Record of the Immunisation Advisory Committee Meeting held on 26 June 2025

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

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

The Immunisation Advisory Committee may:

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

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

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

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

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

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

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

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1. Attendance

Present
Stephen Munn - Chair
Edwin Reynolds
Elizabeth Wilson
Erasmus Smit
Helen Evans
James Ussher
Karen Hoare
Lance Jennings
Nikki Turner
Sarah McClean-Osborn
Stuart Dalziel
Tony Walls

Apologies
David Murdoch
Osman Mansoor
Sean Hanna

2. Summary of recommendations

Pharmaceutical and Indication	Recommendation
• Recombinant varicella zoster vaccine (Shingles vaccine, RVZV) for the prevention of shingles in adults receiving certain immune-modulating agents, within the context of vaccines and immunisation, subject to eligibility criteria	High priority
• Pneumococcal 21-valent conjugate vaccine (PCV21) be included in the upcoming vaccines procurement process for current adult pneumococcal vaccine eligibility criteria.	No formal recommendations
• Pneumococcal 21-valent conjugate vaccine (PCV21), within the context of vaccines and immunisation, for all adults aged 65 years and over.	High priority
• The Committee **recommended** that Pneumococcal 21-valent conjugate vaccine (PCV21), within the context of vaccines and immunisation, for high-risk adult groups subject to eligibility criteria	High priority

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. Pharmac staff provided an overview of the upcoming Various Vaccines and Influenza Vaccine RFP that is due to be released mid-2025. This covered the vaccines included in the RFP together with the potential widened access proposals. The various terms of the agreements for various vaccines, pneumococcal vaccines and influenza vaccine was shared along with an overview of the evaluation process.

6. Matters Arising: COVID-19 vaccine RFP process update post consultation – sharing feedback

6.1. The Committee noted the status of the COVID-19 vaccine RFP process with a provisional agreement pending consultation and Pharmac Board approval.

6.2. The Committee noted the additional single-dose pre-filled syringe presentation that would be listed for adults.

6.3. The Committee noted the feedback provided by various stakeholder groups in response to the consultation.

7. Matters Arising: Recombinant zoster vaccine: Widening access for immunocompromised groups [Update to Australian Immunisation Handbook now available]

Application

7.1. The Committee continued its review of the access criteria for recombinant varicella zoster vaccine (RVZV) for immunocompromised adults.

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

Recommendation

7.3. The Committee **recommended** that recombinant varicella zoster vaccine (Shingles vaccine, RVZV) for the prevention of shingles in adults receiving certain immune-modulating agents be listed with a **high priority**, within the context of vaccines and immunisation, subject to the following eligibility criteria (with wording regarding corticosteroid dosing pending clarification):

Recombinant varicella zoster vaccine [Shingles vaccine]
Either:
1. Two doses for all people aged 65 years; or
2. Two doses for people 18 years of age and over with any of the following:
   a. planning, receiving and post CAR-T cell therapy; or
   b. pre- and post-haematopoietic stem cell transplant; or
   c. pre- or post-solid organ transplant; or
   d. haematological malignancies; or
   e. people living with HIV infection; or
   f. planned or receiving immune-modulating agents with severe or moderate immunosuppressive potential, as listed in the Australian Immunisation Handbook (see note); or
   g. planned or receiving corticosteroids with dosages of severe or moderate immunosuppressive potential; or
   h. end stage kidney disease (CKD 4 or 5); or
   i. primary immunodeficiency.

Notes:
1. For criterion 2.f, the immunosuppressive potential of immune-modulating agents is detailed in the Australian Immunisation Handbook, 2025 in tables in the section 'Vaccination for people who are immunocompromised'. The tables categorise specific agents' immunosuppressive potential (mild, moderate, or severe) by daily dose and duration across various therapies.

7.4. The Committee made this recommendation based on:

7.4.1. the high health need of individuals who are immunocompromised

7.4.2. the evidence that there would be significant health benefit experienced by people who are immunocompromised

7.4.3. the suitability of vaccine to be given to people who are immunocompromised

7.4.4. the prevention of shingles being more effective in preventing the complications of shingles than the current treatments available

7.4.5. the credibility, alignment and practicality of adapting the immunosuppressive potential information detailed in the Australian Immunisation Handbook section on 'Vaccination for people who are immunocompromised' when considering eligibility due to immune-modulating agent exposures.

7.5. The Committee noted that parts of the immune-modulating agent-related and corticosteroid-related criteria await clarification on dosing.

7.6. The Committee considered that Pharmac staff should approach ATAGI for further advice and clarification on the identified aspects of the Australian Immunisation Handbook (i.e. the basis for their classifications of immunosuppressant potential of corticosteroid doses, and the rationale for categorising JAK inhibitors as having moderate immunosuppressive potential).

7.7. The Committee considered that it (or its members or relevant experts) could subsequently reconsider the list of immune-modulating agents and corticosteroid dosages to confirm or better tailor it to the New Zealand funding context.

7.8. The Committee also considered that it may be helpful to similarly review the Australian Immunisation Handbook's tables detailing potentially severely immunocompromising medical conditions and their alignment with the Committee's recommended criteria.

Discussion

Background

7.9. The Committee noted the current funded access for RVZV applies to individuals aged 65 years and to adults living with particular immunocompromising medical conditions or receiving particular immunosuppressing treatments, who meet the following criteria:

Recombinant varicella zoster vaccine [Shingles vaccine]
Either:
1. Two doses for all people aged 65 years; or
2. Two doses for people 18 years of age and over with any of the following:
   a. pre- and post-haematopoietic stem cell transplant or cellular therapy; or
   b. pre- or post-solid organ transplant; or
   c. haematological malignancies; or
   d. people living with poorly controlled HIV infection; or
   e. planned or receiving disease modifying anti-rheumatic drugs (DMARDs) for systemic lupus erythematosus, polymyalgia rheumatica or rheumatoid arthritis; or
   f. end stage kidney disease (CKD 4 or 5); or
   g. primary immunodeficiency.

7.10. The Committee noted it had since considered RVZV for immunocompromised adults in November 2023 and March 2024, with the latter meeting provisionally recommending in effect the following amendments to the access criteria (deletions in ~~strikethrough~~, additions in **bold**, subsequent revisions provided by the Committee separately in [square brackets]):

> Recombinant varicella zoster vaccine [Shingles vaccine]
> Either:
> 1. Two doses for all people aged 65 years; or
> 2. Two doses for people 18 years of age and over with any of the following:
>
> a. pre- [and] post-haematopoietic stem cell transplant ~~or cellular therapy~~; or
> **b. planning, receiving [and] post CAR-T cell therapy; or**
> ~~b.~~**c.** pre- or post-solid organ transplant; or
> ~~c.~~**d.** haematological malignancies; or
> ~~d.~~**e.** people living with ~~poorly controlled~~ HIV infection; or
> ~~e.~~**f.** planned or receiving ~~disease modifying anti-rheumatic drugs (DMARDs) for systemic lupus erythematosus, polymyalgia rheumatica or rheumatoid arthritis~~ **immune-modulating agents (pending specific agents/daily dose/duration/± any age aspects)**; or
> **g. planned or receiving high-dose corticosteroids (pending daily dose (in prednisolone-equivalents), duration ± age); or**
> ~~f.~~**h.** end stage kidney disease (CKD 4 or 5); or
> ~~g.~~**i.** primary immunodeficiency.

7.11. The Committee emphasised that the March 2024 immune-modulating agent-related and corticosteroid-related recommendations (criteria 2.f and 2.g) had been provisional, awaiting further consideration and detail specifying specific agents, their daily doses, durations and any age-related aspects.

7.12. The Committee noted that since the March 2024 meeting, members of the Committee had undertaken considerable work in an attempt to detail the immune-modulating agent-related and corticosteroid-related criteria, but accessing sufficient peer-review had been a barrier to finalisation. The Committee and Pharmac staff thanked the members for their efforts.

General

7.13. The Committee noted that a substantial update to the Australian Immunisation Handbook's section on immunocompromise (Vaccination for people who are immunocompromised), developed by the Australian Technical Advisory Group on Immunisation (ATAGI), was published on 2 May 2025.

7.14. The Committee noted the details regarding the levels of immunosuppressive potential of various medications and the degree of immunocompromise associated with specific medical conditions were available in the following seven tables within the Vaccination for people who are immunocompromised section:

7.14.1. Table. Types of medical conditions and immunosuppressive therapy and associated levels of immunocompromise

7.14.2. Table. Immunosuppressive potential of cancer and organ rejection therapies

7.14.3. Table. Immunosuppressive potential of conventional (non-biological) immunosuppressive therapies

7.14.4. Table. Immunosuppressive potential of small molecule targeted therapies

7.14.5. Table. Immunosuppressive potential of biological therapies

7.14.6. Table. Immunosuppressive potential of corticosteroids

7.14.7. Table. Immunosuppressive potential of certain medical conditions.

7.15. The Committee noted the Australian Handbook's definitions of severe, moderate or mild immunocompromise were as follows:

7.15.1. severe immunocompromise – may result in a significantly increased risk of severe vaccine-preventable disease and poor response to vaccination

7.15.2. moderate immunocompromise – may result in a higher risk of infection and potentially severe outcomes from vaccine-preventable diseases, and often results in a reduced response to vaccination

7.15.3. mild immunocompromise – may increase the risk of infection resulting in a higher likelihood of contracting a vaccine-preventable disease, or may result in a less robust response to vaccination.

7.16. The Committee noted the Australian Handbook's seven tables' categorisations of therapies with severe, moderate and mild immunosuppressive potential as follows:

severe immunosuppressive potential
cancer and organ rejection therapies
chimeric antigen receptor modified t-cell (CAR-T) therapy
conditioning agents for haematopoietic stem cell transplant (HSCT)
conventional chemotherapy for haematological malignancies
immunosuppressive therapies to prevent organ rejection within 6 months after solid organ transplant
conventional (non-biological) immunosuppressive therapies
azathioprine [licenced for prevention of rejection in kidney transplant
methotrexate >25 mg/week [licenced for oncology indications]
cyclophosphamide (40–50 mg/kg/day) [licenced for oncology indications]
mycophenolate [licenced for prevention of rejection after organ transplant]
calcineurin inhibitors
ciclosporin (8–12 mg/kg/day for children) [licenced for prevention of rejection after organ transplant]
tacrolimus [licenced for prevention of rejection after organ transplant]
mammalian target of rapamycin (mTOR) inhibitors
sirolimus (2–5 mg/day) [licenced for prevention of organ rejection after kidney transplant]
everolimus [licenced for prevention of rejection after organ transplant]
biological therapies
agents targeting other cellular markers
alemtuzumab
blinatumomab
daratumumab
anti B-lymphocyte antibodies
rituximab
ofatumumab
ocrelizumab
obinutuzumab
belimumab
anti T-lymphocyte therapies
abatacept
basiliximab
corticosteroids
≥20 mg/day prednisolone equivalents for ≥14 days over a month
moderate immunosuppressive potential
conventional (non-biological) immunosuppressive therapies
general

leflunomide
teriflunomide
mercaptopurine
azathioprine >3 mg/kg/day [licenced for rheumatic disorders]
methotrexate ≤25 mg/week [licenced for oncology indications]
cyclophosphamide (about 3 mg/kg/day) [licenced for nephrotic syndrome]
methotrexate >25 mg/week [licenced for RA, psoriatic arthritis]
calcineurin inhibitors
ciclosporin (about 5 mg/day) [licenced for nephrotic syndrome]
mammalian target of rapamycin (mTOR) inhibitors
sirolimus (1–2 mg/day) [licenced for lymphangioleiomyomatosis]
everolimus (about 10 mg/day) [licenced for oncology indications]
small molecule targeted therapies
antineoplastic kinase (ALK) inhibitors
alectinib, ceritinib
BCR-ABL tyrosine kinase inhibitors
imatinib, dasatinib, ponatinib
bruton tyrosine kinase (BTK) inhibitors
ibrutinib, acalabrutinib
janus kinase (JAK) inhibitors
baricitinib
tofacitinib
ruxolitinib
biological therapies
interleukin (IL) inhibitors
tocilizumab
sarilumab
tildrakizumab
risankizumab
tumor necrosis factor-α inhibitors
infliximab
adalimumab
etanercept
certolizumab
corticosteroids
≥10 to <20 mg/day prednisolone equivalents for <14 days
mild immunosuppressive potential
conventional (non-biological) immunosuppressive therapies
general
hydroxychloroquine
sulfasalazine, mesalazine, osalazine
azathioprine ≤3 mg/kg/day [licenced for rheumatic disorders]
methotrexate ≤25 mg/week [licenced for RA, psoriatic arthritis]
calcineurin inhibitors
ciclosporin (0.25–5 mg/kg/day) [licenced for psoriasis, RA]
small molecule targeted therapies
sphingosine-1-phosphate receptor modulators

fingolimod
biological therapies
calcitonin gene receptor protein (CGRP) inhibitors
eptinezumab
immune checkpoint inhibitors
atezolizumab
pembrolizumab
nivolumab
ipilimumab
inhibitors targeting atopy
dupilumab
mepolizumab
omalizumab
integrin inhibitors
natalizumab
vedolizumab
interferon-α (IFN) receptor inhibitors
anifrolumab
interleukin (IL) inhibitors
anakinra
canakinumab
secukinumab
ixekizumab
ustekinumab
guselkumab
RANK-ligand inhibitors
denosumab
complement inhibitors
eculizumab
ravulizumab
corticosteroids
<10 mg/day prednisolone equivalents for <28 days
<20 mg/day prednisolone equivalents for <14 days

7.17. The Committee noted other allied material in the Australian Immunisation Handbook relevant to RVZV for adults receiving immune-modulating agents as follows:

7.17.1. The Committee noted that in the Zoster (herpes zoster) section of the Australian Immunisation Handbook that ATAGI had recommended RVZV for all people aged ≥18 years who are immunocompromised or shortly expected to become immunocompromised.

7.17.2. Members noted however that the Zoster (herpes zoster) section then referred to RVZV being funded on Australia's National Immunisation Program (NIP) for the subgroup specifically with moderate and severe immunocompromise as being at the highest risk of herpes zoster. This was narrower than what ATAGI had recommended.

7.17.3. Regarding the prior duration of immunosuppression, Members noted the detailed NIP schedule of immunocompromising conditions and therapies eligible for NIP-funded RVZV specified the prior timings of treatments.

7.17.4. Regarding the age of adults receiving immunosuppressive therapies, Members noted the Zoster (herpes zoster) section of the Australian Immunisation Handbook described how herpes zoster can occur at younger ages in people who are immunocompromised but the risk increases with age similar to immunocompetent people; and that while the risk will be elevated in younger people who are immunocompromised compared to a similarly aged immunocompetent person, their risk may still be lower than that of an older immunocompetent individual. Members noted however that the Australian Immunisation Handbook does not provide specific age guidance for particular immunosuppressing treatments, and the NIP schedule of immunocompromising conditions and therapies eligible for NIP-funded RVZV did not state age-based restrictions.

7.17.5. Members noted the NIP list of immunosuppressive therapies eligible for funded RZVZ predated the Handbook's updated Vaccination for people who are immunocompromised section and that the two sources may not necessarily align completely. Members noted again that the Handbook's webpage containing the immunosuppressive therapies eligible for NIP-funded RVZV (https://immunisationhandbook.health.gov.au/resources/tables/table-risk-conditions-and-immunosuppressive-therapies-for-zoster-vaccination-and-eligibility-for-nip-funding) began by noting that ATAGI recommended RVZV for all people aged ≥18 years who are immunocompromised, without specifying severity of immunosuppressive therapies' immunosuppression. Members noted the ATAGI recommendation for all did not equate to the NIP Schedule's restriction to immunosuppressive therapies with the greatest risk of shingles.

7.17.6. Members also noted the NIP Schedule's eligibility for RVZV criteria did not include high-dose corticosteroid use.

7.18. The Committee considered the Australian Immunisation Handbook's updated section on 'Vaccination for people who are immunocompromised' to be applicable to the New Zealand funded immunisation setting, including its cataloguing and definitions of the potentially severely and moderately immunosuppressive medications listed for conventional (non-biological) immunosuppressive therapies, small molecule targeted therapies and biological therapies.

7.18.1. The Committee was however interested that the Immunisation Handbook's Table. Immunosuppressive potential of small molecule targeted therapies categorised janus kinase (JAK) inhibitors as being of moderate immunosuppressive potential. Members also noted that the types of medical conditions and immunosuppressive therapy, and associated levels of immunocompromise, presented on the Vaccination for people who are immunocompromised webpage stated the overall level of immunocompromise with JAK inhibitors to be mild but that there was a specific risk of eg. herpes zoster reactivation. Members noted however that people receiving JAK inhibitors were eligible for NIP-funded RVZV as being at greatest risk of herpes zoster (https://immunisationhandbook.health.gov.au/resources/tables/table-risk-conditions-and-immunosuppressive-therapies-for-zoster-vaccination-and-eligibility-for-nip-funding).

7.18.2. The Committee considered it would be appropriate for JAK inhibitors to be re-categorised as being of severe immunosuppressive potential, and that it would be useful for Pharmac staff to seek ATAGI's view and rationale for categorising JAK inhibitors as only moderately immunosuppressive.

7.18.3. The Committee noted that upadacitinib is both a JAK inhibitor funded in New Zealand and is mentioned specifically in NIP-funded RVZV eligibility as the

example of JAK inhibitors. The Committee considered upadacitinib should be included in the list of JAK inhibitors eligible under criterion 2.f.

7.19. The Committee partly agreed with the Australian Handbook's updated specifications of immunosuppressive potential for corticosteroid dosages contained in its Table. Immunosuppressive potential of corticosteroids, but considered these needed clarification of dosages that were severely or moderately immunosuppressive:

7.19.1. The Committee noted the Australian Handbook's corticosteroid exposures differed from the Committee's previous definition of high dose corticosteroid exposure as ≥20 mg/day prednisolone-equivalent for >10 days in the [immediately preceding] month (section 8.12 of the Committee's March 2024 record).

7.19.2. The Committee noted the Australian Handbook categorised severe corticosteroid immunosuppressive potential as ≥20 mg/day prednisolone-equivalent for ≥14 days over a month; moderate as ≥10 to <20 mg/day for <14 days; and mild as <10 mg/day for <28 days or <20 mg/day for <14 days.

7.19.3. Members assumed that, although not stated explicitly in the table, corticosteroid treatments were non-acute i.e. they were longer-term courses provided chronically over weeks/months for ongoing conditions, rather than infrequent short-term courses.

7.19.4. The Committee therefore considered that the ATAGI classifications of corticosteroid dosage and immunosuppressive potential may not be suitable for use in the New Zealand funding setting as they allowed categorisation of short courses (e.g. 15 mg for 3 days) as having moderate immunosuppressant potential, and did not provide a classification for non-acute use of ≥20 mg/day taken for <14 days per month.

7.20. The Committee considered that the Australian Immunisation Handbook's therapies with moderate and severe immunosuppressive potential should be included as high-priority recommendations in the Committee's proposed revised criteria subject to clarification of dose thresholds for corticosteroids.

7.20.1. The Committee considered this would result in eligibility criteria that include both severe and moderately immunosuppressive therapies, (with alterations and additions indicated with *), with in effect the following eligibility:

immune modulating agents with severe or moderate immunosuppressive potential (relevant to criterion 2.f)
conventional (non-biological) immunosuppressive therapies
general
leflunomide
mercaptopurine
teriflunomide
azathioprine >3 mg/kg/day - for rheumatic disorders
azathioprine - for prevention of rejection in kidney transplant
methotrexate ≤25 mg/week - for oncology indications
methotrexate >25 mg/week - for oncology indications
cyclophosphamide (about 3 mg/kg/day) - for nephrotic syndrome
cyclophosphamide (40–50 mg/kg/day) - for oncology indications
methotrexate >25 mg/week - for RA, psoriatic arthritis
mycophenolate - for prevention of rejection after organ transplant
calcineurin inhibitors

ciclosporin (8–12 mg/kg/day for children) - for prevention of rejection after organ transplant
ciclosporin (about 5 mg/day) - for nephrotic syndrome
tacrolimus - for prevention of rejection after organ transplant
mammalian target of rapamycin (mTOR) inhibitors
sirolimus (1–2 mg/day) - for lymphangioleiomyomatosis
sirolimus (2–5 mg/day) - for prevention of organ rejection after kidney transplant
everolimus (about 10 mg/day) - for oncology indications
everolimus - for prevention of rejection after organ transplant
small molecule targeted therapies
antineoplastic kinase (ALK) inhibitors
alectinib, ceritinib
BCR-ABL tyrosine kinase inhibitors
imatinib, dasatinib, ponatinib
bruton tyrosine kinase (BTK) inhibitors
ibrutinib, acalabrutinib
janus kinase (JAK) inhibitors
baricitinib
ruxolitinib
tofacitinib
* upadacitinib
biological therapies
anti B-lymphocyte antibodies
belimumab
obinutuzumab
ocrelizumab
ofatumumab
rituximab
anti T-lymphocyte therapies
abatacept
basiliximab
interleukin (IL) inhibitors
risankizumab
sarilumab
tildrakizumab
tocilizumab
agents targeting other cellular markers
alemtuzumab
blinatumomab
daratumumab
tumour necrosis factor-α inhibitors
adalimumab
certolizumab
etanercept
golimumab
infliximab
high-dose corticosteroid dosages with severe or moderate immunosuppressive potential *

7.21. The Committee reiterated that if funding RVZV was limited to those people receiving therapies of severe immunosuppressive potential, then this should include JAK inhibitors (currently defined in the Handbook as being of moderate immunosuppressive potential), re-categorising them as being of severe immunosuppressive potential, once ATAGI had advised its view and rationale for categorising JAK inhibitors as only moderately immunosuppressive.

7.22. The Committee noted that further advice and analysis might be necessary to determine medicine/dose/duration specific usage rates (i.e. the numbers of people being dispensed using particular medicines at particular dosages over particular durations) of immune-modulating medicines and corticosteroids, relevant to potential effects on RVZV coverage and total cost.

7.23. The Committee noted that although not directly relevant to criteria 2.f and 2.g, the revision to the Australian Immunisation Handbook's Vaccination for people who are immunocompromised section included tables detailing potentially severely immunocompromising medical conditions (outlined in the tables titled 'Types of medical conditions and immunosuppressive therapy and associated levels of immunocompromise' and 'Immunosuppressive potential of certain medical conditions'). Likewise Members reprised the immunocompromising medical conditions meeting Australia's NIP-funded RVZV eligibility criteria..

7.23.1. Members considered that it would be helpful to review both sets of materials and their alignment with the Committee's earlier March 2024 recommended criteria and with the Handbook's Vaccination for people who are immunocompromised's tables of therapies' immunosuppressive potential linking disease conditions to different levels of immunosuppression, and for Pharmac staff to seek ATAGI's views or further information where needed.

8. Pneumococcal 21-valent conjugate vaccine for prevention of invasive pneumococcal disease in high-risk adults

Application

8.1. The Committee reviewed the application for pneumococcal 21-valent conjugate vaccine (PCV21) for prevention of invasive pneumococcal disease in high-risk adults, 18 years and over.

8.1.1. The Committee acknowledged the proposal to replace the current schedule of Prevenar13 (PCV13) and Pneumovax23 (PPSV23) in high-risk adult groups with a single dose of the 21-valent pneumococcal conjugate vaccine (Capvaxive/PCV21).

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

Recommendation

8.3. The Committee **recommended** that PCV21 be included in the upcoming vaccines procurement process for current adult pneumococcal vaccine eligibility criteria.

8.4. The Committee **recommended** that PCV21 be listed with a **high priority**, within the context of vaccines and immunisation, for all adults aged 65 years and over.

8.5. The Committee **recommended** that PCV21 be listed with a **high priority**, within the context of vaccines and immunisation, for high-risk adult groups subject to the following eligibility criteria:

A single dose for high-risk individuals aged 18 years and over.
All of the following:
1. Person is aged 18 years or over; and

2. Person is or has or is with any of the following:
    2.1. (re-)immunisation of individuals with HIV; or
    2.2. pre- or post-haematopoietic stem cell transplantation; or
    2.3. chemotherapy; or
    2.4. pre- or post-splenectomy; or
    2.5. functional asplenia; or
    2.6. pre- or post-solid organ transplant; or
    2.7. renal dialysis; or
    2.8. complement deficiency (acquired or inherited);
    2.9. cochlear implants; or
    2.10. intracranial shunts; or
    2.11. cerebrospinal fluid leaks; or
    2.12. primary immunodeficiency; or
    2.13. ischemic heart disease; or
    2.14. previously documented episode of invasive pneumococcal disease; and
3. Has not been vaccinated with both PCV13 AND PPV23 within the past five years,

A booster dose every five years for high-risk individuals aged 18 years and over.
All of the following:

1. Person is aged 18 years or over; and
2. Person is or has or is with any of the following:
    2.1. (re-)immunisation of individuals with HIV; or
    2.2. pre- or post-haematopoietic stem cell transplantation; or
    2.3. chemotherapy; or
    2.4. pre- or post-splenectomy; or
    2.5. functional asplenia; or
    2.6. pre- or post-solid organ transplant; or
    2.7. renal dialysis; or
    2.8. complement deficiency (acquired or inherited);
    2.9. cochlear implants; or
    2.10. intracranial shunts; or
    2.11. cerebrospinal fluid leaks; or
    2.12. primary immunodeficiency; or
    2.13. previously documented episode of invasive pneumococcal disease.

8.6. In making these recommendations, the Committee acknowledged the high health need and the presence of inequitable health outcomes with pneumococcal disease in New Zealand. The Committee also considered the evidence of vaccine effectiveness for PCV21, using the opsonophagocytic assay (OPA) and geometric mean concentration (GMC) as an appropriate surrogate measure of immune response.

Discussion

Māori impact

8.7. The Committee discussed the impact of funding PCV21 for high-risk adults on Māori health areas of focus | Hauora Arotahi and Māori health outcomes.

8.7.1. The Committee noted that Māori and Pacific peoples have experienced the highest crude rates of IPD notifications over the past decade, despite the younger age structure of these populations.

8.7.2. The Committee noted data from the then Institute of Environmental Science and Research (ESR) (now the New Zealand Institute for Public Health and Forensic Science (PHF Science)), which noted the notification rates of IPD for Pacific peoples increased in 2024 from 2023, but decreased for Māori, NZ European/other and Asian ethnic groups (ESR, 2025).

Populations with high health needs

8.8. The Committee discussed the impact of pneumococcal disease 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.

8.8.1. The Committee reviewed 2024 incidence of IPD rates by ethnicity (ESR, 2025) and noted significant equity concerns, highlighting marked disparities in IPD incidence among Asian, NZ European, Māori, and Pacific peoples.

8.8.2. The Committee noted that in 2024, Pacific peoples had the highest rates of IPD cases across all age groups (ESR, 2025). The Committee also noted that, excluding infants and toddlers aged <2 years, Pacific adults ≥65 years had the highest rate of IPD, followed by Māori adults in the same age group.

8.8.3. The Committee reviewed the 2024 IPD incidence by deprivation level (ESR, 2025) and noted a clear gradient, with the highest rates observed in the most deprived areas (quintiles 4 and 5). The Committee noted the majority of IPD cases occurred within these quintiles, underscoring significant equity concerns.

Background

8.9. The Committee noted that the Immunisation Advisory Committee (formerly the Immunisation Subcommittee) has provided advice pertaining to pneumococcal vaccines on multiple occasions, most recently in September 2024. For further details and the current status of these recommendations, please refer to the application tracker.

8.9.1. In September 2024, the Immunisation Advisory Committee made a recommendation that the eligibility criteria for PCV13 and PPSV23 vaccines be widened with a high priority, in the context of immunisation and vaccines, to include people of any age who have bronchiectasis and adults who have had a previous episode of IPD.

Health need

8.10. The Committee noted newly available data from the 2024 IPD Annual Report from the Institute of Environment Science and Research (ESR), which provided current epidemiology of invasive pneumococcal disease (IPD) in New Zealand for the period from 1 January to 31 December 2024 (ESR, 2025).

8.10.1. The Committee noted that PCV13 was re-introduced to the National Immunisation Schedule (NIS) in November 2022 in response to increasing incidence of disease caused by serotype 19A. The Committee noted in 2024, cases due to serotype 19A have decreased in all age groups, but 19A still remains the most common serotype causing disease in New Zealand, followed by serotypes 8 and 3.

8.10.2. The Committee noted in 2024, there were 718 cases of IPD notified in New Zealand (13.5 cases per 100,000), a slight decrease compared with 757 cases in 2023 (14.5 per 100,000). The Committee noted that this is the first year IPD incidence has decreased since 2020, though rates remain high compared to 2014–2022.

8.10.3. The Committee noted IPD incidence among older adults aged 50–64 years and ≥65 years reached the highest level in a decade in 2023 and remained elevated in 2024. A significant proportion of cases in these age groups were attributed to serotypes 19A and 3, although incidence of 19A has declined compared to 2023.

8.11. The Committee noted the serotypes prevalent in New Zealand in 2024, with serotype 19A being the most reported, accounting for 26.2% of typed cases, followed by serotype 8 at 18.5%, and by serotype 3 at 10.1%. The Committee also noted the presence of other serotypes including 22F, 9N, 6C, 33F, 23A, 23B, 7C, 16F and 11A (ESR, 2025).

8.11.1. The Committee acknowledged the importance of ongoing surveillance of pneumococcal serotype prevalence in New Zealand. The Committee noted that serotype replacement occurred following previous changes to the childhood immunisation programme, highlighting the need for continued monitoring to inform future immunisation strategy.

8.12. The Committee noted that PCV21 is relevant to the New Zealand context, as it covers the predominant pneumococcal serotypes associated with IPD in the country. The Committee considered that the additional eight serotypes included in PCV21 each contribute modestly to disease prevention, but collectively offer an approximate 35% increase in overall serotype coverage over PCV13 and 12% increase in overall serotype coverage over PPSV23. Members also noted that a conjugate vaccine would be expected to have superior effectiveness of action over a traditional polysaccharide vaccine.

8.13. The Committee noted, when discussing unmet health needs, that the current pneumococcal vaccination schedule presents challenges. The Committee noted in particular, the eligibility criteria for funded adult vaccination are very narrow, and uptake within this group is low due to what the Committee considered was difficulties in identifying individuals at high-risk. The Committee reiterated that targeted vaccination programmes typically achieve significantly lower coverage compared to universal vaccination approaches.

Health benefit

8.14. The Committee noted PCV21 is a 21-valent pneumococcal conjugate vaccine composed of purified capsular polysaccharides from 21 *Streptococcus pneumoniae* serotypes. Each serotype specific polysaccharide is individually conjugated to CRM197 carrier protein, a nontoxic mutant of the diphtheria toxin used as a carrier protein. Members considered PCV21 to be structurally well-designed.

8.15. The Committee noted that PCV21 targets serotypes that are more relevant to adult disease burden in New Zealand. The Committee noted these serotypes are not adequately covered by the childhood immunisation programme PCV13 vaccine, thereby PCV21 would address a gap in pneumococcal disease prevention specifically for adults.

8.16. The Committee noted three pivotal studies evaluating PCV21, highlighting outcomes related to serotype-specific immunogenicity, including IgG concentrations and opsonophagocytic activity (OPA). The Committee noted these studies employed a non-inferiority approach to compare PCV21 with existing pneumococcal vaccines, aiming to demonstrate comparable immune responses across key serotypes.

8.16.1. The Committee noted OPA responses are considered surrogate endpoints likely to predict clinical benefit. However, it was also noted that there is no established immunological bridge to efficacy for non-PCV13 serotypes included in PCV21.

8.16.2. The Committee noted that, although only bridging immunogenicity data is available for PCV21, this was considered acceptable given the well-established nature of pneumococcal conjugate vaccines.

8.16.3. The Committee considered that, while long-term clinical or observational data on the long-term protection for PCV21 is not yet available, pneumococcal conjugate vaccines in adults are generally anticipated to provide protection for approximately 3 to 5 years. If PCV21 were introduced in the New Zealand context, the Committee acknowledged the importance of monitoring emerging international data to better understand its real-world duration of protection.

8.17. The Committee noted the STRIDE-7 (P007) clinical study report (CSR), a phase III, multi-centre, randomised, double-blind trial. The study aimed to assess the immunogenicity and safety of PCV21 compared to PCV15 followed by a PPSV23 booster in individuals aged 18 or older who are HIV-positive.

8.17.1. The Committee reviewed post-vaccination opsonophagocytic activity (OPA) geometric mean titre (GMT) ratios for the common and unique pneumococcal serotypes, as well as the post-vaccination immunoglobulin G (IgG) geometric mean concentration (GMC) ratios.

8.17.2. The Committee noted that PCV21 demonstrated immunogenicity that was at least non-inferior to the comparator regimen of PCV15 followed by PPSV23 for the 13 pneumococcal serotypes shared between vaccines. The Committee also noted that PCV21 demonstrated superior immunogenicity for the eight additional serotypes unique to its formulation, which was consistent with expectations given its broader serotype coverage.

8.17.3. The Committee acknowledged that the study population, comprising HIV-positive adults with a median age of 45 years (range: 19–86 years), is likely to have had prior exposure to pneumococcal disease over their lifetime. The Committee noted as a result, the baseline immune status of the participants with respect to pneumococcal serotypes was uncertain. In this context, the Committee considered, the observed superiority of PCV21 for the eight unique serotypes is particularly encouraging, suggesting a robust immunogenic response despite potential variability in pre-existing immunity.

8.17.4. The Committee noted that the proportion of participants who experienced adverse events (AEs) was lower in the PCV21 plus placebo group (71.6%) compared with the PCV15 followed by PPSV23 group (91%). The Committee acknowledged the difference was partly attributed to a lower frequency of injection-site AEs in the PCV21 group.

8.17.5. The Committee noted there were no significant vaccine-related severe adverse events in either group.

8.18. The Committee noted the STRIDE-8 (P008) CSR, a phase III, randomised, double-blind trial. The study aimed to assess the safety and tolerability of PCV21 in pneumococcal vaccine-naïve adults who were at increased risk for IPD due to an underlying medical condition (eg diabetes, chronic obstructive pulmonary disease (COPD), asthma, coronary heart disease (CHD), and/or chronic kidney disease (CKD)).

8.18.1. The Committee reviewed post-vaccination OPA GMT ratios for the common and unique pneumococcal serotypes, as well as the post-vaccination IgG GMC ratios. The Committee noted that PCV21 demonstrated immunogenicity that was non-inferior compared to PCV15 followed by PPSV23 for the shared 13 serotypes, and was superior for the eight unique serotypes.

8.18.2. The Committee noted that the incidence of adverse events was lower in the PCV21 group (62.4%) compared to the group receiving PCV15 followed by PPSV23 (86.2%), again attributed to a lower frequency of injection-site reactions in the PCV21 group.

8.19. The Committee noted the STRIDE-3 (P003) study, a phase III, randomised, double-blind trial (Platt et al. Lancet Infect Dis. 2024;24:1141-50). The Committee noted the study evaluated OPA and IgG responses to PCV21 or PCV20 across two cohorts: adults aged over the age of 50 years or adults aged 18–49 years (median age: 55 years).

8.19.1. The Committee noted for the ten pneumococcal serotypes common to both PCV21 and PCV20, serotype-specific immunogenicity measures demonstrated at least non-inferiority to PCV20. The Committee noted that PCV21 showed superiority for all shared serotypes except serotype 15C in the 18–49 year age group, and serotypes 6A and 15C in the ≥50 years age group.

8.19.2. The Committee noted that the incidence of vaccine-related adverse events was comparable between PCV21 and PCV20, with most frequently reported adverse events including injection-site pain, fatigue, headache, injection-site erythema, swelling and myalgia. Additionally, the Committee noted there were no vaccine-related severe adverse events reported.

8.20. The Committee was made aware of Farrar et al. Pathogens. 2023;12:732 and noted its pooled estimates for PPSV23 effectiveness of 45% (95% CI: 37% to 51%) against VT-IPD and 18% (95% CI: -4% to 35%) against VT-PP, though variability existed across settings and serotypes.

8.21. The Committee was made aware of Bonten et al. N Engl J Med. 2015;372:1114-25, a randomised, double-blind, placebo-controlled trial involving 84,496 adults aged 65 years of age or older. The study aimed to evaluate the efficacy of 13-valent polysaccharide conjugate vaccine (PCV13) in preventing first episodes of vaccine-type strains of pneumococcal community-acquired pneumonia, nonbacteraemic and non-invasive pneumococcal community-acquired pneumonia, and invasive pneumococcal disease.

8.21.1. The Committee noted PCV13 demonstrated a 45.6% vaccine efficacy (VE) (95.2% CI: 21.8 to 62.5) in preventing first episodes of vaccine-type pneumococcal community-acquired pneumonia (VT-CAP).

8.21.2. The Committee noted PCV13 demonstrated 45.0% VE (95.2% CI: 14.2 to 65.3) in preventing nonbacteraemic/non-invasive VT-CAP.

8.21.3. The Committee noted PCV13 demonstrated 75.0% VE (95% CI: 41.4 to 90.8) in preventing vaccine-type invasive pneumococcal disease (VT-IPD).

8.21.4. The Committee noted that pneumococcal vaccination is likely to provide broader public health benefits beyond its demonstrated efficacy against IPD, including potential reductions in overall pneumococcal disease burden and transmission.

8.22. The Committee noted the following supporting evidence:

8.22.1. STRIDE-4 (P004) CSR, a phase III, randomised, double-blind active comparator-controlled, lot comparison study. The Committee noted this trial evaluated the safety, tolerability and immunogenicity of PCV21 in adults aged 18–46 years.

8.22.2. STRIDE-5 (P005) CSR, a phase III, randomised, double-blind, placebo-controlled study. The Committee noted this trial evaluated the safety, tolerability and immunogenicity of PCV21 when administered concomitantly with influenza vaccine in adults aged ≥50 years. While data on coadministration with influenza vaccine are available, the Committee noted that further information is needed regarding concomitant use with other vaccines, including COVID-19, Shingrix (herpes zoster), and RSV vaccines.

8.22.3. STRIDE-6 (P006), a phase III study evaluating the safety, tolerability and immunogenicity of PCV21 in pneumococcal vaccine-experienced adults aged ≥50 years (Scott et al. Clin Infect Dis. 2024;79:1366-74).

8.22.4. P009 CSR, a phase III, randomised, double-blind, active comparator-controlled clinical study evaluating the safety, tolerability and immunogenicity of PCV21 in pneumococcal vaccine-naïve Japanese adults aged ≥65 years.

8.22.5. P010 CSR, a phase III, randomised, double-blind, active comparator-controlled study evaluating the safety, tolerability and immunogenicity of PCV21 in pneumococcal vaccine-naïve adults aged ≥50 years.

8.23. The Committee reviewed international pneumococcal vaccine recommendations and schedules, noting the following:

8.23.1. The Committee noted in the United States, pneumococcal vaccination is currently recommended for all adults aged 50 years and over, and those between the ages of 19–49 years with high-risk conditions.

8.23.2. The Committee noted that in the United Kingdom (UK), PPSV23 is recommended for all adults aged 65 years and over. In addition, PCV13 is recommended for individuals of any age with certain high-risk conditions, including those who are severely immunosuppressed.

8.23.3. The Committee was made aware that, internationally, 65 out of 161 countries recommend adult pneumococcal vaccination. Of these countries, 58% target both older adults and individuals with high-risk conditions, while 32% focus exclusively on high-risk groups only (Ozisik et al. Vaccines (Basel). 2025;13:498).

- The Committee noted the Ozisik et al, 2025 view that *"PCV20 vaccination in adults aged ≥65 and those aged 18–64 years with underlying comorbidities in the UK is expected to prevent more hospitalizations, save more lives, and yield lower overall costs than current recommendations for PPSV23."*

8.23.4. The Committee noted that in Canada, PCV20 or PCV21 are the preferred options for adults. The Committee noted a single dose is recommended for all adults aged 65 years and older, as well as for individuals under the age of 65 years with high-risk conditions.

8.23.5. The Committee noted in Australia, non-indigenous adults aged 70 years and above are recommended a single dose of PCV13. The Committee noted indigenous adults (Aboriginal and Torres Strait Islander) 50 years and over, as well as individuals of any age with specified medical risk conditions are recommended to receive PCV13 and PPSV23 regimen.

8.24. The Committee noted that many international pneumococcal vaccination strategies have shifted toward age-based recommendations, particularly targeting older adults, rather than focusing solely on individuals with high-risk conditions.

8.24.1. The Committee acknowledged that strategies limited solely to at-risk groups can be difficult to implement effectively.

8.24.2. The Committee expressed interest in reviewing clinical evidence specific to adults aged 75 years and older, in relation to PCV21.

8.25. The Committee noted that broader pneumococcal vaccine coverage could result in wider societal benefits, including a potential reduction in antibiotic use, improved antimicrobial stewardship, and additional health gains through protection against a greater number of serotypes.

Suitability

8.26. The Committee noted the introduction of a single dose pneumococcal vaccine to replace the current PCV13 and PPSV23 schedules for the target adult population would simplify the vaccination schedule.

8.27. The Committee acknowledged that the existing pneumococcal schedule is complex and may benefit from simplification, noting the current programme contributes to confusion, with errors in administration being relatively common.

8.28. The Committee noted PCV21 is stored at standard cold chain temperature and is available as both single-dose and/or 10-dose pack formats.

8.29. The Committee noted that the serotypes in PCV21 is designed only for adults, though the supplier is developing a paediatric formulation that is expected to have a different serotype distribution.

Cost and savings

8.30. The Committee noted there was no price for PCV21 included in the supplier's application, acknowledging the supplier's intention to submit a bid into the upcoming Request for Proposals (RFP). For this reason, the Committee could not comment further on cost effectiveness.

8.31. The Committee noted the proposed PCV21 regimen involves a single dose, in contrast to the current pneumococcal regimen for high-risk adults, which requires two separate vaccines with complex spacing issues. The Committee noted the simplified regimen has the potential to reduce vaccine administration costs. The Committee further noted that the standard fee paid per vaccination visit is $41.20, although costs vary depending on whether other vaccines are administered concurrently. The Committee noted that a switch to a single vaccine regimen could result in savings of up to $123.60 per person vaccinated.

8.32. The Committee noted that while PCV21 has the potential to contribute to improvements in health-sector expenditure, long-term effectiveness, including the need for booster doses (for individuals at the highest risk) remains uncertain due to the current absence of long-term clinical trial or observational data.

Funding criteria

8.33. The Committee noted that current pneumococcal vaccination uptake for high-risk adults is unknown, but likely to be very low. In light of this, the Committee expressed interest in exploring a more effective universal strategy to improve coverage and public health outcomes.

8.33.1. The Committee considered it would be important to prioritise older adults aged 75 years and over, as well as Māori and Pasifika populations aged 65 years and over, recognising the higher burden of pneumococcal disease and the potential benefits of targeted vaccination within these groups.

8.34. The Committee was made aware of Torres et al. Thorax. 2015;70:984-9 and Backhaus et al. BMC Infect Dis. 2016;16:367, which examined the relative incidence of pneumococcal disease among common high-risk groups. The Committee noted that the presence of multiple comorbidities can have a compounding effect, with the relative risk exceeding 14 in individuals with more than one high-risk condition.

8.35. The Committee noted that for individuals who have previously received PPSV23, PCV21 should not be administered within a short interval following that dose. Prior administration of the polysaccharide vaccine may attenuate the immune response to the conjugate vaccine. To optimise immunogenicity, the Committee recommended a minimum interval of 12 months between PPSV23 and PCV21.

8.36. The Committee expressed interest in reviewing further evidence on current targeted strategies, such as influenza vaccine uptake among individuals with high-risk medical conditions and current recommendations for IPD vaccination, in order to explore a more effective, universal uptake strategy based on age, ethnicity and socioeconomic status (SES).

Summary for assessment

8.37. The Committee considered that the table below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for PCV21 if it were to be funded in New Zealand for IPD prevention. 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.

8.38. The Committee noted that elements of in the PICO (population, intervention, comparator, outcomes) for this application is unclear/uncertain at this time. The PICO may develop based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	In line with current provisions in the National Immunisation Schedule, prevention of invasive pneumococcal disease (IPD) in adults ≥ 18 years with any of the following conditions that make them at higher risk of IPD: • with HIV infection • who are pre- or post-HSCT or chemotherapy • who are pre- or post-splenectomy or with functional asplenia • who are pre- or post-solid organ transplant • undergoing renal dialysis • with complement deficiency (acquired or inherited) • with cochlear implants, intracranial shunts or cerebrospinal fluid leaks • with primary immunodeficiency. The applicant also discusses widening access to two additional groups at higher risk of IPD: those who have previously had IPD; and those with bronchiectasis.
Intervention	PCV21 single dose
Comparator (NZ context)	Current recommended vaccination schedule for high-risk adults: • one dose of PCV13 AND • a maximum of three doses of PPSV23 (each dose at least 5 years apart).
Outcomes	• Greater immunogenicity for the eight PCV21 serotypes not in PCV13 + PPV23 • For shared pneumococcal serotypes, equivalent immunogenicity and safety compared to the currently funded PCV13 + PPSV23 vaccines. • Greater immunogenicity for unique pneumococcal serotypes (ie the eight PCV21 serotypes not in PCV13 + PPV23). • Reduced local reactogenicity for PCV21. • Reduced antimicrobial resistance
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).	

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.