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TE PĀTAKA WHAIORANGA

Specialist Advisory Committees
Objective advice to Pharmac
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Record of the Immunisation Advisory Committee Meeting held on 25 May 2026

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.

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1. Attendance

Present
Helen Evans
Christine Pihema
David Murdoch
Edwin Reynolds
James Ussher
Lance Jennings
Nikki Turner
Osman Mansoor
Stephen Munn

Apologies
Elizabeth Wilson
Erasmus Smit
Sean Hanna
Stuart Dalziel

Respiratory Advisory Committee members for part of the meeting
Betty Poot
Neil Whittaker
Tim Christmas
David McNamara

2. Summary of recommendations

	Pharmaceutical and Indication	Recommendation
7.1.	Pertussis vaccine eligibility be amended and widened for parents and primary caregivers of infants admitted to neonatal intensive care unit or specialist baby care units, subject to eligibility criteria	High priority
8.1.	Hepatitis A vaccination for the immunisation of people living with HIV	Decline
8.2.	Hepatitis A vaccination for the immunisation of people living with HIV who are at increased risk (including men who have sex with men, IV drug users, or people with chronic renal failure)	Decline
9.1.	Meningococcal vaccines (MenB and MenACWY) for young people at high-risk	Further work required
10.1.	Meningococcal ACWY vaccine be widened to include one dose for children 1 to 4 years of age inclusive	High priority
10.2.	Meningococcal ACWY vaccine be widened to include one dose and one booster dose after 5 years for young people 14 to 21 years of age inclusive	High priority
11.2.	Meningococcal vaccines (MenB and MenACWY) be widened to provide a booster dose after 5 years for	High priority

	young people in an eligible setting, subject to eligibility criteria	
13.3.	Clesrovimab (Enflonsia) the prevention of RSV LRTD in all infants at birth or in their first RSV season, and for high-risk infants entering their second RSV season, subject to eligibility criteria	High priority
14.4.	RSVpreF (Abrysvo) for the prevention of RSV LRTI in infants by active immunisation of pregnant individuals, subject to eligibility criteria	High priority
15.3.	RSVpreF (Abrysvo) for the prevention of RSV LRTI in adults 60 years of age and older	Medium priority
15.4.	RSVpreF (Abrysvo) for the prevention of RSV LRTI in high-risk adults aged 60 to 74 years with eligible comorbidities and all adults 75 years of age and older, subject to eligibility criteria	High priority
16.3.	RSVpreF (Abrysvo) for the prevention of RSV LRTI in immunocompromised adults	Deferred

These recommendations were made within the context of vaccines and immunisation, unless otherwise stated in the above table.

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.'

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. The Committee noted changes to membership, including the change of Chair of the Committee to Dr Helen Evans. Members noted that recruitment is underway for new members.

5.3. The Committee acknowledged that Respiratory Advisory Committee members would join this meeting for the RSV vaccine discussions.

5.4. The Committee noted updates on the Reset programme, the establishment of a Programme Delivery Office and the Exceptional Circumstances Framework review, which is open for consultation.

5.5. The Committee noted an overview of the Access Criteria Policy published late 2025.

5.6. Pharmac staff also provided an update regarding various vaccines request for proposals (RFP) and consultation timing.

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

6.1. The Committee reviewed and accepted the record of the Immunisation Advisory Committee meeting held on 6 November 2025.

7. Matters Arising: Pertussis vaccine eligibility for parents or primary caregivers of infants admitted to neonatal intensive care unit or specialist care baby units

Recommendations

7.1. The Committee **recommended** that the pertussis vaccine eligibility be amended and widened for parents and primary caregivers of infants admitted to neonatal intensive care units (NICU) or special care baby units (SCBU), with a **high priority**, within the context of immunisation, subject to the following criteria (only relevant criteria shown, with changes in **bold** and ~~strikethrough~~):

> A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit, Specialist Care Baby Unit for **likely** more than ~~3~~ **7** days~~, who had not been exposed to maternal vaccination at least 14 days prior to birth~~; or

7.2. In making this recommendation the Committee considered that:

7.2.1. household contacts, particularly parents and primary caregivers, are a common source of pertussis exposure for infants

7.2.2. the current eligibility does not cover fathers or primary caregivers of infants who had been exposed to maternal vaccination at least 14 days prior to birth and this could put infants admitted to NICU or SCBU at risk if not included as part of a cocooning strategy.

Discussion

7.3. The Committee noted that it had considered pertussis immunisation in various settings on a number of occasions:

- Vaccination of pregnant women regardless of epidemics (Sept 2014)
- Parents of infants born at 28 weeks or less or infants admitted to NICU or SCBU for a minimum stay (May 2016)
- Cocooning strategy (May 2016)
- Widen Access to all pregnant women (Sept 2018)
- Additional 15 month pertussis dose for childhood schedule (Oct 2019)

- Pertussis-containing vaccine in second year of life (Sept 2022)
- Maternal Vaccination (Sept 2024)
- Pertussis-containing vaccine in second year of life (April 2025)

7.4. The Committee noted the strong clinical need to protect infants admitted to NICU or SCBU, and that:

7.4.1. New Zealand is currently experiencing an ongoing pertussis epidemic.

7.4.2. Childhood immunisation coverage remains suboptimal, increasing the risk of transmission from household contacts, including parents and older siblings

7.4.3. Maternal pertussis vaccination coverage remains below 50%

7.4.4. Protection from pertussis vaccination wanes over time, necessitating booster doses every 5 years

7.4.5. Young infants, particularly those born prematurely, are at the greatest risk of severe pertussis-related morbidity and mortality.

7.5. The Committee noted that pertussis is highly transmissible (R_0 estimated for pertussis at 12-17) and that prematurity further increases the risk of severe disease.

7.6. The Committee noted that household contacts, particularly parents and primary caregivers, are a common source of pertussis exposure for infants.

7.7. The Committee noted that transfer of maternal antibodies across the placenta is an active process that occurs throughout pregnancy, but is greatest during the final weeks before term birth. Consequently, premature infants receive lower levels of maternal antibodies than term infants. The Committee further noted that maternally derived antibodies wane rapidly after birth, with many infants having antibody levels below protective thresholds by 6 weeks of age.

7.8. The Committee reviewed the current epidemiology of pertussis in New Zealand and noted that the country remains in a pertussis outbreak.

8. Matters Arising: Hepatitis A vaccine – widening of access to at risk groups and HIV

Recommendations

8.1. The Committee **recommended** that hepatitis A vaccination for the immunisation of people living with HIV be **declined**, within the context of immunisation.

8.2. The Committee **recommended** that hepatitis A vaccination for the immunisation of people living with HIV who are at increased risk (including men who have sex with men [MSM], IV drug (IVD) users, or people with chronic renal failure) be **declined**, within the context of vaccines and immunisation.

8.3. In making this recommendation, the Committee considered:

8.3.1. that there was insufficient evidence to support funding hepatitis A vaccination for the proposed subgroups of people living with HIV, noting that hepatitis A is not endemic in New Zealand

8.3.2. the health need was relatively low

8.3.3. there are a number of other populations at risk of hepatitis A infection that should be considered through a broader review of vaccine access.

Background

8.4. The Committee noted that hepatitis A vaccine is currently funded for limited groups in New Zealand, including transplant recipients, children with chronic liver disease, and close contacts of known cases.

8.5. The Committee noted that widening access to hepatitis A vaccination to people living with HIV, either as a whole population or as higher-risk subgroups, was considered by the Immunisation Subcommittee and PTAC in 2014–2015, and was not supported due to low incidence, uncertainty of benefit and difficulty defining eligible subgroups.

8.6. The Committee noted that PTAC ultimately recommended removal of HIV from the eligibility criteria and the application was ranked for decline, while consideration of specific subgroups remained unresolved.

8.7. The Committee noted that the proposal was revisited in 2023 as part of a broader review of inactive applications; however, feedback identified insufficient information on prior deliberations, and Pharmac is now seeking advice to help progress these proposals.

Discussion

8.8. The Committee noted that, despite generally low incidence in New Zealand, hepatitis A outbreaks continue to occur internationally, including person-to-person transmission outbreaks affecting multiple regions, indicating an ongoing risk of infection and re-emergence (Lin, et al. Hepatology. 2018;68:22-31).

8.8.1. The Committee noted that, while hepatitis A incidence in New Zealand remains low, recent outbreaks have occurred, including outbreaks associated with contaminated food products.

8.9. The Committee noted that people living with HIV may be disproportionately affected during hepatitis A outbreaks (Sachdeva, et al. Can Commun Dis Rep. 2019;45(10):262-268).

8.9.1. The Committee noted that hepatitis A infection in people living with HIV may present with a milder but more prolonged disease course. The Committee further noted that lower CD4 counts in people living with HIV are associated with a more prolonged course of hepatitis A infection and increased viral shedding, which may contribute to higher transmission within this group during outbreaks.

8.9.2. The Committee noted that mortality from hepatitis A is low (Lin, et al. Infect Dis Ther. 2026;15:391-15) and not increased in people living with HIV overall, but may be higher in those with advanced immunosuppression or pre-existing liver disease, many of whom are already eligible for hepatitis A vaccination for those indications.

8.9.3. The Committee noted the potential benefit of vaccination may relate more to reducing infectivity within the cohort, with uncertain impact at a broader population level.

8.10. The Committee noted that international approaches have shifted away from subgroup definitions towards broader vaccination strategies.

8.10.1. The Committee noted that seroconversion rates following hepatitis A vaccination appear lower in people living with HIV than in immunocompetent populations, with evidence suggesting a seroconversion rate of around 64% among those with HIV following HAV vaccination (Shine, et al. Vaccine. 2005, 24(3):272-79). More recent evidence suggests that antibody durability may also be reduced in people living with HIV, with seroreversion reported after

vaccination; however, additional vaccine doses or revaccination may improve serological response rates and/or antibody titres (Lin, et al. Infect Dis Ther. 2026;15:391-15).

8.10.2. The Committee noted that a two-dose hepatitis A vaccination schedule (primary dose followed by a booster) is expected to provide long-term immunity for most individuals in these high-risk groups.

8.10.3. The Committee noted that hepatitis A vaccination is currently funded as post-exposure prophylaxis for close contacts of confirmed hepatitis A cases and is effective when administered within 14 days of exposure.

8.11. The Committee noted that modelling evidence from Taiwan estimated hepatitis A vaccination campaigns targeting people living with HIV averted 80.7% of cases (sensitivity analysis range 48.8–92.7%), reflecting both direct and indirect protection through reduced transmission (Lin, et al. Clin Infect Dis. 2020;70(8):1742-49).

8.11.1. The Committee further noted that, while reductions in hepatitis A incidence may be achieved through vaccination, there is limited evidence that this translates into reduced mortality, with population data not clearly demonstrating a decrease in hepatitis A-related deaths.

8.12. The Committee noted that, while widening access to all people living with HIV is one potential option, defining smaller high-risk subgroups within this population may be difficult and of limited utility.

8.12.1. The Committee considered that including people with HIV and chronic renal failure as a subgroup may not be appropriate, given the very small population size, overlap with existing funded groups, and lack of evidence of worse outcomes.

8.12.2. The Committee considered that defining MSM, or people who inject drugs as higher-risk subgroups of people living with HIV would not provide a clear or evidence-supported approach to targeting hepatitis A vaccination to those with the greatest health need, as these groups would capture a substantial proportion of people living with HIV in New Zealand rather than a discrete higher-risk subgroup.

8.12.3. The Committee considered that other population groups at risk of hepatitis A infection may include international travellers, people with occupational exposure, people experiencing homelessness, close contacts of international adoptees, and people who have substance use disorder (Migueres, et al. Viruses. 2021;13(10):1900). The Committee considered these groups, along with those with poorly controlled HIV, and those with pre-existing liver disease, would be appropriate to consider as part of a wider review.

8.13. The Committee supported further consideration of alternative approaches or strategies to improve access to hepatitis A vaccination for populations at risk of hepatitis A infection and indicated that it would be interested in considering the wider range of at-risk population groups at a future meeting.

9. Matters Arising: Meningococcal vaccines for people living in NZDep Quintile 5 areas or holding or eligible for a Community Services Card (CSC)

Recommendations

9.1. The Committee **recommended** widening of access to meningococcal vaccines (meningococcal B and meningococcal ACWY vaccines) for young people at high-risk and considered more work is required to define the target population.

9.2. In making this recommendation, the Committee:

9.2.1. Noted that at the November 2023 Immunisation Advisory Committee meeting the Committee recommended eligibility criteria for meningococcal vaccines be widened to included peopled aged 13-25 years with, or who are eligible for, a Community Services Card or living in NZDep quintile 5 areas.

9.2.2. Noted Pharmac's current Access Criteria Policy.

9.2.3. Considered that, based on the Access Criteria Policy, available evidence, and limitations of reaching the target population using the Community Services Card or NZDep quintiles, targeting vaccines to high-risk populations as previously recommended was not feasible.

9.2.4. Noted that recent analysis by PHF Science shows Meningococcal B strain disease currently predominates in New Zealand.

9.2.5. Noted its previous consideration that the most equitable access to meningococcal vaccines for young adults and adolescents is universal access.

9.2.6. Considered that it was unclear how to best define criteria to replace that previously recommended, but that it is reasonable to explore targeting people in high-risk groups with a defined, evidence-based incidence of invasive meningococcal disease, or to consider other ways of identifying risk related to household overcrowding.

9.2.7. Considered if new criteria were developed for high-risk groups, the targeted age group should align with population group identified for universal meningococcal vaccination (14-21 years, instead of 13-25 years) as this best defines the target population (see item 10).

Discussion

9.3. The Committee noted that at the November 2023 Immunisation Advisory Committee meeting the Committee reviewed the current eligibility criteria for meningococcal vaccines. At that meeting, the Committee recommended with a medium priority that eligibility for the meningococcal B vaccine and meningococcal ACWY conjugate vaccine be widened to the following groups:

- people aged 13-25 years with a Community Services Card
- people aged 13-25 years who are eligible for a Community Services Card
- dependants aged 13-25 of people with a Community Services Card, or
- people aged 13-25 years living in NZDep quintile 5 areas.

9.4. The Committee noted that Pharmac had subsequently considered whether it is possible to target medicines and vaccines using socioeconomic status as a marker of health need. The Committee noted Pharmac considerations that using socioeconomic status in the criteria is a proxy measure and not a clearly defined group with a direct health need, and is not consistent with the approach outlined in Pharmac's recently published updated Access Criteria Policy. The Access Criteria Policy requires criteria to clearly define the target group and set broad criteria to ensure all people that meet the intent of the criteria can get access.

9.5. The Committee noted the following challenges with the proposed access criteria:

- Community Services Cards' eligibility criteria do not adequately define a target population, and income limits are set by the Ministry of Social Development that may change over time as per its policies and appropriations.
- NZDep quintiles may not capture those without a fixed address or with multiple homes.

9.6. The Committee noted a preliminary submission from the Meningitis Foundation providing evidence to support the identification of high-risk young people aged 13-25 years, and that a further submission is expected. The Committee noted the Meningitis Foundation recommendations, which were to use PHF Science/ESR notification data by ethnicity as the primary evidence base for risk; that eligibility be extended to all young people aged 13–25; and the institution-type requirement be removed (or if full expansion is not possible, that it be extended to those eligible for the Community Services Card or to Māori and Pacific young people).

9.7. The Committee noted a petition had been presented to Parliament calling for all children to receive this vaccine at Year 11 of school. A Meningitis Foundation briefing is currently under consideration of the Health Select Committee (as at July 2026).

9.8. The Committee noted recent data on the incidence and risk of meningococcal disease in New Zealand.

9.8.1. The Committee noted that in the period 2021-2025 there were 240 cases of meningococcal disease and 12 deaths. In the period 2020-2025, 40% of cases were in the Māori population and 16% in Pacific people. (PHF Science, Burton et al., Emerg Infect Dis. 2023)

9.8.2. The Committee noted that Burton et al., Emerg Infect Dis. 2023 undertook a review of paediatric meningococcal disease data in New Zealand in 2004-2020. The study reported that children of Māori and Pacific ethnicity and those living in the most deprived areas were overrepresented. Children living in Auckland's most deprived 20% of neighbourhoods had rates of meningococcal disease 17 times higher than those in the least deprived 20% of neighbourhoods.

9.8.3. The Committee noted hospitalisation data show a higher rate of hospitalisation due to meningococcal disease in children aged 0-14 from low decile areas compared with higher decile areas. The Committee noted the limitations of using NZDep data, including its inability to capture household crowding or differences within a geographical area. Further, hospitalisation data do not capture those cases that do not involve hospital admission.

9.9. The Committee considered that there is evidence that those with lower socioeconomic status, particularly where there is overcrowding, are at highest risk of meningococcal disease. The Committee also considered there is evidence that Māori children and Pacific children are at higher risk of meningococcal disease than children of other ethnic groups.

9.10. The Committee discussed whether funding could be targeted by NZDep quintiles (as opposed to Community Services Card eligibility), however considered that this would be difficult to implement. The Committee considered that the Community Services Card is a practical but blunt mechanism to target vaccination to those in lower decile groups. The Committee considered analysis could be undertaken to determine the ethnicity overlap with the Community Services Card.

9.11. Members discussed alternative eligibility criteria options, including targeting groups using a disease incidence above a specified threshold. Members considered this approach could be difficult for prescribers to apply. Members also suggested there may be other ways to identify risk related to household overcrowding, including methods used for rheumatic fever.

10. Matters Arising: Meningococcal ACWY vaccine applications – clarification of catch-up programmes previously ranked

Recommendations

10.1. The Committee **recommended** that access to the meningococcal ACWY vaccine be widened to include one dose for children 1 to 4 years of age inclusive, with a **high priority**, within the context of vaccines and immunisation.

10.1.1. The Committee considered this recommendation should replace all previous recommendations relating to the meningococcal ACWY vaccine applications for children listed below:

- Children 1 year of age
- Children aged 1 to 4 years

10.2. The Committee **recommended** that access to the meningococcal ACWY vaccine be widened to include one dose and one booster dose after 5 years for young people 14 to 21 years of age inclusive, with a **high priority**, within the context of vaccines and immunisation.

10.2.1. The Committee considered this recommendation should replace all previous recommendations relating to the Meningococcal ACWY vaccine applications for young people listed below:

- Young people at 14 years of age
- Young people 5 to 21 years with catchup (one year only), ongoing 14 years old
- Young people aged 13 to 21 years with catchup (one year only), ongoing vaccination at 14 years of age

10.3. In making these recommendations the Committee considered that:

10.3.1. a time-limited programme (previously described as a catch-up programme) would not provide the required protection and that permanent widened eligibility to these age groups would achieve the desired protection for children and young people groups.

10.3.2. there is a residual unmet need for meningococcal ACWY vaccination in these groups, but this has materially narrowed since the previous recommendations were made.

10.3.3. herd immunity would provide some indirect protection from a broader programme

10.3.4. ongoing support for these applications provided epidemic preparedness and was not based on current case burden

10.3.5. the recommendations supersede all previous recommendations for these age groups.

Discussion

Background

10.4. The Committee noted that several applications for meningococcal ACWY vaccine for children and young people are currently ranked on Pharmac's Options for Investment list. The Committee noted that Pharmac sought updated advice to review the groups targeted by these applications and ensure they reflect the current need.

10.5. The Committee noted the current eligibility criteria for meningococcal ACWY (MenACWY) targets individuals at high risk due to medical conditions that reduce their immune function, close contacts of cases, individuals who have previously had meningococcal disease, and individuals aged 13-25 in specified close living situations.

10.6. The Committee noted the Immunisation Advisory Committee and PTAC had previously considered meningococcal ACWY vaccine for infant and young people groups on a number of occasions. The recommendations made and application statuses at the time of this meeting are shown below:

Population	Recommendations	Status
Children 1 year of age	Immunisation Subcommittee Sep 2018: High PTAC Feb 2019: Low Immunisation Subcommittee Mar 2019: High PTAC May 2019: noted and accepted the SAC's High recommendation	Options compared (ranked onto the Options For Investment [OFI] list)
Children aged 1 to 4 years	Immunisation Subcommittee Sep 2018: High PTAC Feb 2019: Low Immunisation Subcommittee Mar 2019: High PTAC May 2019: noted and accepted the SAC's High recommendation	Options compared (ranked onto the OFI list)
Young people at 14 years of age	Immunisation Subcommittee Sep 2018: High PTAC Feb 2019: Low Immunisation Subcommittee Mar 2019: High PTAC May 2019: noted and accepted the SAC's High recommendation	Options compared (ranked onto the OFI list)
Young people aged 5 to 21 years with catch-up (one year only), ongoing vaccination at 14 years of age	Immunisation Subcommittee Sep 2018: High PTAC Feb 2019: Low Immunisation Subcommittee Mar 2019: High PTAC May 2019: noted and accepted the SAC's high recommendation	Options compared (ranked onto the OFI list)
Young people aged 13 to 21 years with catch-up (one year only), ongoing vaccination at 14 years of age	Immunisation Subcommittee Sep 2018: High PTAC Feb 2019: Low Immunisation Subcommittee Mar 2019: High PTAC May 2019: noted and accepted the SAC's High recommendation	Options compared (ranked onto the OFI list)

10.7. The Committee noted that, in making these recommendations in 2019, the Immunisation Advisory Committee had noted:

10.7.1. An increasing rate of group W and Y cases relative to group C.

10.7.2. It would be easiest to deliver adolescent vaccination as part of the Intermediate School programme, although waning efficacy of the vaccine delivered at this age would leave young people less protected.

10.7.3. Non-vaccinees may receive some indirect protection through reduction of transmission (herd immunity).

10.7.4. At the time, the Committee noted that the UK had about half the rate of meningococcal disease of New Zealand, and other developed countries also had lower incidence rates than New Zealand.

Meningococcal ACWY epidemiology

10.8. The Committee reviewed recent epidemiological data from PHF Science's Meningococcal Reference Laboratory for 2016-2025 and noted that;

10.8.1. In the last 10 years the annual incidence rate for meningococcal disease has been falling from a peak in 2019.

10.8.2. In 2025, meningococcal B was the dominant group type, accounting for 74% of cases, 17% were group Y, 6% were group W and 3% were group C. There has been a substantial drop in cases due to serogroup Y, W and C from 2016 through to 2025. The Committee noted that there was an absence of cases of serogroup A in New Zealand during these years.

10.8.3. The Committee noted the serogroup breakdown by age group showed two cases per year of A, C, W or Y across the 10-29 age group from 2022-2025. This was down from a peak of 16 cases in 2019.

10.9. The Committee reviewed an international comparison of the incidence of MenACWY across a range of programmes (UK Health Security Agency, Published 2025; Australian Meningococcal Surveillance Programme Annual Report 2024, Published 2025). The Committee noted that the incidence of MenACWY in New Zealand (0.15-0.2) was comparable to that of other countries with broader vaccine eligibility (Australia (0.08) and UK (0.1-0.15).

10.10. The Committee considered a residual unmet need for MenACWY vaccination in these groups exists but has materially narrowed since the previous recommendations were made. The Committee considered this is based on epidemic preparedness and structural transmission risk, not current case burden.

Meningococcal ACWY evidence for a booster dose

10.11. The Committee noted that there was no new evidence on waning of vaccine protection against MenACWY and noted the following % with serum bactericidal antibody titres (hSBA) >1:8 at year 5, age 10-25yr; Serogroup C = 92.9% CI:87.3-96.5%, Serogroup W = 87.0% CI:80.2-92.1%, Serogroup Y = 94.4% CI: 89.2-97.5% (Roger et al. Pediatr Infect Dis J. 2015;34:1236-43). The Committee considered that MenACWY vaccine does not provide life-long protection and booster doses would be needed every five years for individuals who remained within an eligible population.

Meningococcal ACWY application review - children

10.12. The Committee noted the following MenACWY vaccine applications relating to children:

- Children 1 year of age
- Children aged 1 to 4 years

10.13. The Committee considered there remained a need to provide MenACWY vaccine coverage for children based on epidemic preparedness.

10.14. The Committee considered that a new application on Pharmac's Application Tracker should be created to reflect the group recommended for widened access (one dose for children 1 to 4 years of age inclusive), and that the two applications covering younger children listed in 10.12 above would be superseded by this recommendation.

Meningococcal ACWY application review - young people

10.15. The Committee noted the following MenACWY vaccine applications relating to young people:

- Young people at 14 years of age
- Young people aged 5 to 21 years, ongoing vaccination at 14 years of age
- Young people aged 13 to 21 years, ongoing vaccination at 14 years of age

10.16. The Committee considered the case for an adolescent MenACWY vaccine programme based on creating herd immunity and carriage reduction remains valid.

10.17. The Committee considered the evidence base for the adolescent dose at 14-years of age remains strong and has a favourable risk-benefit profile given current New Zealand epidemiology. The Committee considered the basis for this was an epidemic preparedness investment with real but modest current direct benefit.

10.18. The Committee considered that a new application on Pharmac's Application Tracker should be created to reflect the group recommended for widened access (one dose and one booster dose after 5 years for young people 14 to 21 years of age inclusive) and that three applications listed in 10.15 above covering older children and young adults would be superseded by this recommendation.

11. Matters Arising: Meningococcal B & Meningococcal ACWY vaccines – widening of access to those remaining at risk (re-dosing)

Application

11.1. The Committee noted that Pharmac sought updated advice from the Committee regarding an application from the Immunisation Advisory Centre (IMAC) to widen access to the meningococcal B vaccine (MenB) and meningococcal ACWY vaccine (MenACWY) for adolescents (young people) remaining at risk, by providing a booster dose for adolescents on entering a second congregate setting.

Recommendations

11.2. The Committee **recommended** that access to meningococcal vaccines (MenB and MenACWY) be widened to provide a booster dose after 5 years for young people in an eligible setting with a **high priority**, within the context of vaccines and immunisation, subject to the following eligibility criteria (only relevant criteria are below, with changes in **bold** and ~~strikethrough~~):

MenB vaccine (Bexsero)

3. Both:
    a. Person is aged between 13 and 25 years (inclusive); and
    b. ~~Either~~**Any of the following**:
        i. Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons; or
        ii. Two doses for individuals who turn 13 years of age while living in boarding school hostels**; or**
        iii. One booster dose if more than 5 years since a previous dose and individual is entering within the next three months, or is continuing to live in, an eligible setting (as defined at 3.b.i).

MenACWY vaccine (MenQuadfi)

2. Both:
    a. Person is aged between 13 and 25 years (inclusive); and
    b. **~~Either~~Any of the following**:
        i. One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons; or
        ii. One dose for individuals who turn 13 years of age while living in boarding school hostels**; or**
        iii. One booster dose if more than 5 years since a previous dose and individual is entering within the next three months, or is continuing to live in, an eligible setting (as defined at 2.b.i).

11.3. In making this recommendation, the Committee considered that:

11.3.1. The available evidence supports a booster dose after about five years post vaccination for both vaccines

11.3.2. There are ongoing challenges with defining how best to target at-risk young people based on residence, as discussed in item 9, and this continues to be worked on.

11.3.3. While this proposal focussed on a particular at-risk group, the evidence-based considerations regarding a booster dose are relevant to other meningococcal vaccine proposals.

Discussion

Background

11.4. The Committee noted that MenACWY vaccine was added to the Pharmaceutical Schedule for eligible high-risk groups in July 2014, with MenB vaccine added in July 2021.

11.5. The Committee noted that current eligibility criteria target access to young people entering or in their first year of living in high-risk settings.

11.6. The Committee noted the preliminary submission from the Meningitis Foundation providing commentary on the complexity of targeting high-risk young people aged 13-25 years based on place of residence. The submission noted the need for booster doses for individuals who continue in reside in eligible settings.

Discussion

11.7. The Committee noted the application proposed a single booster dose of meningococcal vaccines MenB and/or MenACWY for young adults who received primary doses at least five years prior and are entering, or continuing to live in, an eligible congregate setting.

11.8. The Committee noted that waning immunity against PorA strains of *Neisseria meningitidis* is highly relevant for the New Zealand population given that PorA strains predominate in New Zealand and vaccine immunity against this strain decreases more rapidly than for other strains.

11.9. The Committee noted that there is no new evidence since its last review on this topic to indicate the extent of waning of previous meningococcal vaccine efficacy in the target population.

11.9.1. The Committee noted the evidence base includes serological data reported between three and eight years after meningococcal vaccination (Nolan et al. Vaccine. 2019;37:1209-18; Roger et al. Pediatr Infect Dis J. 2015;34:1236-43). The Committee noted following % with hSBA >1:8 at year 5; 10-25yr; Serogroup C = 92.9% CI:87.3-96.5%, Serogroup W = 87.0% CI:80.2-92.1%, Serogroup Y = 94.4% CI: 89.2-97.5% (Roger et al. 2015).

11.10. The Committee considered that the available data support a booster dose of meningococcal vaccines MenB and MenACWY after about five years post vaccination given the high antibody titres required for protection against meningococcal disease.

11.11. The Committee noted that while the application focus was on adolescents residing in eligible settings, the Committee considered it was reasonable to consider the evidence for booster doses as being applicable more broadly.

11.12. The Committee considered that likely booster uptake in the target group was uncertain.

11.13. The Committee noted there were no data to indicate whether there would be any reasons for access to, and benefit from, a booster dose to differ between population

groups including Māori, Pacific peoples and other groups experiencing health inequity.

11.14. The Committee noted current criteria do not cover crowded household situations as discussed in item 9.

Summary for assessment

11.15. The Committee considered that the below summarises its interpretation of the most appropriate PICO table (population, intervention, comparator, outcomes) information if access to meningococcal vaccines (MenB & MenACWY) were widened to provide a booster dose for adolescents in an eligible setting in New Zealand. This PICO table captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO table is based on the Committee's assessment at this time and may differ from that requested by the applicant. The PICO table may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	Persons aged between 13 and 25 years (inclusive) who: • received Meningococcal B (Bexsero) or Meningococcal ACWY (MenQuadfi) more than 5 years previously, and • who are entering within the next three months, or are continuing to live in an eligible setting (defined as: boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons).
Intervention	One dose of meningococcal (A, C, Y, and W-135) conjugate vaccine (MenQuadfi) via 0.5 ml single-dose muscular injection, at least 5 years after a previous dose One dose of meningococcal B multicomponent vaccine (Bexsero) via 0.5 ml single-dose muscular injection, at least 5 years after a previous dose
Comparator(s) (NZ context)	No booster dose
Outcome(s)	Potentially improved protection against invasive meningococcal disease (IMD) relative to receiving no booster dose at five years post-primary course

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.

12. Welcome and introduction to Respiratory Advisory Committee members

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

- Clesrovimab for the prevention of RSV LRTI in newborns and infants
- RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in infants by active immunisation of pregnant individuals
- RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in older adults
- RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in immunocompromised adults

12.2. For the purpose of the items 13, 14, 15 and 16, references to the Committee include members of the Immunisation and Respiratory Advisory Committees.

13. Clesrovimab for the prevention of RSV lower respiratory tract disease in newborns and infants

Application

13.1. The Committee reviewed a supplier application for clesrovimab (Enflonsia) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants.

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

Recommendation

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

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

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 (March–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; March–August); 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 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, and/or will require surgical intervention in the next 3 months; 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 (Mean pulmonary artery pressure more than 25 mmHg); or
                    - 1.2.3.3.2.4. Left ventricular (LV) failure with LV Ejection Fraction less than 40%.

13.4. In making this recommendation, the Committee noted:

13.4.1. the significant health need among infants, as RSV is the leading cause of hospital admission for infants and young children in New Zealand.

13.4.2. the incidence of RSV in New Zealand is the highest globally and emphasised the inequities observed within the population.

13.4.3. the considerable annual RSV burden on general practice (GP), emergency departments (ED), hospitals and intensive care units (ICUs).

13.4.4. In addition, the Committee observed that clesrovimab is associated with a substantial reduction in RSV respiratory tract infection (RTI) or bronchiolitis compared to no immunisation in all infants, and similar efficacy compared to palivizumab in high-risk infants.

Discussion

Māori impact

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

13.6. The Committee noted the significant inequities associated with RSV disease, noting substantially higher rates of hospitalisation among Māori and Pacific infants and among children living in areas of greater socioeconomic deprivation.

Populations with high health needs

13.7. 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 clesrovimab and noted that the ethnic and socioeconomic inequalities are considerable.

Background

13.8. The Committee noted that clesrovimab is a long-acting recombinant human IgG1 monoclonal antibody developed for the prevention of RSV lower respiratory tract disease in neonates and infants entering or born during their first RSV season.

13.8.1. The Committee noted that clesrovimab has an extended half-life through YTE modifications in the Fc domain and targets antigenic site IV of the RSV fusion (F) protein (Li, et al. MedComm 2020. 2024;5(12):e70016).

13.8.2. The Committee further noted that clesrovimab is administered as a single fixed intramuscular dose irrespective of infant weight.

13.9. The Committee noted receipt of correspondence from The Paediatric Society of New Zealand | Te Kāhui Mātai Arotamariki o Aotearoa, previously considered at its November 2025 meeting, and from the Royal New Zealand College of General Practitioners, which supported funding of RSV immunoprophylaxis for infants in Aotearoa New Zealand (NZ).

13.9.1. The Committee noted that the correspondence highlighted the substantial burden of RSV disease in infants, ongoing inequities in RSV-related health outcomes, and the importance of ensuring equitable access to effective RSV prevention strategies for pēpi and tamariki.

Health need

13.10. The Committee noted its previous discussion on the health need for RSV LRTD prevention in newborns and infants during its November 2025 consideration of nirsevimab for the same indication.

13.10.1. The Committee reaffirmed that RSV represents a substantial unmet health need in New Zealand infants, noting that RSV is the leading cause of hospital admission in the first year of life and that bronchiolitis, of which at least two-thirds is attributable to RSV, is among the most common reasons for paediatric hospitalisation.

13.10.2. The Committee noted that the burden of disease is concentrated in early infancy, with hospitalisations peaking in the first six months of life, particularly around two months of age, and that infants aged less than 12 months experience markedly higher rates of RSV-associated hospitalisation than any other age group.

13.10.3. The Committee further noted that New Zealand has among the highest reported rates of bronchiolitis hospitalisation internationally, with approximately one in every 11–12 children admitted with bronchiolitis during their first year of life.

13.10.4. The Committee noted that RSV places considerable seasonal pressure on primary care, emergency departments, hospital wards and paediatric intensive care services, resulting in wider impacts on the health system and on whānau.

Health benefit

13.11. The Committee noted the CLEVER phase 2b/3 clinical trial (Zar, et al. N Engl J Med. 2025;393(13):1292-1303), a randomised, placebo-controlled, multicentre study evaluating the efficacy and safety of clesrovimab for the prevention of RSV-associated lower respiratory tract infection (LRTI) in healthy full-term and preterm infants entering their first RSV season.

13.11.1. The Committee noted the trial design, which included 3,614 healthy infants randomised in a 2:1 ratio to receive either a single intramuscular dose of clesrovimab 105 mg (n=2,412) or placebo (n=1,202), administered before or during their first RSV season. The Committee noted that infants eligible for palivizumab prophylaxis were excluded from the study.

13.11.2. The Committee noted the primary efficacy endpoint was RSV-associated medically attended lower respiratory infection (MALRI) through 150 days following administration. The Committee noted that RSV-associated MALRI occurred in 2.6% of infants receiving clesrovimab compared with 6.5% receiving placebo, corresponding to an efficacy of 60.4% (95% CI 44.1–71.9; p<0.001).

13.11.3. The Committee noted that clesrovimab reduced RSV-associated hospitalisations through 150 days, with 9 hospitalisations in the clesrovimab group compared with 28 in the placebo group, corresponding to a clinically significant efficacy of 84.2% (95% CI 66.6–92.6; p<0.001).

13.11.4. The Committee noted that efficacy appeared to persist throughout the RSV season, with efficacy through 180 days of 91.7% (95% CI 62.9–98.1) against severe RSV-associated medically attended lower respiratory infection and 91.2% (95% CI 77.2–96.6) against hospitalisation for RSV-associated lower respiratory infection.

13.11.5. The Committee noted that the definition of RSV-associated MALRI used in CLEVER differed from that used in the nirsevimab trials, as CLEVER required at least one indicator of lower respiratory tract infection or disease severity, whereas the nirsevimab studies required at least two indicators. The Committee noted that a post-hoc analysis using a nirsevimab-aligned case definition reported efficacy estimates of 88.0% (95% CI 76.1–94.0) through

150 days and 87.2% (95% CI 75.1–93.4) through 180 days (CLEVER interim CSR, Table 14.2-43). The Committee considered that differences in endpoint definitions complicated direct comparisons between clesrovimab and nirsevimab.

13.11.6. The Committee noted no significant safety concerns were identified, with adverse events, serious adverse events, and treatment-related adverse events occurring at similar rates in the clesrovimab and placebo groups. The Committee further noted that deaths were uncommon, and no treatment-related deaths were reported.

13.11.7. The Committee noted that the number needed to immunise to prevent one RSV-associated MALRI through 150 days was 15 (95% CI 11–21), while the number needed to immunise to prevent one severe RSV-associated medically attended lower respiratory infection was 108 (95% CI 60–226).

13.12. The Committee noted the SMART season 1 interim results (Zar, et al. N Eng J Med. 2025;393(13):1343-1345). The SMART clinical trial was a phase 2b/3, randomised, partially blinded, active-comparator study evaluating the safety, efficacy, and pharmacokinetics of clesrovimab compared with palivizumab in infants at increased risk of severe RSV disease.

13.12.1. The Committee noted the trial enrolled 901 palivizumab-eligible infants entering their first RSV season, including infants born prematurely (≤35 weeks gestational age) and infants with chronic lung disease (CLD) of prematurity or haemodynamically significant congenital heart disease (CHD). Participants were randomised 1:1 to receive either a single intramuscular dose of clesrovimab 105 mg (n=450) or monthly palivizumab 15 mg/kg (n=451).

13.12.2. The Committee noted that the primary efficacy period extended through 150 days following administration. The Committee noted that the incidence of RSV-associated medically attended lower respiratory infection was similar between treatment groups, at 3.6% (95% CI 2.0–6.0) with clesrovimab and 3.0% (95% CI 1.6–5.3) with palivizumab, suggesting comparable protection against RSV disease.

13.12.3. The Committee noted that RSV-associated hospitalisation rates were also similar between groups, occurring in 1.3% (95% CI 0.4–3.0) of infants receiving clesrovimab and 1.5% (95% CI 0.6–3.3) of infants receiving palivizumab.

13.12.4. The Committee considered that the SMART season 1 findings supported the conclusion that clesrovimab provides comparable clinical protection to palivizumab for high-risk infants during their first RSV season, while requiring only a single administration rather than monthly dosing.

13.12.5. The Committee noted that adverse events were generally similar between the clesrovimab and palivizumab groups, and that most adverse events were mild or moderate.

13.13. The Committee noted the SMART season 2 interim results (Zar, et al. N Eng J Med. 2025;393(13):1343-1345).

13.13.1. The Committee noted that 276 high-risk children who had participated in season 1 of the SMART study received a single 210 mg dose of clesrovimab prior to entering their second RSV season. Eligible participants included children with CLD, CHD, prematurity, or other risk factors associated with severe RSV disease.

13.13.2. The Committee noted that season 2 was not designed to assess comparative efficacy and did not include a comparator arm. The Committee therefore considered that the efficacy findings were descriptive only.

13.13.3. The Committee noted that RSV-associated medically attended lower respiratory infection occurred in 19 children, corresponding to an incidence of 7.3% of children through day 180 (95% CI 4.4–11.4), while RSV-associated hospitalisation occurred in 8 children, corresponding to an incidence of 3.0% of children through day 180 (95% CI 1.3–5.9).

13.13.4. The Committee noted that rates of RSV-associated disease in season 2 were higher than those observed in season 1, reflecting the substantially higher-risk population enrolled and the absence of a comparator arm. The Committee considered that these data provided supportive evidence regarding the use of clesrovimab in children entering a second RSV season but did not permit conclusions regarding comparative effectiveness.

13.13.5. The Committee noted that clesrovimab was generally well tolerated during the second RSV season. The Committee further noted that no drug-related serious adverse events were reported and that the two deaths observed during follow-up were not considered related to treatment.

13.14. The Committee noted that the supplier provided an indirect comparison of clesrovimab and nirsevimab using a matching-adjusted indirect comparison (MAIC), supported by a Bayesian network meta-analysis, to compare efficacy for the prevention of RSV-MALRI and RSV-associated LRTI hospitalisation in healthy pre-term and full-term infants over the first 150 days following administration.

13.14.1. The Committee noted that the indirect comparison was based on data from the CLEVER trial of clesrovimab and the MELODY and phase 2b trials of nirsevimab, with adjustment for key baseline characteristics including age, weight, and gestational age. The Committee noted that the comparison was limited to infants weighing less than 5 kg, as infants weighing 5 kg or more received a different dose in the nirsevimab phase 3 programme.

13.14.2. The Committee noted that, for RSV-associated MALRI, the Bayesian network meta-analysis estimated a median risk reduction relative to placebo of [redacted] for clesrovimab [redacted] and [redacted] for nirsevimab [redacted]. The Committee noted that the relative risk reduction for clesrovimab compared with nirsevimab was estimated at [redacted], with a wide credible interval.

13.14.3. The Committee noted that the MAIC estimated a relative risk reduction for RSV-associated MALRI of [redacted] before matching and [redacted] after matching. The Committee considered that, because the confidence intervals were wide, no conclusive statement regarding a difference in treatment effect after matching could be made.

13.14.4. The Committee noted that, for RSV-associated LRTI hospitalisation, the Bayesian network meta-analysis estimated a median risk reduction relative to placebo of [redacted] for clesrovimab [redacted] and [redacted] for nirsevimab [redacted]. The Committee noted that the relative risk reduction for clesrovimab compared with nirsevimab was estimated at [redacted], with a wide credible interval.

13.14.5. The Committee noted that the MAIC for RSV-associated LRTI hospitalisation estimated an indirect treatment comparison relative risk reduction of [redacted] before matching and [redacted] after matching. The Committee considered that, as with the MALRI endpoint, the

confidence intervals were wide and did not support a conclusive statement regarding a difference in treatment effect between clesrovimab and nirsevimab after matching.

13.14.6. The Committee noted that both clesrovimab and nirsevimab demonstrated large and statistically significant reductions in RSV-related outcomes compared with placebo in their respective clinical trials. However, the Committee considered that the indirect comparative estimates were uncertain, with confidence intervals crossing the null value, and therefore did not demonstrate a statistically robust difference between the two monoclonal antibodies

13.14.7. The Committee noted that no head-to-head clinical trial comparing clesrovimab and nirsevimab was available. The Committee considered that the available evidence suggested clesrovimab and nirsevimab were broadly comparable in efficacy, but that differences in trial design, study populations, dosing regimens, and endpoint definitions limited the ability to draw firm conclusions regarding comparative effectiveness.

13.15. The Committee was made aware of a recent systematic review and network meta-analysis (Nosho, et al. Journal of Clinical Question. 2026;3(1):e107), which synthesised evidence from 13 randomised controlled trials involving 21,505 participants and compared palivizumab, nirsevimab and clesrovimab for the prevention of RSV-associated disease in infants (full term, preterm, and high risk) and young children. The Committee noted that both direct and indirect comparisons were included, and that the analysis evaluated RSV-associated hospitalisation, medically attended RSV-associated LRTI, severe RSV-associated LRTI, and treatment-associated adverse events over a single RSV season.

13.15.1. The Committee noted that all three monoclonal antibodies were associated with significant reductions in RSV-associated hospitalisation, medically attended RSV-associated LRTI, and severe RSV-associated LRTI compared with placebo or standard care, without evidence of an increased risk of treatment-associated adverse events.

13.15.2. The Committee noted that nirsevimab demonstrated greater efficacy than clesrovimab for medically attended RSV-associated LRTI in the network meta-analysis (OR 0.61, 95% CI 0.38–0.98). The Committee considered that this apparent difference was uncertain with a confidence interval approaching unity, and may in part reflect differences in endpoint definitions used across the underlying clinical trials, noting that the clesrovimab CLEVER study used a broader definition of medically attended RSV-associated lower respiratory infection than the MELODY and phase 2b nirsevimab studies, which may limit the validity of indirect comparisons between the two products.

13.16. The Committee considered that clesrovimab would provide a clinically meaningful reduction in RSV disease burden for infants and their families, and noted that the magnitude of treatment effect appeared broadly comparable to that previously observed with nirsevimab.

13.17. The Committee noted that the clinical trials were not powered to detect differences in RSV-related mortality. However, the Committee considered it reasonable to expect that the observed reductions in severe RSV disease and RSV-related hospitalisations would translate into a reduction in RSV-associated mortality, although the magnitude of mortality benefit remains uncertain.

13.18. The Committee noted that, in addition to preventing acute RSV disease, clesrovimab may provide wider health benefits through reducing subsequent wheeze and asthma-related presentations and reducing hospitalisations for lower respiratory tract

infections from any cause. The Committee considered that these potential benefits were biologically plausible and may be inferred from emerging evidence for RSV monoclonal antibodies (Razzini, et al. Lancet Infect Dis. 2026;26(5):522-34), although direct evidence for clesrovimab remains limited.

13.19. The Committee considered the evidence to be relevant and generalisable to the New Zealand context and noted that, given the high incidence of RSV disease and RSV-related hospitalisation in New Zealand infants, the health benefits observed in the clinical trials would likely translate into a substantial clinical benefit for New Zealand children and their whānau.

13.20. The Committee considered the evidence supporting clesrovimab was of high quality, noting that the efficacy was demonstrated in large, multi-country, randomised controlled trials with placebo and active comparators. The Committee further noted that comparisons with nirsevimab were based on indirect evidence only; however, indirect comparative analyses reviewed suggested that clesrovimab and nirsevimab were broadly comparable in efficacy.

Suitability

13.21. The Committee noted its previous discussion during the November 2025 review of nirsevimab and reaffirmed its view that a universal RSV immunisation programme for infants would likely be more efficient, equitable and simpler to deliver than a targeted high-risk programme.

13.22. The Committee noted that cold-chain requirements may present practical challenges for administration of clesrovimab or nirsevimab in home birth settings, and considered that midwifery-led clinics, general practice, or other community delivery models may be required to support equitable access for these infants.

13.23. The Committee noted that experience with palivizumab highlighted the inefficiencies associated with targeted delivery models, including the need for repeated administration and greater health service resource requirements.

13.23.1. The Committee considered that the available clinical trial and indirect comparative evidence suggested that the health benefits of clesrovimab were broadly comparable to palivizumab in high-risk infants. The Committee noted that clesrovimab requires a single administration compared with monthly palivizumab dosing. The Committee considered that this difference in administration may result in improved access, treatment completion, and programme efficiency in routine clinical practice with clesrovimab compared to palivizumab. However, it noted that no published evidence was available to demonstrate that these potential implementation advantages translate into improved clinical outcomes or real-world effectiveness.

13.24. The Committee considered that a universal programme could improve access and equity, particularly if administration occurred at birth or alongside routine infant healthcare contacts.

13.25. The Committee further noted that uptake among infants would likely be high, particularly for those born during the RSV season, and that alternative delivery pathways, including midwifery-led services, primary care, Plunket, and mobile clinics would be important to support access for infants born outside hospital settings and for high-risk children entering their second RSV season.

13.25.1. The Committee noted that pharmacy-based delivery could provide an additional route of access for RSV immunisation and may be well suited to management of cold-chain requirements. However, Members noted that the number of pharmacist vaccinators accredited to provide infant (<12 months of

age) vaccinations is still low. It is expected to increase as more pharmacists complete the training.

13.26. The Committee noted that clesrovimab is administered as a single fixed dose regardless of infant weight, with a recommended dose of 105 mg for infants entering their first RSV season and 210 mg (2x 0.7 mL injections) for high-risk children entering their second season.

13.26.1. The Committee considered that fixed dosing may simplify programme delivery compared with nirsevimab, which requires weight-based dosing during the first RSV season.

13.26.2. The Committee noted advice from the Australian Technical Advisory Group on Immunisation (ATAGI) that programme complexity and the use of multiple products with different dosing schedules may contribute to administration errors (ATAGI, 2025). The Committee considered that a simpler dosing regimen may reduce operational complexity and support ease of implementation within an RSV immunisation programme. However, it did not consider that any differences in regimen complexity were likely to result in a major difference in clinical outcomes.

13.27. The Committee was made aware of the following studies evaluating RSV monoclonal antibody resistance and viral escape, including analyses of clesrovimab and nirsevimab binding sites, in vitro resistance mutations, molecular surveillance data, and clinical trial sequencing results. The Committee noted that both clesrovimab and nirsevimab target highly conserved regions of the RSV F protein and that resistance-associated variants appeared to be uncommon in circulating RSV strains. The Committee discussed the potential for resistant variants to emerge under selective pressure but noted that ongoing surveillance and susceptibility monitoring would be important to understand the clinical significance of such variants and any future impact on the effectiveness of RSV prevention strategies.

- Fridman, et al. Open Forum Infect Dis. 2025;12:ofae631.2486
- Tang, et al. 2025, BSAC Spring Conference, Birmingham, UK
- Tang, et al. Nature Communications. 2019;10:4153
- Mahool, et al. Open Forum Infect Dis. 2026;13(1):ofaf695.063
- Wetzke, et al. Influenza Other Respir Viruses. 2025;19(9):e70164

Cost and savings

13.28. The Committee noted that no passive or active RSV immunisation options are currently funded for infants outside the high-risk palivizumab-eligible population.

13.29. The Committee considered that funding clesrovimab would likely result in additional health sector costs associated with programme delivery and administration, but that these costs may be partially offset by reductions in RSV-related healthcare utilisation, including primary care visits, emergency department presentations, hospitalisations, and intensive care admissions associated with a reduced burden of RSV disease.

13.30. The Committee noted that administration costs associated with clesrovimab would primarily relate to vaccinator fees and programme delivery. The Committee considered that clesrovimab would likely be administered through the same delivery pathways previously discussed for nirsevimab, with most infants born during the RSV season receiving vaccination prior to hospital discharge and infants born outside the season receiving vaccination in community settings.

13.31. The Committee noted that the single fixed-dose regimen of clesrovimab would reduce dosing complexity compared with palivizumab, which requires multiple weight-based doses throughout the RSV season, and was likely to reduce associated administration costs for high-risk infants.

13.32. The Committee further noted that, while clesrovimab may offer reduced dosing complexity compared with weight-based nirsevimab dosing in the first season, administration costs would be expected to be broadly similar between the two products, particularly for high-risk children entering their second RSV season where both products are administered as a single fixed dose.

13.33. The Committee noted a United States-based cost-effectiveness analysis comparing clesrovimab and nirsevimab (Yarnoff et al. Infect Dis Ther. 2026 Apr;15(4):1047-1073), concluded that nirsevimab was associated with greater clinical and economic benefits. However, the Committee noted that the analysis was funded by the manufacturer of nirsevimab and relied on efficacy estimates that may not have been directly comparable due to differences in trial outcome definitions and modelling assumptions regarding duration of protection.

13.34. Members noted that, compared with clesrovimab or nirsevimab, palivizumab requires substantially greater health service resources to administer, including the establishment of dedicated clinics and up to five doses per RSV season. The Committee considered that the need for repeated clinic visits may increase costs and create barriers to treatment completion, and discussed whether all eligible infants receive a full course of therapy in routine clinical practice.

Funding criteria

13.35. The Committee considered RSV surveillance data (PHFScience, Respiratory Illness Infections Dashboard, 2026) and recommended that March–August be used to define the RSV season for funding eligibility purposes, noting that this timeframe was consistent with recent New Zealand surveillance data and may better reflect the period of RSV circulation than the March–July season currently specified in the nirsevimab criteria.

Summary for assessment

13.36. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for clesrovimab if it were to be funded in New Zealand for the prevention of RSV LRTD in newborns and 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.

Population	**All infants in or approaching their first RSV season**	**High risk subgroup of infants in or approaching their first or second RSV season**
	All infants not otherwise included in the high-risk group	Infants currently eligible for funded palivizumab, ie: - Infants born ≤32 weeks gestational age (wGA) 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.
Intervention	Single dose of clesrovimab 105 mg, administered as intramuscular (IM) injection at birth, in, or approaching the RSV season (1 x 105 mg/ 0.7 mL prefilled syringe)	Season 1: Single dose of clesrovimab 105 mg, administered as IM injection at birth, in, or approaching the RSV season (1 x 105 mg/ 0.7 mL prefilled syringe) Season 2: Single dose of clesrovimab 210 mg, administered as IM injection in or approaching the RSV season (2 x 105 mg/ 0.7 mL prefilled syringes)
Comparator(s) (NZ context)	No passive or active immunisation against RSV.	Palivizumab 15mg/kg per month of RSV season 1 and season 2 (seasons typically last 5 months)
Outcome(s)	A reduction in RSV respiratory tract infection (RTI) or bronchiolitis, resulting in: - Reduced health care utilisation (GP appointments, emergency department [ED] presentations, hospitalisations, intensive care admissions) - Reduced mortality - Reduced parental time off work due to caring for infant with RSV RTI/ bronchiolitis	

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.

14. RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in infants by active immunisation of pregnant individuals

Application

14.1. The Committee reviewed a supplier and consumer application for the recombinant respiratory syncytial virus pre-fusion F protein (RSVpreF) (Abrysvo) vaccine for the prevention of respiratory syncytial virus (RSV) associated lower respiratory tract illness (LRTI) in infants by active immunisation of pregnant individuals.

14.2. The Committee noted that the consumer application was received in September 2024, and the supplier submitted supporting information in March 2026.

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

Recommendation

14.4. The Committee **recommended** that RSVpreF (Abrysvo) for the prevention of RSV LRTI in infants by active immunisation of pregnant individuals be listed with a **high priority**, within the context of immunisation, subject to the following eligibility criteria:

> Respiratory Syncytial Virus Prefusion F Vaccine (RSVpreF; Abrysvo) Maternal indication
>
> Funded for people meeting the following criteria:

1. A single dose for pregnant individuals between 24 and 36 weeks' gestation (inclusive) of each pregnancy.

14.5. In making this recommendation the Committee noted:

14.5.1. the significant health need among infants, as RSV is the leading cause of hospital admission for infants and young children in New Zealand

14.5.2. that New Zealand experiences a comparatively high burden of RSV disease relative to many other high-income countries and emphasised the inequities observed within the population

14.5.3. the considerable annual RSV burden on general practice (GP), emergency departments (ED), hospitals and intensive care units (ICUs).

Discussion

Māori impact

14.6. The Committee discussed the potential impact of funding RSVpreF (Abrysvo) for the prevention of RSV LRTD in children on Māori health areas of focus | Hauora Arotahi and Māori health outcomes.

14.7. The Committee noted the significant inequities associated with RSV disease, noting substantially higher rates of hospitalisation among Māori and Pacific infants and among children living in areas of greater socioeconomic deprivation.

Populations with high health needs

14.8. 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 RSVpreF (Abrysvo) and noted that the ethnic and socioeconomic inequalities are considerable.

Background

14.9. The Committee noted that RSVpreF (Abrysvo) is a bivalent vaccine containing prefusion F glycoproteins from RSV A and RSV B strains. The Committee noted that vaccination during pregnancy induces maternal neutralising antibodies that are transferred across the placenta to the infant, providing passive protection against RSV during the first months of life when the burden of severe disease is highest.

14.10. The Committee noted that RSVpreF (Abrysvo) is administered as a single intramuscular dose between 24 and 36 weeks' gestation, with one dose recommended for each pregnancy.

14.11. The Committee noted correspondence from the Paediatric Society of New Zealand | Te Kāhui Mātai Arotamariki o Aotearoa, previously considered at its November 2025 meeting, and from the Royal New Zealand College of General Practitioners, which supported funding of RSV immunoprophylaxis for infants in Aotearoa New Zealand (NZ).

14.11.1. The Committee noted that the correspondence highlighted the substantial burden of RSV disease in infants, ongoing inequities in RSV-related health outcomes, and the importance of ensuring equitable access to effective RSV prevention strategies for pēpi and tamariki.

Health need

14.12. The Committee noted that it had previously considered RSV prevention in infants during its November 2025 review of nirsevimab and May 2026 review of clesrovimab, and reaffirmed that RSV remains a substantial unmet health need in New Zealand.

14.13. The Committee noted that RSV is the leading cause of hospital admission in the first year of life, that the burden of disease is concentrated in the first six months of life when infants are at greatest risk of hospitalisation, and that New Zealand experiences among the highest reported rates of bronchiolitis hospitalisation internationally.

14.14. The Committee further noted the considerable seasonal pressure RSV places on primary care, emergency departments, hospital services and paediatric intensive care units, with consequent impacts on infants, whānau and the wider health system.

14.15. The Committee noted the following studies which demonstrated a high incidence of RSV-associated hospitalisation in young infants, substantial seasonal variability and epidemic activity and marked inequities for Māori, Pacific peoples, and children living in areas of socioeconomic deprivation:

- Prasad, et al. Epidemiol Infect. 2019:147:e246
- Turner, et al. Influenza Other Respir Viruses. 2024;18(7):e13346
- Hatter, et al. Lancet Child Adolesc Health. 2021;5(12):e44-e45
- Grant, et al. N Z Med J. 2021;134(1540):7-12

Health benefit

14.16. The Committee noted that protection is dependent on sufficient time for transplacental antibody transfer before birth, appears to wane over time, and is less effective at preventing RSV infection than severe outcomes. The Committee further noted that the evidence supports reductions in severe disease and hospitalisation, while any effect on mortality remains uncertain due to the small number of events observed in clinical studies.

14.17. The Committee noted the MATISSE trial (Simões, et al. 2025. Obs & Gyn; 145(2):157-167), a phase 3 randomised, double-blind, placebo-controlled study involving 7,420 pregnant participants vaccinated between 24 and 36 weeks' gestation.

14.17.1. The Committee noted that maternal RSVpreF (Abrysvo) vaccination was associated with clinically meaningful reductions in severe RSV-associated lower respiratory tract illness and RSV-related hospitalisation in infants, with the greatest protection observed during the first 90 days of life.

14.17.2. The Committee noted vaccine efficacy against severe RSV-associated medically attended lower respiratory tract illness was 82.4% at 90 days and 70.0% at 180 days, while efficacy against RSV-related hospitalisation was 69.7% at 90 days and 55.3% at 180 days, suggesting protection waned over time but remained clinically relevant through the first six months of life.

14.17.3. The Committee noted that protection was mediated through transplacental transfer of maternal antibodies and that antibody transfer was greatest when vaccination occurred at least 14 days before birth. The Committee noted that infant antibody concentrations increased with longer intervals between vaccination and delivery, supporting the importance of administering vaccination sufficiently before delivery to maximise infant protection.

14.17.4. The Committee considered the safety profile of RSVpreF (Abrysvo) and noted that rates of adverse events, serious adverse events, congenital abnormalities, preterm birth, and infant adverse events were generally similar between the RSVpreF (Abrysvo) and placebo groups, with no new safety concerns identified during follow-up to 24 months.

14.17.5. The Committee noted that the MATISSE trial identified a numerical imbalance in preterm births among RSVpreF (Abrysvo) recipients compared with placebo (Madhi, et al. Obstet Gynaecol. 2025;145(2):147-156); however, no statistically significant increase in preterm birth, low birth weight, neonatal hospitalisation, or infant mortality was observed, and the overall safety profile was considered reassuring.

14.18. The Committee noted the BERNI study (Marc, et al. Lancet Inf Dis. 2025;25(9):1044-54) from Argentina, which demonstrated that maternal Abrysvo vaccination was associated with reductions in RSV-related hospitalisation in infants, with vaccine effectiveness of 78.6% up to 3 months of age and 71.3% up to 6 months of age.

14.19. The Committee noted the RIMA study (Razzini, et al. Lancet Reg Health. 2025;52:101296) from Argentina, which reported vaccine effectiveness of 80.8% against RSV-related hospitalisation in infants under 3 months of age and 66.1% at 6 months, with additional protection against paediatric intensive care admission and prolonged hospital stay.

14.20. The Committee noted the Scottish population-based study (McLachlan, et al. Lancet. 2025;26(4):632-73), which found maternal RSVpreF (Abrysvo) vaccination was associated with an 82.2% reduction in RSV-related hospitalisation among infants younger than 3 months of age, with similarly high effectiveness observed in preterm infants.

14.21. The Committee noted the UK multicentre study (Williams, et al. Lancet Child Adolesc Health. 2025;9(9):655-62), which demonstrated that protection against RSV-related hospitalisation was greater when maternal vaccination occurred more than 14 days before delivery, supporting the importance of sufficient time for transplacental antibody transfer.

14.22. The Committee was made aware of real-world evidence from England (Wilson, et al. UK Health Security Agency. 2026. London, UK) which demonstrated maternal RSVpreF (Abrysvo) vaccination was associated with an 81.3% reduction in RSV-related hospitalisation among infants, with effectiveness increasing as the interval between vaccination and birth increased, supporting administration earlier within the recommended gestational window to maximise transplacental antibody transfer and infant protection.

14.23. The Committee was made aware of the US VISION study (Moline, et al. JAMA Ped. 2026;180(3):314-24), a multicentre test-negative study of children aged under 2 years, which found that maternal RSV vaccination was associated with a 64% reduction in medically attended RSV-associated LRTI (95% CI 37–79) and a 70% reduction in RSV-related hospitalisation (95% CI 37–86) during the first six months of life. The Committee further noted that effectiveness estimates were lower than those observed with nirsevimab (81%; 95% CI 71–87) against RSV hospitalisation), although no direct comparison between the interventions was possible.

14.24. The Committee was made aware of a French nationwide cohort study (Jabagi, et al. JAMA. 2026;335(9):787-98) comparing maternal RSVpreF (Abrysvo) vaccination with infant nirsevimab prophylaxis, which found that nirsevimab was associated with a lower risk of RSV-associated hospitalisation than maternal vaccination (adjusted HR 0.74; 95% CI 0.61–0.88). The Committee noted that nirsevimab was also associated with lower risks of PICU admission (adjusted HR 0.58; 95% CI 0.42–0.80), ventilatory

support (adjusted HR 0.57; 95% CI 0.40–0.81), and oxygen therapy (adjusted HR 0.56; 95% CI 0.38–0.81).

14.25. The Committee noted the study by Jasset et al. (Jasset, et al. Am J Obstet Gynaecol. 2025;232(6):554.e1-554.e15), which demonstrated that maternal RSVpreF (Abrysvo) vaccination generated higher maternal and cord blood RSV antibody levels than natural infection and that transplacental antibody transfer increased with longer intervals between vaccination and delivery. The Committee noted that cord:maternal antibody transfer ratios were significantly lower when vaccination occurred within 2–4 weeks of delivery compared with more than 5 weeks before delivery, supporting vaccination earlier within the recommended gestational window to maximise infant protection.

14.26. The Committee noted evidence from a human challenge study of RSVpreF (Abrysvo) in healthy adults (Schmoele-Thoma, et al. NEJM. 2022;386:2377-86), which demonstrated complete protection against symptomatic RSV infection following viral challenge, with no vaccinated participants developing symptomatic infection compared with 42% of placebo recipients. The Committee noted that RSVpreF was also associated with lower viral load and more rapid viral clearance, although the relevance of these findings to indirect protection and transmission in real-world settings remains uncertain.

14.27. The Committee noted the following studies and systematic reviews evaluating the potential associated between maternal RSVpreF (Abrysvo) vaccination and preterm birth, which consistently found no statistically significant increase in the risk of preterm birth.

- Michnick, et al. JAMA Open. 2026;9(4):e266190
- Gabet, et al. Obstet Gynecol. 2026;147(1):118-26
- Scott, et al. NEJM. 2025;393(22):2221-42
- Phijffer, et al. Cochrane Database Syst Rev. 2024(5):CD015134

14.28. The Committee considered that ongoing pharmacovigilance and post-marketing studies remain important to further characterise safety outcomes during pregnancy and noted that earlier vaccination within the recommended gestational window may improve transplacental antibody transfer and infant protection, although additional data are needed to better define the optimal timing of vaccination during pregnancy.

14.29. The Committee noted that available clinical trial and immunogenicity data indicate that protection from maternal RSVpreF (Abrysvo) vaccination is greatest during the first six months of the infant's life and is expected to decline over time as passively acquired maternal antibodies wane.

14.29.1. The Committee considered that evidence for protection beyond six months of age is limited, and that it remains uncertain whether maternal vaccination alone would provide sufficient protection to cover a full RSV season for all infants, particularly those born early in the season.

14.30. The Committee noted that both maternal RSVpreF (Abrysvo) vaccination and long-acting monoclonal antibodies provide clinically meaningful protection against severe RSV disease in infants, but considered that monoclonal antibodies are likely to provide greater and more durable protection when compared with maternal vaccination alone. The Committee considered that achieving high population coverage is likely to be a critical determinant of overall programme success.

14.31. The Committee considered the evidence supporting maternal RSVpreF (Abrysvo) vaccination to be of high quality overall, noting consistent findings across the pivotal MATISSE randomised controlled trial and multiple real-world effectiveness studies demonstrating substantial reductions in severe RSV-associated LRTD and hospitalisation in infants.

14.32. The Committee noted that the available evidence was generally applicable to the New Zealand setting, although uncertainty remained regarding the duration of protection beyond six months of age, rare safety outcomes, and effects on RSV-related mortality due to the small number of events observed.

Suitability

14.33. The Committee noted that implementation of a maternal RSV immunisation programme would require consideration of practical delivery issues, including integration with existing antenatal vaccination schedules, cold-chain and distribution requirements, and the ability of immunisation information systems to accurately record maternal vaccination and link infant protection status. The Committee considered that these factors would be important to support programme delivery, coverage monitoring and decisions regarding the use of subsequent infant RSV preventive interventions.

Cost and savings

14.34. The Committee considered the mortality benefit uncertain.

14.35. The Committee discussed the potential long-term benefits of preventing severe RSV infection in early life, including possible reductions in recurrent wheeze and asthma later in childhood. The Committee considered that further New Zealand-specific evidence may help inform consideration of these potential benefits.

Funding criteria

14.36. The Committee considered that maternal RSV vaccination may offer advantages through integration with established antenatal immunisation programmes and could improve protection from birth, while monoclonal antibodies could provide an important complementary strategy for infants who are not protected through maternal vaccination or who remain at higher risk of severe RSV disease. The Committee considered that it would like to review optimal RSV protection strategies at a future meeting.

Summary for assessment

14.37. The Committee considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for RSVpreF (Abrysvo) if it were to be funded in New Zealand for the prevention of RSV LRTI in infants by active immunisation of pregnant people. 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	Vaccination of the pregnant person between 24 and 36 weeks of gestation to prevent RSV-associated lower respiratory tract illness (LRTI) in infants aged 0 to 6 months
Intervention	Single dose of 0.5 mL RSVpreF vaccine, administered via intramuscular injection at 24–36 weeks gestation.

Comparator(s) (NZ context)	No vaccination
Outcome(s)	Outcomes in relation to infants: • Reduction in RSV-related LRTI • Reduction in RSV-related acute respiratory illness • Reduction in RSV-related hospitalisations • Current evidence does not support infant mortality reduction • Reduction on health system resources

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.

15. RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in older adults

Application

15.1. The Committee reviewed a supplier application for RSVpreF (Abrysvo) vaccine for the prevention of respiratory syncytial virus (RSV) associated lower respiratory tract infection (LRTI) in older adults.

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

Recommendation

15.3. The Committee **recommended** that RSVpreF (Abrysvo) for the prevention of RSV LRTI in adults 60 years of age and older be listed with a **medium priority,** within the context of immunisation, subject to eligibility criteria.

15.4. The Committee **recommended** that RSVpreF (Abrysvo) for the prevention of RSV LRTI in high-risk adults aged 60 to 74 years with eligible comorbidities and all adults 75 years of age and older, be listed with a **high priority,** within the context of immunisation, subject to the following eligibility criteria:

1. Any of the following:
    - 1.1 A single dose for individuals aged 75 years and over; 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.

15.5. In making this recommendation, the Committee noted:

15.5.1. the substantial health need among older adults, particularly those aged 75 years and over, and those with comorbidities, due to the risk of severe RSV disease and hospitalisation.

15.5.2. that RSVpreF (Abrysvo) vaccination is expected to reduce primary care visits, emergency department presentations and hospitalisations associated with RSV infection in older adults.

15.5.3. that reducing RSV-related illness in older adults may lessen pressures on the health system, particularly for people with underlying comorbidities who are at increased risk of healthcare utilisation.

15.5.4. the potential for RSVpreF (Abrysvo) vaccination to improve health outcomes for Māori and Pacific peoples, who experience a higher burden of RSV-associated hospitalisation.

Discussion

Māori impact

15.6. The Committee discussed the impact of funding RSVpreF (Abrysvo) for the prevention of RSV LRTI in older adults with respect to Māori health areas of focus | Hauora Arotahi and Māori health outcomes. The Committee noted that Māori are at greater risk of RSV-associated hospitalisation when compared to New Zealand European and other ethnicities (non-Pacific peoples) (Prasad et al. 2020).

Populations with high health needs

15.7. The Committee discussed the health needs associated with RSV infection among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024–2027 as having high health needs.

15.7.1. The Committee noted that Māori and Pacific peoples are at increased risk of RSV-associated hospitalisation compared with other ethnic groups, and that adults living in areas of higher socioeconomic deprivation are also at greater risk of RSV-associated hospitalisation (Prasad et al. 2020).

Background

15.8. The Committee noted that it had previously considered RSV vaccination in older adults through its review of RSVpreF3 (Arexvy). Its recommendations evolved from an initial deferral in March 2024 due to uncertainties regarding disease burden, vaccine efficacy in high-risk populations, and duration of protection, to a recommendation in November 2025 with medium priority for adults aged 60 years and over and high priority for adults aged 60 to 74 years with eligible comorbidities and all adults aged 75 years and over.

Health need

15.9. The Committee noted that the health needs associated with RSV-related illness in older adults had been recently considered at its November 2025 meeting and therefore did not revisit these in detail.

15.10. The Committee noted that RSV infection in older adults, particularly those aged 75 years and over and those with comorbidities, is associated with substantial morbidity and mortality rates, including higher rates of hospitalisation, ICU admission, post-discharge care needs, readmission, and death. The Committee further noted that the burden of disease in New Zealand is likely underestimated due to limitations in RSV surveillance.

15.11. The Committee noted New Zealand SHIVERS data indicating that RSV is associated with a substantial burden of disease in older adults, with an adjusted incidence of RSV-associated acute respiratory infection (ARI) requiring hospitalisation of 99.2 per 100,000 population among adults aged 65 years and over, a median hospital stay of

four days, and mortality occurring both during hospitalisation and in the 30 days following discharge (Prasad, et al. PLOS ONE. 2020;15(6):e0234235).

15.12. The Committee further noted New Zealand SHIVERS data demonstrating that chronic medical conditions are common among adults hospitalised with RSV-associated acute respiratory infection, with 81% of cases having at least one underlying condition. The Committee further noted that asthma, chronic obstructive pulmonary disease, and diabetes mellitus were among the most frequently reported comorbidities (Prasad, et al. Clin Infect Dis. 2021;73(1):e158-e163).

Health benefit

15.13. The Committee noted this application is for recombinant respiratory syncytial virus pre-fusion F protein (RSVpreF; Abrysvo), a bivalent vaccine containing RSV-A and RSV-B prefusion F antigens. It is administered as a single intramuscular dose, and the Committee noted that prefusion F protein is a key target of neutralising antibodies against RSV infection.

15.14. The Committee noted the RENOIR trial (Walsh, et al. Clin Infect Dis. 2025;81(6):e680-e689), a phase 3 multicentre, randomised, double-blind, placebo-controlled study involving 36,862 adults aged 60 years and over, including participants with stable chronic medical conditions, that evaluated a single dose of RSVpreF (Abrysvo) over two RSV seasons.

15.14.1. The Committee noted that RSVpreF (Abrysvo) demonstrated clinically meaningful efficacy in prevention of RSV-associated LRTI, with vaccine efficacy against RSV-LRTI with three or more symptoms of 88.9% (95% CI 53.6–98.7) after the first RSV season and 77.8% (95% CI 51.4–91.1) after the second RSV season.

15.14.2. The Committee noted that vaccine efficacy against RSV-LRTI with two or more symptoms was 65.1% (95% CI 35.9–82.0) after the first RSV season and 55.7% (95% CI 34.7–70.4) after the second RSV season, indicating that protection waned over time but remained clinically relevant across two seasons.

15.14.3. The Committee noted that RSVpreF (Abrysvo) reduced medically attended RSV disease, with vaccine efficacy of 76.3% (95% CI 50.2–89.9) against medically attended RSV-LRTI with three or more symptoms, 60.0% (95% CI 37.2–75.2) against medically attended RSV-LRTI with two or more symptoms, and 53.2% (95% CI 35.7–66.2) against medically attended RSV-associated acute respiratory illness.

15.14.4. The Committee noted that efficacy appeared generally consistent across age groups and among participants with stable chronic medical conditions, although the trial included relatively few participants aged 80 years and over, resulting in uncertainty regarding the magnitude of benefit in the oldest age groups.

15.14.5. The Committee noted that immunogenicity analyses demonstrated robust neutralising antibody responses following vaccination, with geometric mean fold rises of 11.6 against RSV-A and 12.7 against RSV-B one month after vaccination, and antibody levels remaining above baseline before the second RSV season.

15.14.6. The Committee considered the safety profile of RSVpreF (Abrysvo) and that adverse event rates were generally similar between RSVpreF (Abrysvo) and the placebo groups, including severe or life-threatening adverse events (0.6% vs 0.5%), serious treatment-related adverse events (<0.1% vs 0%), and no vaccine-related deaths.

15.14.7. The Committee noted that two cases of Guillain–Barré syndrome (GBS) variants were reported among RSVpreF (Abrysvo) recipients; however, both cases had potential alternative or confounding aetiologies, no vaccine-related deaths were reported, and no additional related cases were identified through the second RSV season. The Committee considered that ongoing post-marketing surveillance would remain important given the rarity of these events.

15.14.8. The Committee noted several limitations of the RENOIR trial, including small samples sizes in some stratified subgroups, particularly among participants aged over 80 years, assessment of immunogenicity in only a subset of participants which prevented correlation of antibody levels with subsequent RSV disease, and conduct of the trial during the COVID-19 pandemic, where public health measures such as masking and social distancing may have reduced RSV circulation and affected case accrual, particularly in the first RSV season.

15.14.9. The Committee considered the RENOIR trial to provide moderate to high-quality evidence for Abrysvo efficacy and safety, noting that the trial was well designed but had limitations including defined sources of bias and involvement of Pfizer-employed authors. The Committee noted that supporting evidence from real-world studies was of lower quality, but was generally consistent with the RENOIR trial in demonstrating vaccine effectiveness, immunogenicity, and an acceptable safety profile.

15.15. The Committee noted the study by Athan et al. (Athan, et al. Clin Infect Dis. 2023;78(5):1360-1368), a phase 3 randomised, double-blind, placebo-controlled study involving 1,399 adults aged 65 years and over that evaluated concomitant administration of Abrysvo with seasonal inactivated influenza vaccine (SIIV) compared with sequential administration one month apart.

15.15.1. The Committee noted that immune responses to both Abrysvo and SIIV met prespecified non-inferiority criteria when administered concomitantly, suggesting that coadministration did not result in a clinically meaningful reduction in immunogenicity.

15.16. The Committee noted the DAN-RSV trial (Lassen, et al. N Eng J Med. 2025;394:138-151), a pragmatic, randomised study of 131,276 adults aged 60 years and older evaluating Abrysvo vaccination under real-world conditions.

15.16.1. The Committee noted that Abrysvo was associated with a reduction in RSV-related respiratory tract disease hospitalisations, with vaccine effectiveness of 83.3% (95% CI 42.9–96.9).

15.16.2. The Committee noted that the prespecified analysis of the DAN-RSV trial (Lassen, et al. JAMA. 2025;334(16):1431-1441) which evaluated cardiorespiratory and cardiovascular hospitalisations among older adults receiving Abrysvo. The Committee noted that RSVpreF (Abrysvo) reduced all-cause cardiorespiratory hospitalisations, corresponding to an estimated vaccine effectiveness of approximately 10%. The Committee noted that Abrysvo was not associated with a statistically significant reduction in all-cause cardiovascular hospitalisations. The Committee noted that no statistically significant differences were observed for myocardial infarction, heart failure, atrial fibrillation or stroke.

15.17. The Committee noted real-world evidence from RSV vaccination programmes in the United Kingdom, including studies from Scotland and a UK-wide analysis (Hameed, et al. Lancet Infect Dis. 2025;25(3):256-258); (Bucholc, et al. Lancet Reg Health

Europe. 2026;101620), which demonstrated reductions in RSV-related hospitalisations among older adults following Abrysvo vaccination.

15.17.1. The Committee considered that the real-world evidence was broadly consistent with the efficacy observed in clinical trials and supported the effectiveness of Abrysvo vaccination in reducing RSV-related hospitalisations in older adults.

15.18. The Committee noted the phase 1/2 study by Walsh et al (Walsh, et al. J Infect Dis. 2024;230(4):e905-e916), which evaluated antibody persistence and revaccination with RSVpreF (Abrysvo) in healthy adults aged 18–49 years and 65–85 years.

15.18.1. The Committee noted that RSVpreF (Abrysvo) elicited strong neutralising antibody responses following initial vaccination, with antibody levels remaining above baseline 12 months after vaccination.

15.18.2. The Committee noted that revaccination at 12 months generated only modest increases in antibody levels and that peak antibody responses following revaccination were lower than those observed after the initial dose.

15.19. The Committee noted a real-world test-negative case-control study (Tartof, et al. Lancet Reg Health – Americas. 2026;60:101520) evaluating RSVpreF (Abrysvo) effectiveness over two RSV seasons in adults aged 60 years and older presenting to hospital or emergency departments with RSV-associated respiratory illness.

15.19.1. The Committee noted that RSVpreF (Abrysvo) demonstrated sustained effectiveness against RSV-associated LRTD requiring hospitalisation or emergency department presentation, with vaccine effectiveness of 81% (95% CI 68–88) in the first RSV season and 75% (95% CI 47–89) in the second RSV season.

15.19.2. The Committee noted that vaccine effectiveness remained high among participants vaccinated in the first season, with effectiveness of 87% (95% CI 37–97) at less than 6 months following vaccination and 77% (95% CI 53–89) at 6 to 18 months, suggesting protection waned over time but remained clinically meaningful.

15.20. The Committee noted that, in the absence of head-to-head comparative trials, there was no clear evidence of clinically meaningful differences between RSVpreF (Abrysvo) and RSVpreF3 (Arexvy) in terms of efficacy, effectiveness, or durability of protection. The Committee noted that evidence from both vaccine programmes was broadly consistent, with both vaccines demonstrating protection across at least two RSV seasons and no evidence to support routine revaccination prior to the second season.

15.21. The Committee considered the available evidence was insufficient to reliably quantify any mortality benefit. The Committee noted that the RENOIR trial was not powered to detect differences in RSV-related or all-cause mortality. The Committee further noted the Cochrane review (Saif-Ur-Rahman, et al. Cochrane Database Syst Rev. 2025;9(9):CD016131) found little to no difference in mortality between RSVpreF (Abrysvo) vaccines and placebo (RR 0.94; 95% CI 0.71–1.24), and previous advice from the Committee noted that reductions in RSV-related hospitalisation should not be assumed to correspond directly to reductions in mortality.

Suitability

15.22. The Committee noted that RSVpreF (Abrysvo) is administered as a single intramuscular dose, requires refrigerated storage, and can be co-administered with seasonal influenza vaccination, which may support vaccine uptake and programme delivery.

15.23. The Committee noted that co-administration of RSVpreF (Abrysvo) with influenza vaccine and Tdap had been evaluated and was not associated with any significant safety concerns.

Cost and savings

15.24. The Committee noted that there remains uncertainty regarding the long-term effectiveness of RSVpreF (Abrysvo), including the potential impact on mortality outcomes and the optimal revaccination schedule.

Funding criteria

15.25. The Committee considered the proposed eligibility criteria to be appropriate for identifying older adults at greatest risk of severe RSV disease and considered that the criteria were broadly aligned with the available clinical evidence and the populations most likely to derive benefit from vaccination.

Summary for assessment

15.26. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for RSVpreF (Abrysvo) if it were to be funded in New Zealand for the prevention of RSV-LRTI in older adults. 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 and older • Adults aged 60 to 74 years with eligible factors or comorbidities, and all adults aged ≥ 75 years
Intervention	0.5mL RSVPreF vaccine administered via intramuscular injection
Comparator(s) (NZ context)	No vaccination
Outcome(s)	• Reduction in RSV-related LRTI • Reduction in RSV-related acute respiratory illness • Reduction in RSV-related hospitalisations • No evidence to support a reduction in RSV-related mortality based on the RENOIR trial
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.	

16. RSVPreF Vaccine (Abrysvo) for the prevention of RSV LRTI in immunocompromised adults

Application

16.1. The Committee reviewed the application for RSVpreF (Abrysvo) for the prevention of RSV) lower respiratory tract infection (LRTI) in immunocompromised adults (18-59 years).

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

Recommendation

16.3. The Committee **recommended** that RSVpreF (Abrysvo) for the prevention of RSV LRTI in immunocompromised adults be **deferred**.

16.4. In making this recommendation, the Committee considered there was insufficient long-term and real-world evidence to support the clinical effectiveness of the vaccine in this population at this time.

Discussion

Māori impact

16.5. The Committee discussed the impact of funding RSVpreF (Abrysvo) for the prevention of RSV LRTI in immunocompromised adults on Māori health areas of focus | Hauora Arotahi and Māori health outcomes.

16.5.1. The Committee noted Respiratory Health (Romaha Ora) as a Hauora Arotahi (Pharmac Māori Health Areas of Focus).

16.5.2. The Committee noted that Māori are at greater risk of RSV-associated hospitalisation when compared to New Zealand Europeans (Prasad et al. PLoS ONE. 2020).

16.5.3. The Committee noted the limited data available for the immunocompromised subgroup but also noted the significant inequities associated with RSV disease experienced by Māori.

Populations with high health needs

16.6. The Committee discussed the health need(s) of RSV LRTI among immunocompromised 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 RSVpreF (Abrysvo) and considered:

16.6.1. New Zealand data report that Māori and Pacific peoples show increased rates of hospitalisation associated with RSV (Prasad et al. PLoS ONE. 2020).

16.6.2. The same study reports increased RSV-associated hospitalisation rates for those living in or nearby areas with low socioeconomic status (Prasad et al. PLoS ONE. 2020).

Background

16.7. The Committee noted its previous consideration of RSVpreF3 (Arexvy) vaccination in November 2025 and noted that moderate or severe immunodeficiency has been previously identified as a risk factor for severe RSV disease in adults.

16.8. The Committee noted that, in its November 2025 recommendations, it had prioritised RSV vaccination for older adults at increased risk of severe disease, including those with moderate or severe immunodeficiency with high priority, reflecting the increased burden and severity of RSV-associated illness in these populations.

Health need

16.9. The Committee noted that severe comorbidities and risk factors can have a substantial negative impact on health-related quality of life associated with severe RSV infection outcomes. The Committee further noted evidence of immunocompromised individuals or those with chronic medical conditions, such as cardiac disease, pulmonary disease, diabetes, and chronic kidney disease are at increased risk of poor quality-of-life outcomes associated with RSV (Njue et al. Open Forum Infect Dis. 2023).

16.10. The Committee considered RSV waning immunity to be a concern for severely immunocompromised individuals and is a contributing factor to elevated risk of RSV infection. The Committee noted that the optimal revaccination interval remains uncertain.

16.11. The Committee noted that immunocompromised individuals are extremely high risk and would benefit significantly from vaccination.

Health benefit

16.12. The Committee noted the MONeT trial was supplied as key evidence for RSVpreF LRTI efficacy in immunocompromised adults. The Committee noted the trial was divided into two sub-studies, SubStudy A (SSA; adults 18-59 years with chronic medical conditions, Davis et al. Clin Infect Dis. 2.25) and SubStudy B (SSB; immunocompromised, renally impaired adults ≥ 18 years, Almeida et al. Vaccines (Basel). 2025).

16.12.1. The Committee considered the relevance of bridging immunogenicity data from other populations to severely immunocompromised people, using immunogenicity endpoints from the MONeT trial, including neutralising geometric mean titres (GMTs) and neutralising titre geometric mean fold rises (GMFRs). The Committee considered it remained unclear how well these immunogenicity findings would predict vaccine effectiveness in severely immunocompromised people.

16.13. The Committee noted SSA (n=678; 453 active, 225 placebo) was a phase 3, randomised (2:1), double-blinded, and placebo-controlled trial. The Committee noted the study evaluated the safety and immunogenicity of a single dose of RSVpreF (120 µg) in adults aged 18–59 years with prespecified chronic medical conditions associated with increased risk of severe RSV disease. The Committee noted that the study aimed to determine non-inferiority of RSV-A and RSV-B responses at 1 month post-vaccination in adults compared with a randomly selected subset of adults ≥60 years who had received RSVpreF in the pivotal RENOIR efficacy trial (Walsh et al. Clin Infect Dis. 2025).

16.13.1. The Committee noted chronic medical conditions included in the trial were chronic pulmonary disease (including asthma), cardiovascular disease (excluding isolated hypertension), renal, hepatic, neurologic, haematologic, and metabolic disorders (including diabetes).

16.13.2. The Committee noted that individuals with immunocompromising conditions were excluded.

16.13.3. The Committee noted that non-inferiority criteria were met for all 4 immunogenicity endpoints across all prespecified medical conditions. The Committee considered that RSVpreF was expected to be effective in young adults with chronic medical problems.

16.14. The Committee noted SSB (n=203) was a phase 3, single-arm, open-label, descriptive study evaluating the safety and immunogenicity of RSVpreF in adults aged ≥18 years with immunocompromising conditions or end-stage renal disease requiring haemodialysis. The Committee noted individuals received 2 doses of RSVpreF, 1 month apart.

16.14.1. The Committee noted that immunocompromised participants included solid organ transplant recipients, individuals receiving immunomodulatory therapy for autoimmune inflammatory disorders, individuals undergoing treatment for advanced non-small-cell lung cancer, and individuals on maintenance haemodialysis.

16.14.2. The Committee noted the trial was a descriptive assessment of individuals' immune responses.

16.14.3. The Committee noted findings that 1 month after the first dose, RSVpreF elicited robust neutralising antibody responses against RSV-A and RSV-B across age groups and immunocompromised subgroups, with overall geometric mean fold rises of 8.3 (RSV-A) and 9.0 (RSV-B). The Committee noted neutralising responses were lower in solid organ transplant recipients.

16.14.4. The Committee noted the second dose did not provide any meaningful further increase in antibody response compared to the first dose.

16.14.5. The Committee noted there were no serious adverse events attributed to the vaccines.

16.14.6. The Committee considered the population in SSB to be appropriate to include as an explicitly eligible population for vaccination in the New Zealand context if <60 years.

16.14.7. The Committee noted that the study was not an RCT, did not have a comparator group, and only reported whether an immunocompromised group of young adults would elicit an immune response to the vaccine.

16.15. The Committee noted the Tartof et al. SSRN (Lancet preprint) 2025 study as supporting evidence for RSVpreF for the prevention of RSV LRTI for immunocompromised adults. The Committee noted the trial was a retrospective test-negative case-control study of adults ≥60 years with lower respiratory tract disease (LRTD) or acute respiratory illness (ARI) hospitalisation/ED.

16.15.1. The Committee noted that vaccine effectiveness (VE) in immunocompromised persons was 72% (95% CI: 34-88) in the first season and dropped to 46% (95% CI: -69 to 83) in the second season. The Committee considered that if immunocompromised individuals were to be vaccinated, the duration of vaccine efficacy is unclear and may be relatively short.

16.15.2. The Committee noted the cohort consisted of adults ≥60 years and, therefore, considered the applicability of the findings to the patient group outlined in the application (18-59 years).

16.16. The Committee noted Surie et al. JAMA. 2025 as a test-negative, case-control study of adults ≥60 years (n=6958). The Committee noted VE against RSV-associated hospitalisation across two seasons was 58% (95% CI: 45-68). The Committee noted, however, this was significantly lower for immunocompromised adults (30%; 95% CI -9 – 55) vs immunocompetent adults (67%). The Committee noted the wide confidence intervals and considered the uncertainty with results they infer.

16.17. The Committee noted Fry et al. JAMA. 2025 as a test-negative, case-control designed study to estimate VE. The Committee noted the study cohort was comprised of adults ≥60 years (n=787,822). The Committee noted that VE against RSV-associated ARI was 75.1% (95% CI: 73.6-76.4). The Committee noted that VE in immunocompromised adults was 67.0% (95% CI: 62.6-79.0) in ages 60-74 and 73.1% (95% CI 69.9-76.0) in ages ≥75.

16.17.1. The Committee noted an excess of 11.2 cases of Guillain-Barré Syndrome (GBS) followed administration of 1,000,000 doses of RSVpreF and considered the importance of monitoring GBS in the context of RSVpreF vaccines. The Committee considered that the risk of GBS may not be vaccine specific, ie monitoring of GBS risk is relevant for Abrysvo and other RSV vaccines.

16.18. The Committee considered the health benefits of funding RSVpreF for immunocompromised adults ≤ 60 years.

16.18.1. The Committee considered that, while a plausible biological rationale for benefit in immunocompromised adults exists, the evidence base for RSVpreF vaccine efficacy and duration of vaccine effectiveness in this population is lacking.

16.18.2. The Committee noted that the key evidence in this application was largely restricted to immunogenicity data from a small, single-arm study without a comparator, and that effectiveness estimates were derived primarily from observational studies in adults aged ≥60 years, limiting applicability to the proposed population.

16.18.3. The Committee noted the need for relevant, real-world evidence prior to any future recommendation.

Suitability

16.19. The Committee noted that both the formulation of the vaccine and its cold-chain storage were standard.

16.20. The Committee noted that co-administration with the seasonal influenza vaccine was possible.

16.21. The Committee noted that co-administration with a tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) was possible.

16.21.1. The Committee noted that co-administration in non-pregnant women resulted in non-inferior immune responses to RSV-A, RSV-B, diphtheria, and tetanus. However, an inferior immune response to acellular pertussis (measured as lower geometric mean antibody concentrations to acellular pertussis antigens) was observed compared to Tdap alone (Peterson, et al. J Infect Dis. 2021;225(12):2077-86).

Cost and savings

16.22. The Committee considered that potential savings, assumed through reduced healthcare utilisation, are dependent on VE and uptake within the target population.

Summary for assessment

16.23. The Committee noted that elements of the PICO (population, intervention, comparator, outcomes) for this application are unclear/uncertain at this time.

16.24. The PICO may be developed further based on new information, additional clinical advice, or further analysis by Pharmac staff.
