

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Immunization for Children Aged 6 Weeks to 17 Years

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 pneumococcal 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 children aged 6 weeks to 17 years

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

- **Vaxneuvance** (Pneu-C-15) for those aged 6 weeks to 4 years at low-risk for IPD
- **Prennar 20** (Pneu-C-20) for those aged 6 weeks to 17 years at high-risk for IPD

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

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 publicly funded 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 group	Risk of IPD	Recommended schedule	Publicly funded vaccine
Starting at 6 weeks of age	Low-risk	2, 4, and 12 months of age* See Table 2 and Figure 1	Pneu-C-15
Starting at 6 weeks of age	High-risk ^δ - Except HSCT ^β	2, 4, 6 and 12 months of age* See Table 3 and Figure 1	Pneu-C-20
Starting 3-9 months post HSCT	High-risk ^δ - HSCT ^β	See Table 4 and Figure 1	Pneu-C-20
^δ For criteria that place individuals at high-risk of IPD, see below. * The number of doses required to complete a Pneu-C series for children with interrupted or incomplete schedules varies with the age of the child. ^β HSCT: hematopoietic stem cell transplant recipients			

Immunization with pneumococcal conjugate vaccine is not recommended for children 5 years of age and older who are at low-risk for IPD. Children who are at low-risk for IPD who have completed a vaccine series with Pneu-C-13 and/or Pneu-C-15 are not recommended for an additional dose of Pneu-C-15.

All children who are at high-risk of IPD and have completed their immunization schedule with Pneu-C-13 should receive 1 dose of Pneu-C-20. Pneu-C-20 should be provided at a minimum interval of 8 weeks since the last dose of Pneu-C-13, or at least 1 year since a dose of Pneu-P-23. Children at high-risk of IPD who have completed a vaccine series that includes at least one dose of Pneu-C-20 do not require any additional doses of Pneu-C-20.

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 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	8 weeks minimum, except post HSCT (See Table 4 for post HSCT intervals)
Pneu-P-23 and Pneu-C	1 year minimum
Vaccines not listed above	Pneu-C-15 OR Pneu-C-20 vaccines may be given at the same time with other vaccines, or at any time before or after other vaccines. If Pneu-C-15 OR Pneu-C-20 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 or their parents or guardians 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 or their parents or guardians 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 “Pneumovax 20” (if Pneumovax-20 was administered) or “Vaxneuvance” (if Pneumovax-15 was administered) under the “vaccine brand name” column. Vaccine recipients, or their parents or guardians, 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.

Infants born prematurely

Premature infants in stable clinical condition should be immunized with a Pneumovax at the same chronological age and according to the same schedule (i.e., Table 3, Table 4 or Table 5) as full-term infants.

Persons with inadequate immunization records

Children 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](#) provides recommendations on the use of pneumococcal conjugate vaccines. Individuals who are not eligible for publicly funded Pneu-C-15 or Pneu-C-20 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:

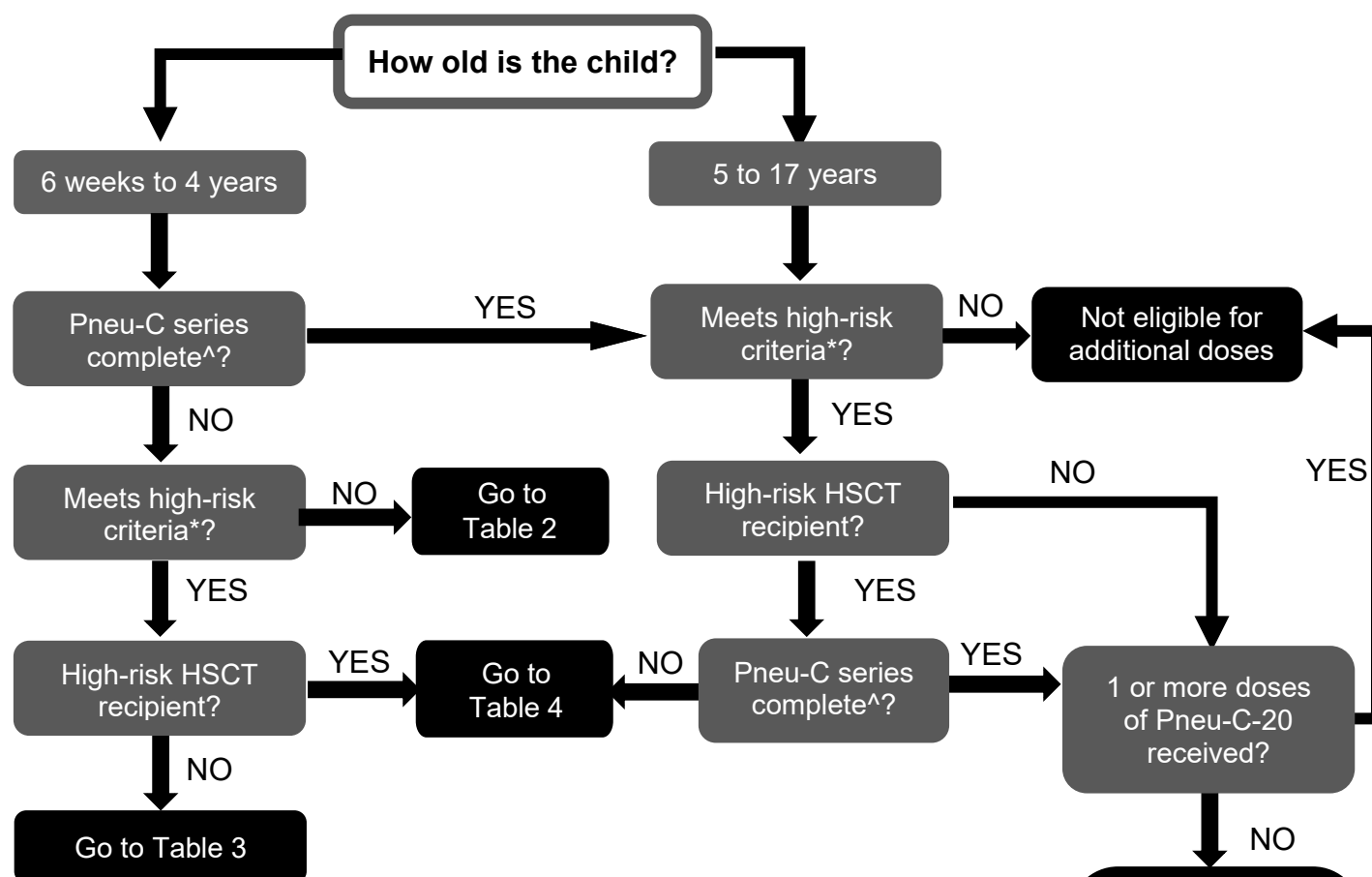
- **Pneu-C-15:** primary care providers (e.g., family physicians, pediatricians, nurse practitioners), public health units, community health centres and hospitals
- **Pneu-C-20:** available to all providers listed for Pneu-C-15, as well as long-term care homes and congregate living settings (e.g., retirement homes)

Appendices

Table 1: Pneu-C vaccines

Vaccine	Pneumococcal Conjugate 15-valent	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-15	Pneu-C-20
Vaccine name	Vaxneuvance	Prevnar 20
Manufacturer	Merck	Pfizer
Protects against	IPD	IPD
<i>Streptococcus pneumoniae</i> serotypes	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F
Dosage	0.5 mL	0.5 mL
Route of administration	Intramuscular Injection (IM)	Intramuscular Injection (IM)
Package format	1 prefilled syringe 10 prefilled syringes	10 prefilled syringes
Package size (cm) L x W x H	1 syringe: 4.9 x 3.2 x 13.3 10 syringes: 11.4 x 5.2 x 12.4	12.45 x 9.91 x 5.33
Specific storage considerations	N/A	Syringes should be stored horizontally to minimize the re-dispersion time.
Product monograph	Vaxneuvance	Prevnar 20
Eligibility Criteria	Children 6 weeks to 4 years not at high-risk for IPD (low-risk)	Individuals 6 weeks to 64 years at high-risk for IPD (high-risk).

Figure 1: Immunization decision flowchart for individuals 6 weeks to 17 years



***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 chronic care facilities or wards 18. Hematopoietic stem cell transplant (HSCT) (recipient)

^Pneu-C series can be completed with:

- High-risk for IPD: Pneu-C-13 and/or Pneu-C-20
- Low-risk for IPD: Pneu-C-13 and/or Pneu-C-15

Table 2: PNEU-C-15 vaccination series for children aged 6 weeks to 4 years at LOW-RISK for IPD

Child's current age	# of previously received Pneu-C ^β doses	# of <u>PNEU-C-15</u> dose(s) required to complete series	Intervals between doses ^γ
2* to 11 months	0 doses	2 doses + 1 dose at age ≥12 months	2 months
	1 dose	1 dose + 1 dose at age ≥12 months	2 months
	2 doses	1 dose at age ≥12 months	2 months
12 to 23 months	0 doses	2 doses	2 months
	1 dose at age <12 months	2 doses	2 months
	1 dose at age ≥12 months	1 dose	2 months
	1 dose at age <12 months + 1 dose at age ≥12 months	1 dose	2 months
	≥2 doses at age <12 months	1 dose	2 months
	Completed series	0 doses	N/A
24 to 59 months	0 doses	1 dose	N/A
	Any incomplete series	1 dose	2 months
	Completed series	0 doses	N/A

* immunization may start at 6 weeks of age

^γ Recommended interval between doses is 2 months and the minimum is 8 weeks

^β Unless noted any Pneu-C vaccine can be used

Table 3: PNEU-C-20 vaccination series for children aged 6 weeks to 17 years at HIGH-RISK for IPD [▲] (except HSCT see Table 4)

Child's current age	# of previously received Pneu-C^β doses	# of <u>PNEU-C-20</u> dose(s) required to complete series	Intervals between doses^{γδ}
2* to 6 months	0 doses	3 doses + 1 dose at age ≥12 months	2 months
	1 dose	2 doses + 1 dose at age ≥12 months	2 months
	2 doses	1 dose + 1 dose at age ≥12 months	2 months
7 to 11 months	0 doses	2 doses + 1 dose at age ≥12 months	2 months
	1 dose	1 dose + 1 dose at age ≥12 months	2 months
	2 doses	1 dose at age ≥12 months	2 months
12 to 23 months	0 doses	2 doses	2 months
	1 dose at age <12 months	2 doses	2 months
	1 dose at age ≥12 months	1 dose	2 months
	1 dose at age <12 months + 1 dose at age ≥12 months	1 dose	2 months
	≥2 doses at age <12 months	1 dose	2 months
	Completed series with 0 doses of Pneu-C-20	1 dose	2 months
	Completed series with ≥1 dose of Pneu-C-20	0 doses	N/A
24 to 59 months	0 doses	1 dose	2 months
	Any incomplete series	1 dose	2 months
	Completed series with 0 doses of Pneu-C-20	1 dose	2 months
	Completed series with ≥1 dose of Pneu-C-20	0 doses	N/A
5 to 17 years	0 doses of Pneu-C-20	1 dose	2 months
	≥1 dose of Pneu-C-20	0 doses	N/A

* immunization may start at 6 weeks of age

▲ For a list of high-risk criteria that increase an individual's risk for IPD, see pages 3-4

β Unless noted, any Pneu-C (e.g., Pneu-C-13, Pneu-C-15, Pneu-C-20) can be used

γ Recommended interval between doses is 2 months and the minimum is 8 weeks

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

Table 4: Pneu-C-20 vaccination series for HIGH-RISK HSCT recipients aged 6 weeks to 17 years

# of Pneu-C doses received post HSCT^β	# of Pneu-C-20 dose(s) required to complete series and intervals^δ
0 doses post HSCT	1 st dose, 3-9 months post HSCT 2 nd dose, ≥4 weeks after 1 st dose 3 rd dose, ≥4 weeks after 2 nd dose 4 th dose, 12-18 months post HSCT and 6-12 months after 3 rd dose
1 dose post HSCT	2 nd dose, ≥4 weeks after 1 st dose 3 rd dose, ≥4 weeks after 2 nd dose 4 th dose, 12-18 months post HSCT and 6-12 months after 3 rd dose
2 doses post HSCT	3 rd dose, ≥4 weeks after 2 nd dose 4 th dose, 12-18 months post HSCT and 6-12 months after 3 rd dose
3 doses post HSCT	4 th dose, 12-18 months post HSCT and 6-12 months after 3 rd 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 of Pneu-C
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-15, 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](#).