



## ATAGI CLINICAL ADVICE ON CHANGES TO RECOMMENDATIONS FOR THE USE AND FUNDING OF PNEUMOCOCCAL VACCINES FROM 1 JULY 2020

*It is important to read this statement in conjunction with The Australian Immunisation Handbook available at [immunisationhandbook.health.gov.au](http://immunisationhandbook.health.gov.au) and other related ATAGI statements on NIP schedule changes from 1 July 2020*

### Key points

- The primary aim of ATAGI recommendations on pneumococcal vaccination and use in the National Immunisation Program (NIP) is to prevent pneumococcal disease in people with increased risk of disease.
- Pneumococcal disease incidence is highest in infants and toddlers (aged <5 years) and older people. The risk of pneumococcal disease is also high in Aboriginal and Torres Strait Islander people, and people with certain underlying medical or lifestyle conditions.
- From 1 July 2020, recommendations for pneumococcal vaccine use are changing to make pneumococcal vaccines more readily available and give extra protection to people who are most at risk of disease. They also seek to simplify vaccination advice by making it easier to understand who should be vaccinated, when and which vaccine they should get.
- The population groups that these changes apply to are:
  - *Children and adults with conditions that increase their risk from pneumococcal disease (refer to [ATAGI clinical advice on changes to vaccine recommendations and funding for people with risk conditions from 1 July 2020](#))*
  - *Aboriginal and Torres Strait Islander children in Northern Territory (NT), Queensland (Qld), South Australia (SA) or Western Australia (WA)*
  - *All Aboriginal and Torres Strait Islander older (age ≥50 years) adults (refer to [ATAGI clinical advice on changes to vaccine recommendations and funding for Aboriginal and Torres Strait Islander people from 1 July 2020](#))*
  - *All non-Indigenous older (age ≥70 years) adults (refer to [ATAGI clinical advice on changes to vaccine recommendations and funding for older non-Indigenous adults from 1 July 2020](#))*
- Clinicians should ensure careful screening of all patients to determine if they have either; risk conditions for pneumococcal disease or identify as Aboriginal and Torres Strait Islander, as this means they should receive additional vaccine doses, as described below. These risk factors should be considered in addition to their age.
- There are no changes to the NIP schedule and recommendations for pneumococcal vaccination in children aged ≤12 months.

### Children and adults with conditions that increase the risk of pneumococcal disease

- The list of conditions associated with an increased risk of pneumococcal disease has been updated. There is now a single list of risk conditions, as supported by current clinical evidence, that replaces the previous 'Category A' and 'Category B' lists.
- The definitions of some risk conditions have been updated to improve their recognition and application.
  - *Consolidation of category A and B lists into a single updated list is designed to simplify the risk condition based pneumococcal vaccination recommendations and improve adherence to recommended schedules.*
- As of 1 July 2020, pneumococcal vaccines recommended for many of those with risk conditions are funded under the NIP for children and adults. However, for other risk conditions in the updated list, where the rate of disease is not sufficiently high enough to be cost-effective given the cost of vaccine purchase and delivery, people will not be eligible to receive the pneumococcal vaccines funded under the NIP.

**List. Updated list of risk conditions for pneumococcal vaccine recommendations and their eligibility for funding under the national immunisation program (NIP)**

Risk condition	Eligibility for NIP funding	
	<5 years of age	≥5 years of age
Previous episode of invasive pneumococcal disease	✓	✓
<b>Functional or anatomical asplenia, including</b>		
– sickle cell disease or other haemoglobinopathies	✓	✓
– congenital or acquired asplenia (for example, splenectomy) or hyposplenia	✓	✓
<b>Immunocompromising conditions, including</b>		
– congenital or acquired immune deficiency, including symptomatic IgG subclass or isolated IgA deficiency	✓	✓
– haematological malignancies	✓	✓
– solid organ transplant	✓	✓
– haematopoietic stem cell transplant	✓	✓
– HIV infection	✓	✓
– immunosuppressive therapy, where sufficient immune reconstitution for vaccine response is expected; this includes those with underlying conditions requiring but not yet receiving immunosuppressive therapy		
– non-haematological malignancies receiving chemotherapy or radiotherapy (currently or anticipated)		
<b>Proven or presumptive cerebrospinal fluid (CSF) leak, including</b>		
– cochlear implants	✓	✓
– intracranial shunts	✓	✓
<b>Chronic respiratory disease, including<sup>¶</sup></b>		
– suppurative lung disease, bronchiectasis and cystic fibrosis	✓	✓
– chronic lung disease in preterm infants	✓	✓
– chronic obstructive pulmonary disease (COPD) and chronic emphysema		
– severe asthma (defined as requiring frequent hospital visits or the use of multiple medications)		
– interstitial and fibrotic lung disease		
<b>Chronic renal disease</b>		
– relapsing or persistent nephrotic syndrome	✓	✓
– chronic renal impairment – eGFR <30 mL/min (stage 4 or 5 disease)	✓*	✓*
<b>Cardiac disease, including<sup>¶</sup></b>		
– congenital heart disease	✓	
– coronary artery disease	✓	
– heart failure	✓	
Children born less than 28 weeks gestation	✓	
Trisomy 21	✓	
<b>Chronic liver disease, including<sup>¶</sup></b>		
– chronic hepatitis		
– cirrhosis		
– biliary atresia		
Diabetes		
Smoking (current or in the immediate past)		
Harmful use of alcohol (Defined as consuming on average ≥60 g of alcohol (6 Australian standard drinks) per day for males and ≥40 g of alcohol (4 Australian standard drinks) per day for females)		

\* Funded under the NIP for eGFR <15 mL/min only (including patients on dialysis)

¶ Individual conditions listed beneath or those that are similar based on clinical judgment

**Note:** All children and adults with above conditions are recommended to receive additional pneumococcal vaccine doses but they are funded under the NIP for those with the shaded conditions

## Recommended schedule of pneumococcal vaccines for people with risk conditions

- Pneumococcal vaccine recommendations for people with the listed risk conditions are 1 dose of 13vPCV followed by 2 doses of 23vPPV.
  - *In Australia, data for invasive pneumococcal disease (IPD) shows that a considerable proportion of disease in people with risk conditions is caused by the additional serotypes in the 23vPPV above those in the 13vPCV (23v-non-13v types). Therefore the schedule that uses both 13vPCV and 23vPPV will maximise benefit from pneumococcal vaccination in people with risk conditions.*
- The recommended interval between the last dose of 13vPCV and the first dose of 23vPPV is 12 months (although an interval of at least 2 months is acceptable). The recommended interval between 23vPPV doses is at least 5 years.
  - *Evidence shows that 23vPPV elicits a good immune response when given at least 2 months after a PCV. The 2–12 month interval between doses is recommended to ensure that extended protection against 23v-non-13v serotypes is achieved without delay, while acknowledging that initial protection from the serotypes in common between the two vaccines will be provided by 13vPCV.*
- The youngest age recommended for receiving the first dose of 23vPPV after the required dose(s) of 13vPCV is 4 years.
- For children with risk conditions, this will mean an extra dose of 13vPCV additional to what is recommended for healthy children of the same age (with the exception of Aboriginal and Torres Strait Islander children in NT, Qld, SA or WA who already receive an additional 13vPCV dose at 6 months of age).
- The number of recommended lifetime doses of 23vPPV is now **limited to 2 doses** for all people. The doses of 23vPPV received in the past are also counted when deciding how many more are required. If a person has already received at least two doses based on previous recommendations, no further doses of 23vPPV are to be given (refer to [The Australian Immunisation Handbook](#) for further details). When administering 13vPCV for people who have previously received 23vPPV, the interval should be a minimum of 12 months.
  - *Immunogenicity data supports the use of one repeat dose of 23vPPV approximately 5 years after the first 23vPPV doses, but more doses of 23vPPV beyond that have not been shown to provide significant further benefit. Repeat doses of 23vPPV are associated with higher rates of adverse events, especially injection site reactions. There is also a possibility that additional doses of 23vPPV beyond 2 doses may lead to immune hyporesponsiveness.*

## Aboriginal and Torres Strait Islander people

- Aboriginal and Torres Strait Islander children in the NT, Qld, SA or WA are already recommended to receive an extra dose of 13vPCV (i.e. 3 primary doses in infancy followed by a booster dose of 13vPCV at 12 months of age [3+1 schedule]). They are now recommended to also receive 2 doses of 23vPPV, first at 4 years of age, followed by the second dose at least 5 years later
  - *Evidence shows that a large proportion of IPD in Aboriginal and Torres Strait Islander children living in the NT, Qld, SA or WA is caused by serotypes that are included in the 23vPPV but not in the 13vPCV. Therefore a schedule that includes both 13vPCV and 23vPPV will maximise protection for these children.*
- The recommendation of pneumococcal vaccines for all Aboriginal and Torres Strait Islander adults from age 50 will continue. It is now recommended that they receive a single dose of 13vPCV followed by two doses of 23vPPV (replacing the recommendation for 23vPPV only). All pneumococcal vaccine doses recommended specifically for Aboriginal and Torres Strait Islander adults will be funded under the NIP.
  - *Compared with non-Indigenous adults, in Aboriginal and Torres Strait Islander adults IPD incidence starts to increase at a younger age and reaches a 13-fold higher rate than for non-Indigenous Australians. The presence of risk conditions for pneumococcal disease is also higher at younger ages in Aboriginal and Torres Strait Islander adults. Therefore, ATAGI recommends that all Aboriginal and Torres Strait Islander adults continue to receive pneumococcal vaccines **from 50 years of age**.*
  - *Although PCVs have been used in the population for more than a decade, the incidence of IPD has continued to increase in Aboriginal and Torres Strait Islander adults, with the herd protection impact resulting from the use of PCVs in the population less than in non-Indigenous Australians. The new 13vPCV recommendation is expected to reduce the burden of IPD and community acquired pneumonia due to 13vPCV serotypes among Aboriginal and Torres Strait Islander adults.*
  - *A considerable proportion of IPD in Aboriginal and Torres Strait Islander adults is still caused by serotypes that are included in the 23vPPV but not in the 13vPCV, therefore two doses of 23vPPV following the dose of 13vPCV is considered essential to offer maximum protection.*

## Non-Indigenous older adults with no risk conditions

- All non-Indigenous older adults aged 70 years or over with no risk conditions are recommended to receive one dose of 13vPCV, regardless of receipt of 23vPPV previously. This will replace the previously recommended single dose of 23vPPV at 65 years of age.
  - *Among Australian adults the incidence of IPD is much greater from 70 years of age than 65–69 years of age. Because the effectiveness of pneumococcal vaccines reduces over time, moving the age of pneumococcal vaccination from 65 years of age to 70 years of age will provide better protection as people move into older age groups with increasing pneumococcal disease risk.*
  - *The dose of 13vPCV will provide more assured protection against community acquired pneumonia due to vaccine serotypes, compared to 23vPPV, and will also further reduce remaining 13vPCV type IPD among older adults.*
- This single dose of 13vPCV is NIP-funded for those turning 70 years of age on or after 1 July 2020, regardless of whether the person has previously received a NIP-funded dose of 23vPPV. Those who are already 70 years of age or older on 1 July 2020 are also eligible for a single NIP-funded dose of 13vPCV, which can be given opportunistically at a suitable clinical encounter.
- For those who were previously vaccinated with 23vPPV, the dose of 13vPCV should be given at least 12 months after their last 23vPPV dose.
- Older non-Indigenous adults with risk conditions for pneumococcal disease are recommended to receive additional doses of 23vPPV. Refer to [ATAGI clinical advice on changes to vaccine recommendations and funding for people with risk conditions from 1 July 2020](#).
- Older non-Indigenous adults with no risk conditions for pneumococcal disease are no longer recommended to receive 23vPPV.
  - *IPD data for non-Indigenous older adults shows that disease caused by serotypes that are included in the 23vPPV but not in the 13vPCV, is predominantly in those who have underlying risk conditions; therefore, the use of 23vPPV is limited to this group of people only.*
- The 13vPCV can be administered at the same time as the zoster [Zostavax] vaccine and influenza vaccine at ≥70 years of age

**Figure 1. Summary of revised recommendations for pneumococcal vaccination**

*To be used in conjunction with The Australian Immunisation Handbook.*

