake in this subgroup would be expected to exceed 80%, but would be unlikely to surpass 95%.

11.45.1. The Committee considered that uptake for infants born outside of the RSV season was likely to also be high though would be lower than uptake at birth. Infants born outside of the RSV season would likely receive the vaccine at a 6-week, 3-month, or 5-month primary care visit and would not require an additional visit for vaccine administration. The Committee considered that uptake was likely to improve over time as nirsevimab became established in the vaccine schedule.

11.45.2. The Committee considered that palivizumab uptake was not an appropriate indicator for nirsevimab uptake as the hospital visits and multiple administrations would be a barrier not present with nirsevimab.

11.46. The Committee noted that trial data indicate nirsevimab significantly reduces the risk of hospitalisation and considered that there is no biological reason to assume it would not also reduce mortality. The Committee further noted that efficacy rates of 70–80% and a reduction in ICU admissions would be expected to result in a proportionate reduction in mortality. The Committee noted that even a small mortality benefit would be clinically and economically meaningful.

11.47. The Committee noted that universal funding for newborns would help to improve newborn enrolment and registration into AIR, as that would be the first vaccine delivered and recorded after the birth (except in infants of Hep B carrier mothers).

Funding criteria

11.48. The Committee noted that it would be more appropriate for nirsevimab to be managed and distributed as a vaccine, and delivered as part of the National Immunisation Schedule (NIS), as opposed to managing and distributing in the same way as other funded medicines.

11.49. The Committee expressed a strong preference for nirsevimab to be considered as a universal vaccination for the prevention of RSV in infants, rather than as a one-dose replacement for five doses of palivizumab in the high-risk subgroup.

11.49.1. The Committee further noted that appropriately powered trials comparing nirsevimab to palivizumab for clinically meaningful endpoints do not exist.

11.50. The Committee further noted that targeted vaccine campaigns in New Zealand have historically failed to reach all eligible high-risk children.

11.50.1. The Committee noted that the majority of infants admitted to intensive care with RSV in New Zealand do not have the traditional risk factors for eligibility for palivizumab (such as prematurity, CLD, or CHD).

11.51. The Committee noted a systematic review (Loveys, et al. J Paediatr Child Health. 2025;61(10)1549-65), which examined risk factors for bronchiolitis and RSV infection in infants <12 months in Australia and New Zealand (N=895,276; 10 studies). The Committee noted that the following risk factors were identified as relevant and are prevalent:

- Gestational age <37 weeks;
- Younger chronological age at presentation;
- Prenatal and/or postnatal exposure to tobacco smoke;
- Reduced breastfeeding exposure;
- Faltering growth/ slow weight gain (failure to thrive);
- Comorbidities including congenital heart disease, chronic lung disease, chronic neurological condition, congenital diaphragmatic hernia, trisomy 21, and other genetic disorders;
- Being an indigenous infant;
- Being an economically disadvantaged infant;
- Timing and severity of illness onset at hospital presentation.

11.52. The Committee noted that Australia has implemented maternal RSV immunisation, which is active immunisation (at 32-36 weeks' gestation), whereas nirsevimab is passive immunisation given to infants; maternal vaccination provides transplacental protection for around six months, while nirsevimab provides season-long protection, so where maternal vaccination is used the incremental need for infant nirsevimab may be reduced.

11.52.1. The Committee further noted that, in Australia, infants who have received maternal vaccination during pregnancy are ineligible for nirsevimab in their first year of life. The Committee considered that this approach would need to be taken into account when planning future RSV vaccination programmes in New Zealand.

11.52.2. The Committee noted that maternal immunisation rates for vaccines currently funded in Aotearoa New Zealand are at best 50%.

Summary for assessment

11.53. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for nirsevimab if it were to be funded in New Zealand for prevention of RSV in infants. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that requested by the

applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

<table>
<tr><td>Population</td><td colspan="2">The Committee has proposed that both groups below be funded together. These have been split in the table to more clearly illustrate the difference in intervention, comparator, and relative outcome for each group</td></tr>
<tr><td></td><td>All infants in or approaching their first RSV season</td><td>High risk subgroup of infants in or approaching their first or second RSV season</td></tr>
<tr><td></td><td>All infants not otherwise included in the high-risk group</td><td>Infants currently eligible for funded Palivizumab, ie:
Infants born ≤32wGA aged ≤12 months and entering their first RSV season
Infants with congenital heart disease (CHD), chronic lung disease (CLD), or immunodeficiency aged ≤24 months and entering their first or second RSV season.</td></tr>
<tr><td>Intervention</td><td>During the infant’s first RSV season
If < 5kg, nirsevimab 50 mg IM (thigh), once per season
If ≥ 5kg, nirsevimab 100 mg IM, once per season</td><td>Season 1
If < 5kg, nirsevimab 50 mg IM (thigh), once per season
If ≥ 5kg, nirsevimab 100 mg IM, once per season
Season 2
Nirsevimab, 2x 100 mg doses (IM) in a single administration</td></tr>
<tr><td>Comparator(s)
(NZ context)</td><td>No passive or active immunisation against RSV.</td><td>Palivizumab 15mg/kg per month of RSV season 1 and season 2 (seasons typically last 5 months)</td></tr>
<tr><td>Outcome(s)</td><td>A reduction in the following due to RSV infection or bronchiolitis:
- GP RSV infection/bronchiolitis
- ED presentations RSV RTI/bronchiolitis
- Hospitalisation RSV RTI/bronchiolitis
- PICU admissions RSV RTI/bronchiolitis
- Death from RSV RTI/bronchiolitis
- Parental time off work due to caring for infant with RSV RTI/bronchiolitis</td><td>Nirsevimab demonstrates similar efficacy to palivizumab across incidence and hospitalisation outcomes in both pre-term infants and infants with CLD/CHD</td></tr>
<tr><td colspan="3"><u>Table definitions:</u>
Population: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup)
Intervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation).
Comparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation).
Outcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.</td></tr>
</table>

12. RSVPreF3 Vaccine (Arexvy) for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older – resubmission

Application

12.1. The Committee reviewed the resubmission for RSVPreF3 Vaccine (Arexvy) for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older.

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

Recommendation

12.3. The Committee **recommended** RSVPreF3 Vaccine (Arexvy) be listed with a **medium priority**, within the context of vaccines and immunisation, for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older.

12.4. The Committee **recommended** RSVPreF3 Vaccine (Arexvy) be listed with a **high priority**, within the context of vaccines and immunisation, for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes in high-risk adults aged 60 to 74 years with eligible comorbidities and all adults 75 years of age and older.

1. Any of the following:
   - 1.1 A single dose for individuals aged 75 years and over who has not received an RSV vaccine within the last five years; or
   - 1.2 A single dose for individuals at higher-risk aged 60–74 years (inclusive) with any of the following factors or comorbidities:
     - 1.2.1 The person resides in an Aged Residential Care Facility, or
     - 1.2.2 Cardiac or pulmonary disorders (including COPD), asthma, cystic fibrosis or conditions affecting ability to clear airway secretions); or
     - 1.2.3 Diabetes mellitus or other metabolic diseases; or
     - 1.2.4 Moderate or severe immunodeficiency; or
     - 1.2.5 Chronic renal disease; or
     - 1.2.6 Chronic liver disease; or
     - 1.2.7 Chronic neurological conditions.

12.5. In making these recommendations, the Committee:

12.5.1. Noted that RSV infection causes a significant burden of disease in adults aged 60 years and older, with high rates of acute respiratory illness, hospitalisation, and complications. The Committee further noted this burden is particularly pronounced in those with underlying health conditions and in residential care settings.

12.5.2. Noted that mortality rates from RSV are highest in the oldest age groups, especially those aged 75 years and above.

12.5.3. Noted that RSV vaccination is expected to reduce hospitalisations for lower respiratory tract disease and RSV-related mortality in older adults

Discussion

Populations with high health needs

12.6. The Committee discussed RSV burden and incidence among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs.

12.6.1. The Committee noted the 2024 Acute Respiratory Illness Surveillance Report (New Zealand Institute for Public Health and Forensic Science [PHF Science], 2024). The Committee noted that RSV-associated hospitalisation rates were highest among Māori and Pacific peoples, with pronounced peaks during mid-year, while rates among Asian and other ethnic groups remained comparatively low.

12.6.2. The Committee noted that RSV causes regular outbreaks in aged residential care facilities during the winter season.

Background

12.7. The Committee noted the previous application for RSVPreF3 was deferred in March 2024 and September 2024 due to uncertainties surrounding burden of RSV disease in those over 60 years of age, vaccine efficacy in those over 80 years of age or under 65 years of age with immunosuppression, and revaccination interval.

12.8. The Committee noted that the resubmission of this application included the following updates:

12.8.1. An expanded discussion of RSV disease burden among older adults in New Zealand, including a rationale for comparison with Australia;

12.8.2. Updated efficacy data covering three RSV seasons, along with new evidence demonstrating immunogenicity at 42- and 48-months and additional real-world evidence in high-risk populations.

Health need

12.9. The Committee noted that children have the highest incidence of RSV infection, but typically experience shorter hospital stays and better clinical outcomes compared to older adults. The Committee considered that older adults, particularly those aged 75 years and older, experience significantly longer hospital stays, often twice as long as those for children, higher rates of ICU admission, greater post-discharge care requirements, increased mortality and higher readmission rates (Prasad, et al. PLoS One. 2020;15(6):e0234235); (Saravanos, et al. Med J Aust. 2019;210(10):447-53); (Kenmoe, et al. Curr Opin Infect Dis. 2024;37(2):129-36)

12.9.1. The Committee noted that adults with at least one comorbidity are at significantly higher risk of severe outcomes, including increased rates of hospitalisation, longer admissions and higher mortality from RSV infection (Kenmoe, et al. Curr Opin Infect Dis. 2024;37(2):129-36).

12.10. The Committee noted that the supplier's model estimated approximately 1,700 RSV-associated hospitalisations for Severe Acute Respiratory Infection (SARI) among older adults in New Zealand each year. The Committee further noted that this estimate is based on the original incidence assumptions (5.83 cases per 100 person-years in ≥60 years after correction for under-ascertainment). The Committee considered that this remains the most reliable measure of the clinical and economic impact for this age group.

12.10.1. The Committee noted that the supplier's assumed hospitalisation rates for New Zealand were the same as those used for Australia, estimated at 107/100,000 for adults 60–74 years, rising markedly to ≥256/100,000 in adults ≥75 years of age (unadjusted).

12.10.2. The Committee noted the Acute Respiratory Infection (ARI) RSV hospital incidence rates for 2012–2015 in Auckland was 72.9 (57.4–88.3)/100,000 for 65–79 years and 191 (137.6–244.0)/100,000 for those over the age of 80 years (Prasad, et al. PLoS One. 2020;15(6):e0234235).

12.10.3. The Committee noted the SARI RSV incidence rates for 2012–2019 in Auckland is 20 (16–24)/100,000 for 65–75 years of age, and 39 (33–46)/100,000 in those over the age of 75 years (Boderick, et al. Lancet Reg health West Pac. 2024;51:101221).

12.10.4. The Committee noted that, when considering the validity of RSV incidence estimates for the Auckland region, influenza-like-illness (ILI) testing cannot be relied upon to determine incidence in older populations, as older adults with RSV do not present with fever. The Committee therefore noted that it is difficult to extrapolate data to wider New Zealand. The Committee further noted that, overall, a higher burden RSV burden would be expected in Auckland due to greater population density.

12.11. The Committee noted that the assumption in the supplier's resubmission, that the respiratory burden of RSV in New Zealand is comparable to Australia, may not be appropriate. The Committee considered that the burden of RSV in New Zealand is probably lower, given the availability of existing ARI and SARI SHIVERS data, laboratory data from 2023 and 2024 and lower population density compared to Australia.

12.11.1. Members considered that SARI is not a reliable measure for RSV burden in older adults in New Zealand, as it requires both cough and fever, and older adults with RSV often do not present with fever. Members considered that SARI underestimates the true burden of RSV in this population and that it is necessary to use additional measures and data sources to more accurately assess RSV incidence in older adults.

12.11.2. The Committee expressed interest in reviewing Well Kiwis bridging data, particularly the community-based dataset collected year to year. Members noted that, although this dataset may capture more mild RSV disease, it would provide some further insight into the burden of RSV across all age groups.

12.12. The Committee noted the *Seasonal Respiratory Infection Report* dashboard from Te Toka Tumai, which summarises PCR testing data for respiratory pathogens across three recent seasons at Auckland hospital and Starship.

12.12.1. The Committee noted that COVID-19 accounted for the highest number of positive results early in 2023, with detections declining substantially and becoming minimal by winter 2024. The Committee noted distinct seasonal peaks were observed for influenza A and B, and RSV activity was evident in mid-2025.

12.13. The Committee noted the Laboratory-based Virology Weekly Report, for weeks ending 27 October 2024 and 28 October 2025 (PHF Science, 2025). The Committee noted that this report includes data from approximately 70% of the country, incorporating the Southern Hemisphere Influenza and Vaccine Effectiveness Research and Surveillance (SHIVERS) and general practice reporting, and provides an indication of the burden of respiratory disease in New Zealand.

12.13.1. The Committee noted for the week ending 27 October 2024, 7,287 of 18,387 positive non-influenza respiratory specimens were RSV positive. The Committee noted for the week ending 28 October 2025, 4,563 of 12,491 positive non-influenza respiratory specimens were RSV positive. The Committee noted that this reduction in the number of RSV positive specimens was likely attributed to decreased testing rather than a lower RSV burden.

12.14. The Committee noted that the total number of laboratory-confirmed RSV PCR-positive cases in Australia up to the end of 2024 was 174,764 (Immunisation Coalition, Respiratory Syncytial Virus [RSV] Statistics, 2025). The Committee noted

that the total number of laboratory-confirmed RSV PCR-positive cases in New Zealand up to December 2024 was 10,474, including an estimated 30% missing data (equivalent to 7,332 cases).

12.14.1. The Committee noted that, based on population size, New Zealand would be expected to report approximately 34,952 RSV-positive cases if testing and reporting were equivalent to Australia.

12.14.2. The Committee noted that Australia reports approximately 3.3 times more RSV cases than New Zealand, even after adjusting for population, however, the Committee noted this is likely influenced by lower levels of RSV testing and surveillance in New Zealand.

12.14.3. The Committee noted that RSV notifications in Australia show clear seasonal peaks, with higher notifications in 2024 compared to 2023.

12.14.4. The Committee noted that the highest proportion of RSV notifications in Australia (42%) occurred in children aged less than 5 years.

12.14.5. The Committee noted that differences in reported RSV cases between Australia and New Zealand likely reflect variations in testing intensity and surveillance coverage.

12.15. The Committee noted year-to-date RSV surveillance data for Western Australia (PathWest, Virus Watch, Week ending 31 Aug 2025), which reported 9,358 RSV notifications, 1,716 hospitalisations and 5 deaths. The Committee noted that RSV-associated mortality is challenging to determine with accuracy, these figures provide a reasonable indication of mortality.

12.16. The Committee noted, that unlike RSV in children, where bronchiolitis can serve as a surrogate for estimating incidence and burden, RSV in older adults is more difficult to measure. The Committee noted that SARI was developed primarily for influenza rather than RSV, and that neither SARI nor ARI provide accurate estimates, with ARI tending to over-diagnose as viral RNA can be detected by PCR for a prolonged period of time. More importantly, symptoms of lower respiratory tract infection are not captured.

12.16.1. The Committee noted PHF Science Respiratory Dashboard data (PHF Science, 2025) reporting cumulative hospitalisation rates with SARI by age, comparing influenza-positive and RSV-positive SARI rates. The Committee noted the incidence rate of RSV-positive SARI for those aged 65 years and over was approximately 28 per 100,000 compared to influenza at 167 per 100,000.

Health benefit

12.17. The Committee noted the updated application provided robust vaccine efficacy estimates for those above 60 years of age, with real-world evidence data supporting high vaccine effectiveness in the first season. However, the Committee noted that randomised controlled trial data specifically on hospitalisation outcomes were lacking.

12.17.1. Committee Members noted that for RSV in older adults, a significant concern is infection precipitating the worsening of underlying conditions such as cardiovascular disease, chronic obstructive pulmonary disease (COPD), congestive heart failure, or precipitating a transition into residential care. Members considered that this broader burden, which is likely to be similar to that seen with influenza, should be a focus of assessment, however, these outcomes have not been well explored in RSV studies to date in New Zealand and may be significant.

12.18. The Committee noted the updated data for cumulative efficacy against first occurrence of RSV-LRTD in adults ≥60 years over three RSV seasons (Ison, et al. Lancet Respir Med. 2025;13(6):517-29). The Committee noted that vaccine efficacy varied by age group, with 60.3% (95% CI: 39.5–74.8) for adults aged 60–69 years and 70.6% (95% CI: 48.4–84.3) for adults aged 70–79 years, when season was included as a covariate.

12.18.1. The Committee noted that vaccine efficacy showed minimal waning over extended follow-up, with efficacy at 23.3 months of 61.4% for adults aged 60–69 years and 74.9% for 70–79 years.

12.18.2. The Committee noted for adults over the age of 80 years, vaccine efficacy was 36.2% (95% CI: -94.0–82.5), when season was included as a covariate. The Committee noted the confidence interval was wide and crossed zero, indicating considerable uncertainty and that the efficacy in this age group could not be reliably established.

12.19. The Committee noted the supplier's updated vaccine efficacy and waning data based on a median follow-up of 30.6-months. The Committee noted that vaccine efficacy at five years was estimated at 28%, although confidence intervals were wide during this period. The Committee further noted that, based on these data, the supplier has extended the recommended revaccination interval from three years in the original submission, to five years.

12.19.1. The Committee noted there is better clarity regarding the revaccination timeline for the RSVPreF3 vaccine, with modelled vaccine efficacy against RSV-LRTD at 28.2% after five years. While the assumption of a five-year revaccination interval is considered acceptable, the Committee acknowledged that the optimal time for boosting may be when antibody levels are at their lowest, and that the appropriate interval could be less than five years; however, this remains uncertain at this time.

12.19.2. The Committee noted that the vaccine efficacy waning using the supplier's Cox model with time varying effect, which was updated from the linear waning effect in the previous submission was also acceptable.

12.20. The Committee noted real-world evidence on RSV vaccine effectiveness from four observational studies based in the United States, which was presented at the Advisory Committee on Immunization Practices (ACIP) in 2024 (Surie, et al. Centers for Disease Control and Prevention [CDC], 2024).

12.20.1. The Committee noted vaccine effectiveness (using either Arexvy or Abrysvo) against documented RSV infection and RSV-associated ED/UC visit or hospitalisation for adults aged 70–79 years was approximately 77% (95% CI: 69–83), and for adults aged 80 years and older, was 72% (95% CI: 59–81).

12.20.2. The Committee noted these results were based on the first season only, reflecting high efficacy prior to waning.

12.21. The Committee noted that three RSV vaccines, Arexvy (GSK), Abrysvo (Pfizer), and mResvia (Moderna), were considered to have similar efficacy in adults by the UK's Joint Committee on Vaccination and Immunisation (JCVI) based on preliminary data available at the time of review.

12.22. The Committee noted that, when considering the health benefits from RSVPreF3 for whānau and wider society, potential gains such as increased productivity among working individuals and carers aged 60 and above were important, although these are not currently included in Pharmac's Factors for Consideration. For older adults, the Committee noted the potential benefits of reduced need for community care and fewer hospital readmissions.

Suitability

12.23. The Committee noted that the RSVPreF3 vaccine is administered as a single dose, ideally at the start of winter, every five years, and can be co-administered with other vaccines, and is adjuvanted.

12.24. The Committee noted that the reactogenicity profile was similar at month 36 revaccination, with pain (64.8%), arthralgia (14.8%), fatigue (32.4%), headache (21.3%), and myalgia (32.4%) reported.

12.25. The Committee noted that Guillain-Barré syndrome (GBS) was included as a rare side effect in older adults.

12.25.1. The Committee noted the risk of GBS following RSV vaccination was 9 excess cases per million doses for Abrysvo and 7 excess cases per million doses for Arexvy in individuals aged 65 years or older. The Committee also noted that the estimated incidence rate ratios was 2.46 (95% CI: 1.19–5.08) for Arexvy and 2.02 (95% CI: 0.93–4.40) for Abrysvo (US Food and Drug Administration [FDA], 2025).

12.25.2. Members noted a recent evidence review for respiratory viruses in the USA for the 2025–2026 season (Scott, et al. N Engl J Med. 2025;393:2221-42), which showed the RSVpreF3 vaccine was associated with 18.2 excess cases of GBS per million doses in older adults.

Cost and savings

12.26. The Committee noted the results of the supplier's cost-effectiveness model across different cohorts, reflecting greater cost-effectiveness in older age groups and priority populations.

12.27. The Committee noted results from the supplier's cost-effectiveness model that suggest RSV vaccination in adults aged 60 years and over may prevent 912 hospital admissions, 235 emergency department presentations, 3,847 antibiotic prescriptions, and 4,546 GP visits per 100,000 people vaccinated over a five-year period.

12.27.1. The Committee considered that the predicted number of hospitalisations avoided was too high. Based on data from Prasad, et al. PLoS One. 2020;15(6):e0234235, it is reasonable to assume that there are approximately 155/100,000 hospitalisations per year in adults aged 60 years and over in New Zealand. This suggests approximately 775 (155*5) hospital admissions in five years, a lower number of total admissions than the number of avoided admissions that was predicted by the supplier's model.

12.27.2. The Committee noted it was difficult to assess antibiotic usage and GP utilisation. The Committee further noted that the rate of bacterial superinfection following RSV infection is difficult to estimate.

12.27.3. The Committee noted that updated effectiveness data discussed at the UK's Joint Committee on Vaccination and Immunisation (JCVI) suggested RSV vaccination, which also included Abrysvo, could prevent approximately 113 hospital admissions and 8.6 deaths per 100,000 doses in adults aged 75–79 years over three seasons, based on conservative vaccine effectiveness assumptions (Symes, et al. J Infect. 2025;91(3):106570).

12.27.4. The Committee noted that SHIVERS surveillance data from 2012–2022 (excluding 2020) recorded fewer than 10 in-hospital RSV-SARI deaths (Boderick, et al. Lancet Reg health West Pac. 2024;51:101221).

12.28. The Committee considered the key assumptions used in the supplier's cost-effectiveness model: i) RSV incidence of 5.83 per 100 person years ii) case-hospitalisation rates rising with age – 5.68% per RSV-LRTD infection for those aged 60-64, 14.94% aged 65-74, 20% aged 75+. The Committee considered that resulting estimated hospitalisation rate was too high, noting that:

12.28.1. The values used by the supplier imply approximately 1.17% (5.83*20%) of the 75 years and older population are hospitalised with RSV ARI

12.28.2. This is considerably higher than the RSV ARI incidence of 199/100,000 person years (Prasad, et al. PLoS One. 2020;15(6):e0234235) that implies 0.199% of the 80 years and older population will be hospitalised with RSV ARI.

12.29. The Committee considered it was reasonable to assume that a reduction in hospitalisation due to RSV would result in a proportionate decrease in RSV-related mortality among older adults, however the mortality benefit implied by the supplier's model was likely too high.

12.30. The Committee noted that the mortality reduction is uncertain.

12.30.1. The Committee noted a Cochrane review (Saif-Ur-Rahman, et al. Cochrane Database of Systematic Reviews. 2025;9:CD016131), which identified two phase III trials that reported data on mortality from RSV-related illness and all-cause mortality in older adults. The Committee noted that there was little to no difference in mortality for vaccinated individuals.

12.30.2. The Committee noted a Nature Medicine article (Du, et al. Nature Med. 2025;31:647-52) that described an individual based simulation model of RSV transmission dynamics to estimate the number of deaths averted in 13 high income countries.

Funding criteria

12.31. The Committee noted that adopting an age-based cohort approach, as used in the United Kingdom, prioritises those aged 75 years and older for RSV vaccination due to the highest health need in this group. The Committee noted this group experiences the highest rates of RSV-related mortality and severe outcomes. The Committee noted that funding vaccination for this cohort would directly target those at greatest risk of death and serious complications.

12.32. The Committee noted that individuals aged 65 to 74 years, particularly those with underlying health conditions, such as chronic respiratory or cardiovascular disease, are also at elevated risk of severe RSV infection and hospitalisation.

12.33. The Committee noted the importance of including residents of Aged Residential Care facilities in the funding criteria. The Committee noted that this population is highly susceptible to RSV outbreaks due to close living arrangements and underlying frailty, and experience higher rates of hospitalisation and mortality.

Summary for assessment

12.34. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for RSVPreF3 vaccine if it were to be funded in New Zealand for the prevention of lower respiratory tract disease cause by RSV (subtypes RSV-A and RSV-B) in adults 60 years of age and older. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Committee's assessment at this time and may differ from that

requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Adults aged ≥ 60 years	Adults aged 60 to 74 years with eligible comorbidities and all adults 75 years of age and older
Intervention	0.5mL RSVPreF3 vaccine administered via intramuscular injection **every five years** Can be co-administered with the influenza vaccine.	
Comparator(s) (NZ context)	No vaccination	
Outcome(s)	• **RSV-related lower respiratory tract disease**: In the overall group from the AresVi-006 (Papi et al. N Engl J Med. 2023;388:595-608) trial, VE was 82.6% (95% CI: 57.9-94.1) over one RSV season. Updated analyses from 3 seasons: 69.1% (95% CI: 55.8, 78.9) • **RSV-related acute respiratory illness:** In the overall group from AreSVi-006, VE was 71.7% (95% CI: 56.2-82.3) over one RSV season. Updated analyses from 3 seasons: 57.9% (95% CI: 48.6, 65.6) • RSV related hospitalisations • RSV related mortality	
Table definitions: **P**opulation: The target population for the pharmaceutical, including any population defining characteristics (eg line of therapy, disease subgroup) **I**ntervention: Details of the intervention pharmaceutical (dose, frequency, treatment duration/conditions for treatment cessation). **C**omparator: Details the therapy(s) that the patient population would receive currently (status quo – including best supportive care; dose, frequency, treatment duration/conditions for treatment cessation). **O**utcomes: Details the key therapeutic outcome(s), including therapeutic intent, outcome definitions, timeframes to achieve outcome(s), and source of outcome data.		

13. Matters arising: Discussion about Pharmac approach to limited programme extensions (catch up programmes)

Discussion

13.1. The Committee noted the discussion paper from Pharmac staff about the various approaches previously taken with funding recommendations for immunisation catch-up programmes.

13.2. The Committee considered that the terminology and definition used was important to understand what the term “catch-up programme” means as this could be differently understood between Pharmac eligibility criteria and the health sector for implementation purposes. Members noted it could be confused with individual catch-up immunisations for people who have not received scheduled vaccines. The Committee considered the term ‘limited programme extension’ may be more appropriate for Pharmac eligibility purposes.

13.3. The Committee noted that catch-up immunisation programmes (or limited programme extensions) have often been recommended for funding of new vaccines or widening access for vaccines that are already funded. The Committee noted Pharmac has funded “catch-up programmes” for a number of vaccines since it started managing vaccine funding in 2013.

13.4. The Committee noted catch-up programmes/limited programme extensions are implemented for a range of reasons:

- to ensure that individuals who missed scheduled vaccinations can still receive protection against vaccine-preventable diseases

- to provide effective immunisation cover after disruptions eg helping to restore herd immunity, emergency outbreaks or to protect people who have incomplete or unknown vaccination histories
- to accelerate immunity for a wider age group where a vaccine is to be given at an immunisation milestone visit
- to manage the financial impact of funding a new vaccine for a wide age range of eligible people.

13.5. The Committee considered and reflected on a selection of catch-up programmes that had been recommended or funded for several vaccines including: Herpes Zoster, Meningococcal ACWY, Meningococcal B and Pneumococcal conjugate (PCV13) vaccines.

13.6. The Committee noted in relation to catch up programmes/ limited programme extensions that any recommendation for eligibility criteria that includes catch-up programmes with age restrictions must have clear medical justification and comply with the New Zealand Bill of Rights Act 1990.

13.7. The Committee noted relevant considerations could include, where appropriate, the age range a vaccine has Medsafe approval for, and whether a specific age range is at much higher risk of a vaccine preventable disease than those who are older or younger, or are more likely to benefit or respond to vaccination.

13.8. The Committee noted that catch-up programmes/limited programme extensions often have large cost implications due to the size of the groups to be vaccinated and the resource requirements from the sector to administer those vaccinations.

13.9. The Committee noted the challenges that come with high system administration costs and the impact it can have on the cost-effectiveness of proposals.

13.10. The Committee considered that discussion of any catch-up programme must be made at the same time an initial vaccine recommendation is made. This ensures the Committee can make a recommendation for the vaccine eligible groups including any limited programme extension to ensure they are progressed through the Pharmac funding process together.

13.11. The Committee considered a fixed period of 12 to 24 months for a catch-up programme/limited programme extension may not align with available health immunisation resource to support a catch-up initiative.

13.12. The Committee considered other system wide immunisation priorities can impact uptake when the catch-up programme/limited programme extension is funded.

13.13. The Committee considered the implementation of catch-up programmes/limited extension programmes need to be delivered alongside robust communication plans to be successful.

13.14. The Committee considered it should review all the vaccine “catch-up programmes” currently on Pharmac’s Options for Investment list (OFI) at a future meeting to consider if they remain appropriate. Members noted this should include considering the evidence to support the use of a limited extended programme or other suitable approaches to meet the health needs of the population.

13.15. The Committee noted Pharmac staff also plan to discuss this issue with partner immunisation agencies and stakeholders to seek broader feedback into this work.