Ontario

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Adults Aged 18 Years and Older

This fact sheet provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice

Pneumococcal vaccine programs in Ontario

There are three pneumococcal vaccine programs in Ontario:

1. Routine immunization program for children aged 6 weeks to 4 years
2. Routine immunization program for adults aged 65 years and older
3. High-risk immunization program for individuals aged 6 weeks and older who have certain medical or non-medical conditions that increase their risk of invasive pneumococcal disease (IPD)

Infectious agent

Streptococcus pneumoniae (S. pneumoniae) is the bacterium responsible for IPD and is a common cause of respiratory infections, including community-acquired pneumonia (CAP) and acute otitis media (AOM). While there are over 90 known serotypes, a small number of these are responsible for the majority of pneumoccocal infections in Ontario.

Transmission

S. pneumoniae is transmitted by direct contact with respiratory droplets or indirect contact with respiratory secretions of infected or colonized persons. The incubation period for IPD has not been clearly defined and may be as short as 1 to 3 days.

Risk factors

IPD is most common in the very young, the elderly, and groups at high-risk due to an underlying medical, environmental or living condition. Additionally, the incidence rate of IPD is significantly higher in northern Canada, including northern Ontario, compared to the rest of Canada.

Spectrum of clinical illness

Asymptomatic upper respiratory tract colonization with *S. pneumoniae* is common. Infection with *S. pneumoniae* more commonly results in bronchitis, otitis media, sinusitis, or pneumonia. *S. pneumoniae* infections are considered invasive when they involve normally sterile sites, such as the blood or central nervous system.

Bacteremia and meningitis are the most common manifestations of IPD in children 2 years of age and younger. Pneumococci cause 50% of all cases of bacterial meningitis. The case-fatality rate of pneumococcal meningitis is 8% among children and 22% among adults. Permanent neurologic damage is common among survivors.

Pneumococcal pneumonia with or without bacteremia is the most common presentation among adults and is a common complication following viral infections. The case fatality rate of bacteremic pneumococcal pneumonia is 5% to 7% and is higher among elderly persons and those with multiple comorbidities.

Pneumococcal vaccines authorized for use in Canada

Type of Vaccine	Vaccine Name	Abbreviation	Eligible age groups in Ontario
Pneumococcal conjugate (Pneu-C)	Prevnar 13	Pneu-C-13	No longer publicly funded
	Vaxneuvance	Pneu-C-15	Children 6 weeks to 4 years of age at low-risk for IPD.
	Prevnar 20	Pneu-C-20	Individuals ≥6 weeks to 64 years of age at high-risk for IPD.
	Capvaxive	Pneu-C-21	Individuals ≥65 years of age.
Pneumococcal polysaccharide (Pneu-P)	Pneumovax 23	Pneu-P-23	No longer publicly funded

Publicly funded vaccines for adults aged 18 years and older

Pneumococcal conjugate (Pneu-C) vaccines that will be available are:

- **Prevnar 20** (Pneu-C-20) for those aged 18 to 64 years at high-risk for IPD.
- **Capvaxive** (Pneu-C-21) for those aged 65 years and older.

For additional information see Table 1: Pneu-C vaccines available in the Appendices.

Eligibility for pneumococcal vaccines depends on whether an individual has previously received all publicly funded pneumococcal vaccines for which they were eligible. Therefore, individuals aged 18 years and older who have already received pneumococcal vaccines (e.g., Pneumovax 23 [Pneu-P-23] and/or Prevnar 13 [Pneu-C-13]) may not be eligible for additional doses of publicly funded pneumococcal vaccines.

Vaccine preparation and administration

Refer to the individual vaccine product monographs for detailed instructions on administration and expiry information. To ensure the correct volume is drawn up accurately, consult Table 1 in the Publicly Funded Immunization Schedules for Ontario for guidance on selecting the appropriate needle length and gauge.

Vaccine storage and handling

The Vaccine Storage and Handling Guidelines detail the provincial requirements for the storage and handling of refrigerated vaccines. Please also refer to the product monographs (see Table 1 in the Appendices) for additional information.

Recommendations for use

The immunization schedules in this document consider only doses of publicly funded pneumococcal vaccines. Individuals remain eligible for publicly funded pneumococcal vaccines regardless of any privately purchased pneumococcal vaccines they may have received. Health care providers should consider an individual's complete pneumococcal immunization history when determining whether additional doses are recommended.

Eligible age group	Risk of IPD	Recommended schedule	Publicly funded vaccine
18 to 64 years	High-risk δ except HSCTβ	See Table 3a, Table 3b and Table 3c and Figure 1	Pneu-C-20
	High-risk δ - HSCTβ	See Table 3d and Figure 1	Pneu-C-20
65 years and older	All individuals except HSCTβ	See Table 2a and Figure 1	Pneu-C-21
	High-risk δ - HSCTβ	See Table 2b and Figure 1	Pneu-C-21

δ For criteria that place individuals at high-risk of IPD, see below.

β HSCT: hematopoietic stem cell transplant recipients

Criteria that place individuals at high-risk of IPD

The following medical or non-medical conditions increase an individual's risk of IPD:

1. Asplenia (functional or anatomic), splenic dysfunction
2. Congenital (primary) immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions
3. HIV infection
4. Immunocompromising therapy including use of long-term systemic corticosteroid, chemotherapy, radiation therapy, post-organ transplant therapy, certain anti-rheumatic drugs and other immunosuppressive therapy
5. Malignant neoplasms, including leukemia and lymphoma
6. Sickle-cell disease and other sickle cell hemoglobinopathies

7. Solid organ or islet cell transplant (recipient)
8. Hepatic cirrhosis due to any cause
9. Chronic renal disease, including nephrotic syndrome
10. Chronic cardiac disease
11. Chronic liver disease, including hepatitis B and C
12. Chronic respiratory disease, excluding asthma, except those treated with high-dose corticosteroid therapy
13. Chronic neurologic conditions that may impair clearance of oral secretions
14. Diabetes mellitus
15. Cochlear implant recipients (pre/post implant)
16. Chronic cerebral spinal fluid leak
17. Residents of nursing homes, homes for the aged and chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

Intervals between vaccines and co-administration

Vaccines	Minimum intervals
Two different Pneu-C vaccines or Pneu-P-23 and Pneu-C	1 year minimum Note: An 8 week minimum may be considered in those who might be anticipating initiation of immunosuppressive treatments or who have diseases that might lead to immunodeficiency. This does not apply to HSCT recipients. See Table 4 for post HSCT intervals
Vaccines not listed above	Pneu-C-20 or Pneu-C-21 vaccines may be given at the same time with other vaccines, or at any time before or after other vaccines. Note: If Pneu-C-20 or Pneu-C-21 are given by injection at the same time as other vaccine(s), separate limbs should be used if possible. Alternatively, the injections may be administered into the same muscle separated by at least 2.5 cm (1”). Different immunization equipment (needle and syringe) must be used for each vaccine.

Contraindications and precautions

Do not administer a pneumococcal conjugate vaccine to:

- Persons with a history of anaphylaxis after previous administration of the vaccine, and/or
- Persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine, including diphtheria toxoid.

In situations of suspected hypersensitivity or non-anaphylactic allergy to vaccine components, investigation is indicated, which may involve immunization in a controlled setting. Consultation with an allergist is advised.

Administration of pneumococcal vaccine should be postponed in persons suffering from severe acute illness. Immunization should not be delayed because of minor acute illness, with or without fever.

Vaccine safety

Pneumococcal conjugate vaccines authorized for use in Canada are safe and well tolerated. As with other vaccines, they must be authorized for use by the Canadian regulator, Health Canada, following review of a product's safety and how well it works (e.g., clinical trial and other evidence.)

Once a vaccine is authorized for use in Canada, vaccine safety is continuously monitored through provincial surveillance in Ontario and national surveillance systems, with coordination and collaboration between Health Canada, the Public Health Agency of Canada, and provincial and territorial partners.

Adverse events

Mild to moderate reactions that are more commonly seen include:

- Pain, swelling or redness at the injection site
- Low grade fever
- Fatigue
- Headaches
- Irritability
- Increased or decreased sleep
- Decreased appetite

Pneumococcal conjugate vaccines have been used in Ontario's publicly funded immunization programs for more than 20 years. Severe adverse effects are rare following immunization. In most cases, it does not cause any reaction. There is an extremely rare possibility (less than one in a million people) that anaphylaxis may occur.

Any unexpected or serious reaction to a vaccine should be reported to your local public health unit.

Guidance on reporting Adverse Events Following Immunization (AEFI)

To ensure the ongoing safety of vaccines in Ontario, reporting of AEFIs by physicians, nurses, pharmacists, or other persons authorized to administer an immunizing agent is mandatory under the *Health Promotion and Protection Act*. Vaccine providers are asked to report AEFIs through local public health units using the Ontario AEFI Reporting Form. A list of public health units is available at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx.

Those administering vaccines should ensure that the vaccine recipients are aware of the need to immediately report AEFIs to their health care provider. Subsequently, health care providers should report any serious or unexpected adverse events temporally related to vaccination to their local public health unit.

Vaccine recipients should be advised to go to the nearest emergency department if severe reactions develop, including the following:

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C)
- Convulsions (seizures)
- Other serious reactions

Observation period following immunization

The National Advisory Committee on Immunization (NACI) recommends a 15-minute post-vaccination observation period, as specified in the Canadian Immunization Guide (CIG). If there is a specific concern about possible vaccine allergy, 30 minutes is a preferred interval.

Record of immunization

Each vaccine recipient should be provided with a permanent personal immunization record, the Yellow Immunization Card. Please write “Prevnar 20” (if Pneu-C-20 was administered) or “Capvaxive” (if Pneu-C-21 was administered) under the “vaccine brand name” column. Vaccine recipients should be instructed to keep the record in a safe place and to present it at every health care visit so that it can be updated.

Persons with inadequate immunization records

Adults with incomplete immunization records, or no immunization records, should be considered unimmunized and should receive pneumococcal vaccines on a schedule appropriate to their age and risk factors, regardless of possible previous immunization.

Individuals who are not eligible for publicly funded vaccines

NACI and the Ontario Immunization Advisory Committee (OIAC) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-20 or Pneu-C-21 vaccines can privately purchase pneumococcal conjugate vaccines.

Providers with access to publicly funded pneumococcal vaccines

The following providers can access Pneu-C through their vaccine supply source:

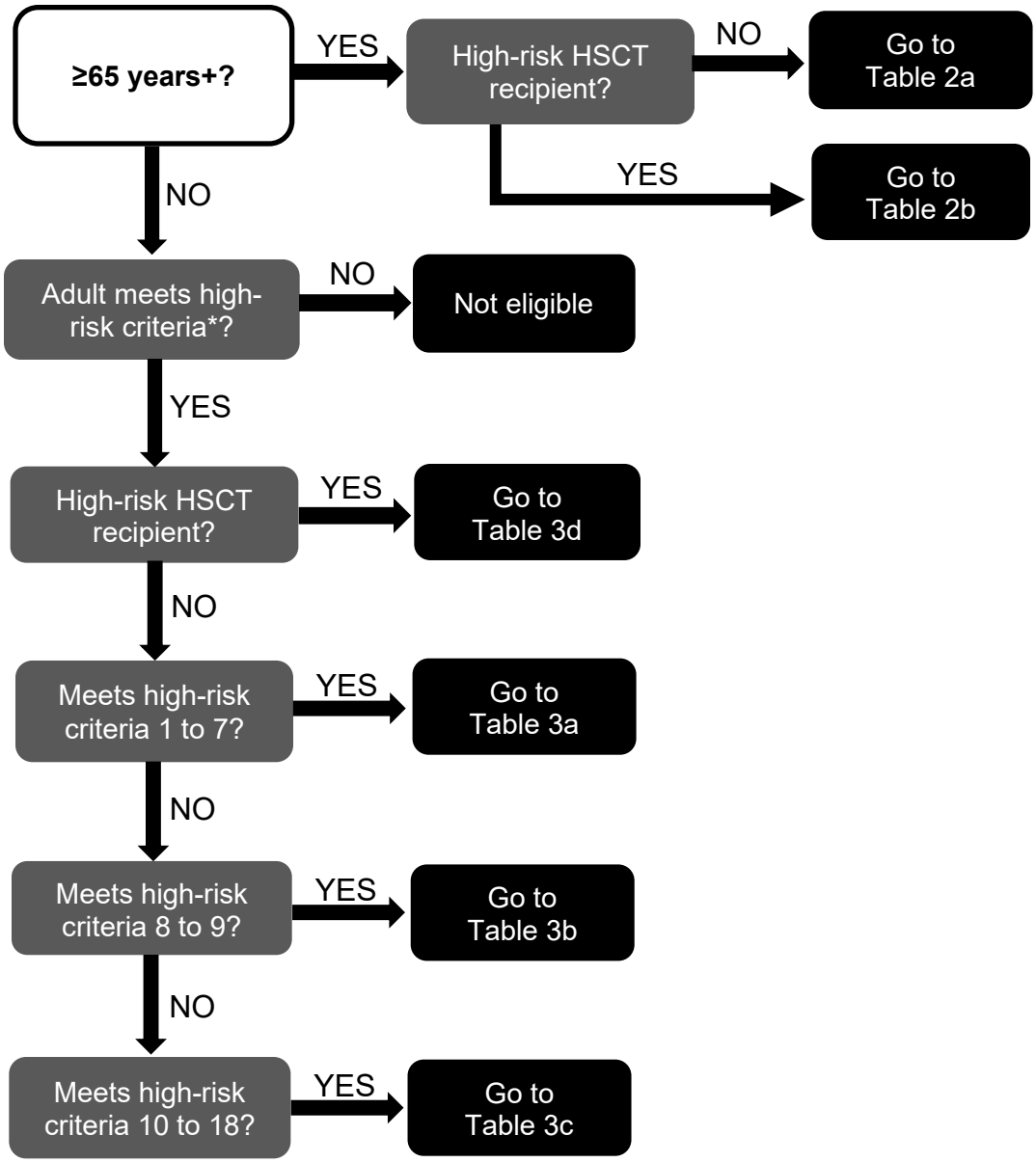
- **Pneu-C-20:** primary care providers (e.g., family physicians, pediatricians, nurse practitioners), public health units, community health centres, hospitals, long-term care homes and congregate living settings (e.g., retirement homes)
- **Pneu-C-21:** available to all providers listed for Pneu-C-20, as well as pharmacies

Appendices

Table 1: Pneu-C vaccines

Vaccine	Pneumococcal Conjugate 20-valent	Pneumococcal Conjugate 21-valent
Vaccine abbreviation	Pneu-C-20	Pneu-C-21
Vaccine name	Prevnar 20	Capvaxive
Manufacturer	Pfizer	Merck
Protects against	IPD and pneumonia	IPD
***Streptococcus* pneumoniae serotypes**	1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F	3, 6A, 6C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B Note: Although 23 serotypes are listed, 6A and 15C provide cross-protection against 6C and 15B, respectively.
Dosage	0.5 mL	0.5 mL
Route of administration	Intramuscular Injection (IM)	Intramuscular Injection (IM)
Package format	10 prefilled syringes	1 prefilled syringe 10 prefilled syringes
Package size (cm) **L x W x H**	12.45 x 9.91 x 5.33	1 syringe: 13.3 x 4.9 x 3.2 10 syringes: 11.4 x 5.2 x 12.4
Specific storage considerations	Syringes should be stored **horizontally** to minimize the re-dispersion time.	N/A
Product monograph	Prevnar 20	Capvaxive
Eligibility Criteria	Individuals 6 weeks to 64 years at high-risk for IPD	Adults 65 years and older

Figure 1: Immunization decision flowchart for adults aged 18 years and older



***High-risk criteria for those at risk for IPD:** 1. Asplenia (functional or anatomic), splenic dysfunction 2. Congenital (primary) immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions 3. HIV infection 4. Immunocompromising therapy including use of long-term systemic corticosteroid, chemotherapy, radiation therapy, post-organ transplant therapy, certain anti-rheumatic drugs and other immunosuppressive therapy 5. Malignant neoplasms, including leukemia and lymphoma 6. Sickle-cell disease and other sickle cell hemoglobinopathies 7. Solid organ or islet cell transplant (recipient) 8. Hepatic cirrhosis due to any cause 9. Chronic renal disease, including nephrotic syndrome 10. Chronic cardiac disease 11. Chronic liver disease, including hepatitis B and C 12. Chronic respiratory disease, excluding asthma, except those treated with high-dose corticosteroid therapy 13. Chronic neurologic conditions that may impair clearance of oral secretions 14. Diabetes mellitus, 15. Cochlear implant recipients (pre/post implant), 16. Chronic cerebral spinal fluid leak 17. Residents of nursing homes, homes for the aged and chronic care facilities or wards. 18. Hematopoietic stem cell transplant (HSCT) (recipient)

Table 2: PNEU-C-21 vaccination for adults aged ≥65 years

Table 2a: Vaccination schedule for those aged ≥65 years (except HSCT recipients)

Adult's current age	# of previously received doses of		# of Pneu-C-21 doses recommended
	Pneu-P-23 (routine dose) at age ≥65 years	Pneu-C-20 at age ≥65 years	
≥65 years	0 doses	0 doses	1 dose
	1 dose	0 doses	0 doses
	0 doses	1 dose	0 doses

Table 2b: Vaccination schedule for HSCT recipients aged ≥65 years

# of Pneu-C doses received post HSCT[β]	# of Pneu-C-21 doses recommended to complete series and intervals[δ]
0 doses post HSCT	1st dose, 3-9 months post HSCT 2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
1 dose post HSCT	2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
2 doses post HSCT	3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
3 doses post HSCT	4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
4 doses post HSCT with 0 doses of Pneu-C-21	1 dose, 12-18 months post HSCT and 8 weeks after last dose
4 doses post HSCT with ≥1 dose of Pneu-C-21	0 doses

δ Pneu-C-20/Pneu-C-21 should be given 1 year after last dose of Pneu-P-23
β Unless noted, any Pneu-C (e.g., Pneu-C-13, Pneu-C-20, Pneu-C-21) can be used

Note:

- Individuals aged 65 years or older who undergo HSCT should receive Pneu-C-21 dose(s) after HSCT as outlined in Table 2b, regardless of prior vaccination of routine Pneu-C-21 dose at age 65 or older. Those who did not receive their routine Pneu-C-21 dose at age 65 or older are not eligible for this dose after completion of the HSCT schedule indicated in Table 2b.
- Pneu-C vaccination post HSCT should be determined in consultation with the recipient's transplant specialist as per NACI.

Table 3: PNEU-C-20 vaccination for adults aged 18 to 64 year at HIGH-RISK for IPD

For individuals that meet one or more high-risk criteria (in Table 3a, Table 3b, Table 3c and/or Table 3d), ONE immunization schedule should be selected (i.e., ONE of either Table 3a, Table 3b, Table 3c OR Table 3d).

Table 3a: Vaccination schedule for those meeting the following high-risk criteria:

1. Asplenia (functional or anatomic), splenic dysfunction
2. Congenital (primary) immunodeficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity, T-lymphocyte (cell) mediated immunity, complement system (properdin, or factor D deficiencies), or phagocytic functions
3. HIV infection
4. Immunocompromising therapy including use of long-term systemic corticosteroid, chemotherapy, radiation therapy, post-organ transplant therapy, certain anti-rheumatic drugs and other immunosuppressive therapy
5. Malignant neoplasms, including leukemia and lymphoma
6. Sickle-cell disease and other sickle cell hemoglobinopathies
7. Solid organ or islet cell transplant (recipient)

Adult's current age	# of previously received doses of		# of Pneu-C-20 doses recommended
	Pneu-P-23	Pneu-C	
18 to 49 years	0 to 1 dose	0 doses	1 dose$^{\delta}$
	0 to 1 dose	1 dose of Pneu-C-20	0 doses
	2 doses	0 doses	0 doses
50 to 64 years	0 to 2 doses	0 doses	1 dose$^{\delta}$
	0 to 1 dose	1 dose of Pneu-C-13	1 dose$^{\delta}$
	2 doses	1 dose of Pneu-C-13	0 doses
	0 to 2 doses	1 dose of Pneu-C-20	0 doses

δ Pneu-C-20 should be given 8 weeks after last dose of Pneu-C and/or 1 year after last dose of Pneu-P-23

Table 3b: Vaccination schedule for those meeting the following high-risk criteria:

8. Hepatic cirrhosis due to any cause
9. Chronic renal disease, including nephrotic syndrome

Adult's current age	# of previously received doses of		# of Pneu-C-20 doses recommended
	Pneu-P-23	Pneu-C-20	
18 to 64 years	0 doses	0 doses	1 dose$^{\delta}$
	2 doses	0 doses	0 doses
	0 to 1 doses	1 dose	0 doses

δ Pneu-C-20 should be given 1 year after last dose of Pneu-P-23

Table 3c: Vaccination schedule for those meeting the following high-risk criteria:

10. Chronic cardiac disease
11. Chronic liver disease, including hepatitis B and C
12. Chronic respiratory disease, excluding asthma, except those treated with high-dose corticosteroid therapy
13. Chronic neurologic conditions that may impair clearance of oral secretions
14. Diabetes mellitus
15. Cochlear implant recipients (pre/post implant)
16. Chronic cerebral spinal fluid leak
17. Residents of nursing homes, homes for the aged and chronic care facilities or wards

Adult's current age	# of previously received doses of		# of Pneu-C-20 doses recommended
	Pneu-P-23	Pneu-C-20	
18 to 64 years	0 doses	0 doses	1 dose$^{\delta}$
	1 dose	0 doses	0 doses
	0 doses	1 dose	0 doses

δ Pneu-C-20 should be given 1 year after last dose of Pneu-P-23

Table 3d: Vaccination schedule for HSCT recipients aged 18 to 64 years

# of Pneu-C doses received post HSCT[β]	# of Pneu-C-20 doses recommended to complete series and intervals[δ]
0 doses post HSCT	1st dose, 3-9 months post HSCT 2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
1 dose post HSCT	2nd dose, ≥4 weeks after 1st dose 3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
2 doses post HSCT	3rd dose, ≥4 weeks after 2nd dose 4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
3 doses post HSCT	4th dose, 12-18 months post HSCT and 6-12 months after 3rd dose
4 doses post HSCT with 0 doses of Pneu-C-20	1 dose, 12-18 months post HSCT and 8 weeks after last dose
4 doses post HSCT with ≥1 dose of Pneu-C-20	0 doses

δ Pneu-C-20 should be given 1 year after last dose of Pneu-P-23
β Unless noted, any Pneu-C (e.g., Pneu-C-13, Pneu-C-20) can be used

Note:

- Pneu-C vaccination post HSCT should be determined in consultation with the recipient's transplant specialist as per NACI.