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AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI) | **CLINICAL ADVICE**

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ATAGI CLINICAL ADVICE ON CHANGES TO VACCINE RECOMMENDATIONS AND FUNDING FOR PEOPLE WITH RISK CONDITIONS FROM 1 JULY 2020

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

Overview of key changes to recommendations for individuals with risk conditions

- From 1 July 2020, there are changes to the recommendations and vaccine doses funded through the National Immunisation Program (NIP) for individuals with risk conditions (refer to Appendix).
  These changes are designed to:
  - *Further improve protection against meningococcal, pneumococcal and Haemophilus influenzae type b diseases, and;*
  - *Make these vaccines more readily available to those who are at increased risk of these diseases.*
- The vaccines that these changes apply to are:
  - *Meningococcal B (MenB) vaccine (Bexsero®)*
  - *Meningococcal ACWY (MenACWY) vaccine (Nimenrix®)*
  - *13-valent pneumococcal conjugate vaccine (13vPCV, Prevenar 13®)*
  - *23-valent pneumococcal polysaccharide vaccine (23vPPV, Pneumovax 23®)*
  - *Haemophilus influenzae type b (Hib) vaccines (ActHIB®)*
- For pneumococcal vaccination risk categories, A and B have been replaced with a single updated list of conditions
- Pneumococcal Polysaccharide vaccine (23vPPV) recommendation for those with risk conditions is now limited to two lifetime doses only, with doses already received counted towards the lifetime doses.

Vaccine specific recommendations for individuals with risk conditions:

Meningococcal B (Bexsero®) and Meningococcal ACWY (Nimenrix®) vaccines

- Recommendations for the use of MenB and MenACWY vaccines, including scheduling and dose requirements, remain unchanged. However, some of the recommended doses will now be **funded under the NIP**.
- MenB and MenACWY vaccines are now funded under the NIP for people of all ages with medical conditions associated with the highest risk of invasive meningococcal disease, namely; **asplenia and hyposplenia**, **complement deficiency** and those receiving treatment with **eculizumab**. People with ongoing increased risk of invasive meningococcal disease due to these specified medical conditions are also eligible for NIP-funded booster doses of MenACWY vaccine as recommended in the Australian Immunisation Handbook. Also refer to the *ATAGI clinical advice on changes to recommendations for the use and funding of meningococcal vaccines from 1 July 2020*
- For a few other medical conditions that are associated with an increased risk of invasive meningococcal disease (human immunodeficiency virus infection and haematopoietic stem cell transplant), cost-effectiveness thresholds for a nationally-funded population program have not been met to-date. People with these medical conditions are still recommended to receive these vaccines, but **are not** eligible to receive funded MenACWY and MenB vaccines under the NIP, except Aboriginal and Torres Strait Islander infants with these conditions who are eligible for NIP funded doses of MenB vaccine.
- For infants <12 months of age with risk conditions, the number and spacing of MenB and MenACWY vaccine doses required depends on the starting age for vaccination (Table 1).

- Adults and children >12 months of age should receive 2 doses of MenB vaccine and 2 doses of MenACWY vaccine. A minimum interval of 8 weeks is required between doses for each vaccine (Table 1).
- Booster doses of MenACWY are recommended for people with ongoing increased risk of invasive meningococcal disease. The interval between boosters depends on the age at completion of primary course.
  - *If completed at ≤6 years of age — give a booster dose 3 years after completing the primary schedule, then every 5 years.*
  - *If completed at ≥7 years of age — give a booster dose every 5 years after completing the primary schedule*
- Booster doses of MenB vaccine are not recommended currently.
- Children <2 years of age are recommended to receive prophylactic paracetamol with every dose of Bexsero®. This is because of the increased risk of fever associated with receiving Bexsero®.
  - *Give first dose (15 mg/kg/dose) of paracetamol within 30 minutes before, or as soon as practicable after, receiving the vaccine, regardless of whether the child has a fever.*
  - *This can be followed by 2 more doses of paracetamol given 6 hours apart.*

Table1. Bexsero (MenB) and Nimenrix (MenACWY) dose recommendations for people with a specified medical condition that increases their risk of invasive meningococcal disease

Age at start of vaccination	Dose requirements for people with a specified medical condition associated with increased risk of meningococcal disease*
6 weeks to 5 months	4 doses* (8 weeks between doses; 4th dose at 12 months of age or 8 weeks after 3rd dose, whichever is later)
6–11 months	3 doses* (8 weeks between 1st and 2nd doses; 3rd dose at 12 months of age or 8 weeks after 2nd dose, whichever is later)
≥12 months	2 doses* (8 weeks between doses)

*Specified medical conditions include inherited defects or deficiency of properdin or complement components, receiving treatment with eculizumab, functional or anatomical asplenia, HIV infection and haematopoietic stem cell transplant. Bexsero is NIP-funded for Aboriginal and Torres Strait Islander infants with any of these conditions. Otherwise, Bexsero and Nimenrix are NIP funded only for people with *asplenia and hyposplenia, complement deficiency and those receiving treatment with eculizumab*.

13-valent pneumococcal conjugate vaccine (13vPCV; Prevenar 13®) and 23-valent pneumococcal polysaccharide vaccine (23vPPV; Pneumovax 23®)

- The list of conditions associated with an increased risk of pneumococcal disease has been updated. There is now a single list of risk conditions 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.
- The pneumococcal vaccines recommended for many of those with risk conditions are now funded under the NIP for children and adults. However, for some other conditions where the rate of disease is not sufficiently high enough to be cost-effective given the cost of vaccine purchase and delivery, people are not eligible to receive the recommended pneumococcal vaccines under the NIP (refer to Appendix).
- Children diagnosed with risk conditions at ≤12 months of age are recommended to receive 4 doses of 13vPCV and 2 doses of 23vPPV.
  - *13vPCV in a 4-dose schedule at 2, 4, 6 and 12 months of age (the first dose may be given as early as 6 weeks of age).*
  - *2 doses of 23vPPV; 1 dose at 4years of age and another dose at least 5 years later.*
  - *All Aboriginal and Torres Strait Islander children who live in the NT, Qld, SA and WA will receive these extra doses as part of their routine schedule now (refer to ATAGI clinical advice on changes to vaccine recommendations and funding for Aboriginal and Torres Strait Islander people from 1 July 2020).*
- Individuals aged >12 months with risk conditions (other than haematopoietic stem cell transplant recipients) are recommended to receive 1 dose of 13vPCV and 2 doses of 23vPPV.
  - *Give 1 dose of 13vPCV at diagnosis (at least 2 months after any previous doses of 13vPCV).*
  - *1 dose of 23vPPV 12 months after 13vPCV (2–12 months later is acceptable) or at 4 years of age whichever is later.*
  - *A second dose of 23vPPV at least 5 years later.*
- For children <5 years of age with risk conditions who require catch-up doses of 13vPCV, the number and spacing of doses depends on the age of presentation and the number of doses already received (refer to Table 2).

- Individuals aged ≥5 years with risk conditions who have previously received 23vPPV are recommended to receive 1 dose of 13vPCV 12 months after their last 23vPPV.
- The number of **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. Review of the Australian Immunisation Register (AIR) is recommended.
- People who have received a haematopoietic stem cell transplant are recommended to receive 3 doses of 13vPCV after transplantation, followed by 23vPPV at the intervals described above (*refer to the Pneumococcal disease chapter in the Australian Immunisation Handbook*).

Table2. Catch-up schedule for 13vPCV for all children with any medical condition(s) associated with an increased risk of invasive pneumococcal disease, aged <5 years

Number of 13vPCV doses received previously	Age at presentation	Age at 1st dose of PCV	Age at 2nd dose of PCV	Age at 3rd dose of PCV	Number of further primary PCV dose(s) needed	Number of PCV booster doses needed at age ≥12 months
None	<12 months	Na	na	na	3	1
	12–59 months	Na	na	na	1	1
1	<12 months	Any age	na	na	2	1
	12–59 months	<12 months	na	na	1	1
	12–59 months	≥12 months	na	na	None	1
2	<12 months	Any age	Any age	na	1	1
	12–59 months	<12 months	<12 months	na	1	1
	12–59 months	<12 months	≥12 months	na	None	1
	12–59 months	≥12 months	≥12 months	na	None	None
3	<12 months	Any age	Any age	Any age	None	1
	12–59 months	<12 months	<12 months	Any age	None	1
	12–59 months	<12 months	≥12 months	≥12 months	None	None

This schedule does not apply to people who have had a haematopoietic stem cell transplant. Please refer to the Vaccination for people who are immunocompromised chapter in the Australian immunisation handbook.
The minimum interval between doses is 1 month if child aged <12 months, and 2 months if aged ≥12 months.

Haemophilus influenzae type b vaccines (Hib) vaccine

- The Hib vaccine, ActHIB®, recommended for adults and children >5 years of age with asplenia and hyposplenia is also now funded under the NIP.
  - *A single dose of Hib vaccine is required if the person was not vaccinated in infancy or was incompletely vaccinated.*
  - *Booster doses of Hib vaccine are not required.*
- Hib vaccination is also recommended for adults and children >5 years of age who receive a haematopoietic stem cell transplants, but this is not funded under the NIP (refer to the Haemophilus influenzae type b chapter in the Australian Immunisation Handbook).

Appendix. Risk conditions for which meningococcal, pneumococcal and *Haemophilus influenzae* type b vaccines are recommended

Condition	Recommended vaccine		
	Pneumococcal vaccines – 13vPCV and 23vPPV	Meningococcal vaccines – MenB and Men ACWY	Hib vaccine
Previous episode of invasive pneumococcal disease	✓		
Functional or anatomical asplenia, including			
– sickle cell disease or other haemoglobinopathies	✓	✓	✓§
– congenital or acquired asplenia (for example, splenectomy) or hyposplenia	✓	✓	✓§
Immunocompromising conditions, including			
– 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)	✓		
Proven or presumptive cerebrospinal fluid (CSF) leak, including			
– cochlear implants	✓		
– intracranial shunts	✓		
Chronic respiratory disease, including¶			
– 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	✓		
Chronic renal disease			
– relapsing or persistent nephrotic syndrome	✓		
– chronic renal impairment – eGFR <30 mL/min (stage 4 disease)	✓*		
Cardiac disease, including¶			
– congenital heart disease	✓†		
– coronary artery disease	✓†		
– heart failure	✓†		
Children born less than 28 weeks gestation	✓†		
Trisomy 21	✓†		
Chronic liver disease, including¶			
– chronic hepatitis	✓		
– cirrhosis	✓		
– biliary atresia	✓		
Diabetes	✓		
Smoking (current or in the immediate past)	✓	✓#	
Harmful use of alcohol‡	✓		
Defects in, or deficiency of, complement components, including factor H, factor D or properdin deficiency		✓	
Current or future treatment with eculizumab (a monoclonal antibody directed against complement component C5)		✓	

Note: ✓Recommended; shaded boxes indicate eligibility for NIP funding.
¶ Individual conditions listed beneath or those that are similar based on clinical judgment
* Funded under the NIP for eGFR <15 mL/min only (including patients on dialysis)
† Funded under the NIP only for children aged <5 years at diagnosis of the condition
# Recommended for young adults aged 15–24 years
‡ 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)
§ Only for those who were not fully vaccinated in early childhood according to the Hib vaccination recommendations for infants and children